CliChem 200C PLUS
Auto Chemistry Analyzer
User's Manual

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How to use this manual

We greatly appreciate your purchasing CliChem 200C Plus Automatic chemistry analyzer.
This User's Manual is the operation instruction for CliChem 200C Plus Automatic chemistry analyzer produced by BGT BioGenTechnologies GmbH and it will offer you the introduction to the installation, routine operation and maintenance of the analyser etc.
Functions of analysers with different revisions or configurations may be varied.

Warning: The following comments must be strictly observed so as to ensure proper operation of the analyser without causing any danger.

Note:

- The AC power supply must be properly grounded (Null voltage less than 5 V).
- The AC power supply must be kept steady. It is forbidden for the analyser to share a same power supply with other large power electric appliances with large power consumption.
- While unplugging the power cord, be sure to hold the plug instead of the power cord.
- In case of smoke, abnormal smell or strange sound given by the analyser, please shut off the power supply immediately and contact the supplier.
- Sample cup and reaction tray must be disposable.
- Upon the completion of testing, be sure to switch off the analyser in accordance with the standard procedure so as to avoid loss of data.
- This product belongs to desktop type testing apparatus and involves no contraindication.
- While removing the housing for maintenance or other reasons, please cut off the power supply and switch off the apparatus.

Chapter I Brief Introduction to Analyser

1.1 Principle and scope of application

Based on the principle of optic colorimetry, this apparatus is suitable for routine clinical biochemical testing.
This product is desktop type testing apparatus and involves no contraindication.
As this apparatus has no energy output, it involves no risk related to output of overheating and excessive radiation.
The most important thing is to pay attention to risks of mechanical movement and electric shock. While removing the housing for maintenance or other reasons, please cut off the power supply and switch off the apparatus.
With simple operation, unique display screen interface and perfect information communication system, CliChem 200C Plus is an ideal analyser for clinical chemical laboratories.

CliChem 200C Plus system can realize the following operations：

1. It has strong software functions and includes a routine worksheet, a STAT worksheet and a worksheet for calibration and quality control. Besides, it allows creating eight independent different worksheets, each of which can accommodate 60 samples (Note: A STAT worksheet can only accommodate 30 samples).

2. The apparatus has two reagent racks consisting of 36 reagent positions. The positions for single reagent and double reagents can be randomly combined.

3. It can display and print the results in different modes including patient report and data storage.

4. End-point method, kinetic method, two-point method, double wavelength method and differential method (double wavelength method and differential method belong to end-point method) can be used.

5. It is allowed to make measurement upon standard and factor.

6. Eight pieces of standard filters can be randomly selected including 340nm, 405 nm, 492 nm, 510 nm, 535 nm, 546 nm, 578 nm and 620 nm. In addition, there is also a reserved position for placing a special filter so as to meet the demands of different users.

7. During the operation, the system will continuously conduct detection and control to less the making errors. In case of any abnormal condition, the system will send a signal and at the same time display error message on

the display screen so as to prompt the operator to properly select the button and operation.

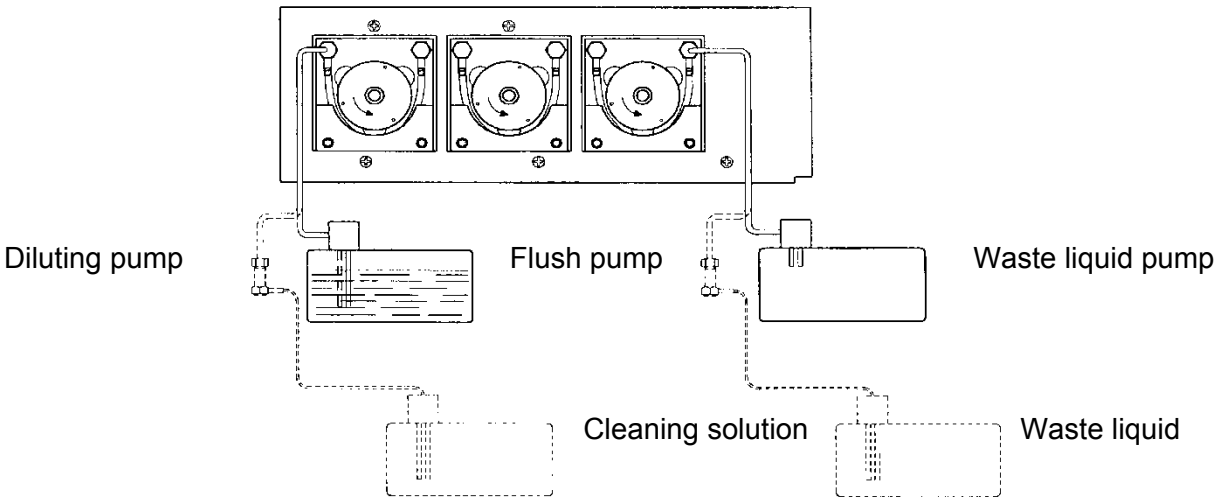
1.2 Construction of apparatus

The analyser mainly consists of ten components including cleaning system, display, reaction chamber, sample chamber, reagent chamber, aspiration system, rinsing system, diluting system, spectrophotometer and drainage system.

1.2.1 Cleaning system

After removing the rear cover board, you can see three peristaltic pumps installed on the right side and interior chambers used to place cleaning solution bottle and waste liquid bottle (refer to figure below). Three peristaltic pumps continuously rotate to inspire distilled water to rinse the interior of the apparatus (such as the aspiration probe, flow cell, mixer and diluting

injector, etc.). Then discharge waste liquid to the waste liquid bottle, which is located inside the cabinet with the washing solution bottle.



Cleaning solution bottle and waste liquid bottle

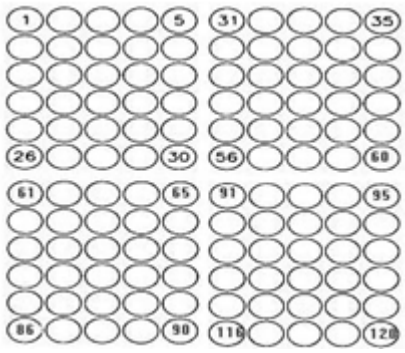
1.2.2 Monitor

CliChem 200C Plus applies a color LCD monitor and WINDOWS software. The image is clear and animated. The operator may operate the analyser in accordance with the command displayed by the monitor.

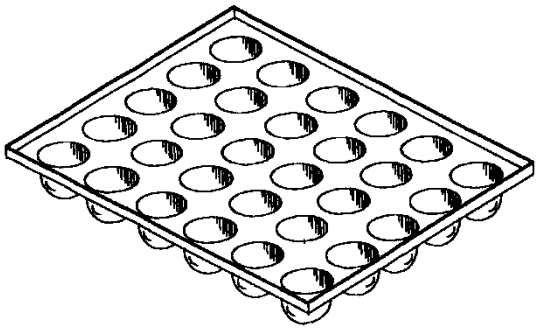
1.2.3 Reaction chamber

The reaction plate is made of special alloy materials and consists of 4 sections. Each section has 30 reaction hole positions and there are totally 120 reaction hole positions (refer to figure below). The reaction can be
controlled under three levels of temperature, 25°C, 30°C and 37°C. The reaction tray can be replaced during the operation. While all of the 120 reaction holes are occupied, the display screen will prompt the operator to replace the reaction tray as required. The reaction tray is to be replaced during the rinsing process between two reactions and this will not affect the normal operation.

The reaction tray is disposable and made of low-heat resistance inert plastics. Every reaction tray consists of 30 reaction holes (refer to figure below). While placing a reaction tray, confirm that no hole is broken. A reaction tray can be used only once.



Reaction chamber



Reaction tray

1.2.4 Sample chamber

There are three sample racks inside the sample chamber, among which the rightmost one is a STAT sample rack only for STAT usage. Each sample rack can accommodate 30 samples (standard or quality control inclusive). Cuvettes (12mm×75mm) or alternatively small plastic sample cups (700 μL) can be placed on the sample rack.

1.2.5 Reagent chamber

There are two reagent racks inside the reagent chamber. Each can accommodate 9 second large bottles and 9 small bottles, or 9 large bottles, or 18 small bottles. The volume of large, second large and small bottles are separately 46ml,32ml,and 16ml. Large and small reagent bottles can be used alternatively.

The system can automatically set the position of each reagent. Before each operation, the screen will display the position of each reagent to be placed and the automatically calculated total volume of reagent requested by this operation.

The position of each reagent on the reagent rack can be automatically set by the system or be determined manually.

1.2.6 Aspiration system

CliChem 200C Plus applies a smart X-Y-Z three-dimensional system to control two probes and one mixer. The probe with a function of liquid receptor will gently contact liquid and inspire requested quantity. In case of inadequate reagent or samples, the apparatus will automatically display prompting message. Probe 1 is a sampling probe and will inspire the reagent and sample into a reaction hole for incubation. Probe 2 is an aspiration probe and will inspire the reactant liquid into the flow cell for measurement. During the operation of CliChem 200C Plus, the cycle for aspiration of probes is as follows.

1. The sampling probe is immerged into a reagent bottle to inspire reagent of fixed volume and a bit of air.
2. The probe is moved to the cleaning basin for cleaning.
3. The sampling probe will inspire the sample and a bit of air.
4. The probe is again moved to the cleaning basin for cleaning.
5. The sample and reagent are transferred into a hole on the reaction tray.
6. As the mechanical arm moves to the cleaning basin, the probe and the mixer are cleaned.
7. Distilled water is filled into the flow cell to clear residual sample remained inside.
8. The aspiration probe will inspire 80μL reactant liquid and a bit of air, which will be filled into the flow cell to rinse the colorimetric basin so as to avoid contamination caused by different samples.
9. The aspiration probe will inspire rest reactant liquid into the flow cell to make measurement.
10. The mechanical arm will again moves to its original position (cleaning basin) to clean the probe. Then the recycle of inspiring sample will again start.

Generally, the mixer is requested only when double reagents are applied.

1.2.7 Rinsing system

In order to prevent the system from being crossly contaminated, the rinsing basin will be continuously filled with distilled water to clean the probes, flowcell, mixer and injector.

Each time upon sampling, the system will automatically clean the diluter. The volume of distilled water is set by the parameters of methodology.

1.2.8 Diluting system

The diluting system of CliChem 200C Plus is controlled by a computer with high precision and good repeatability. The injector of the diluter will only contact distilled water and the reagent will not flow into the injector. Each time after dilution, distilled water will flow out of the injector to clean the probes.

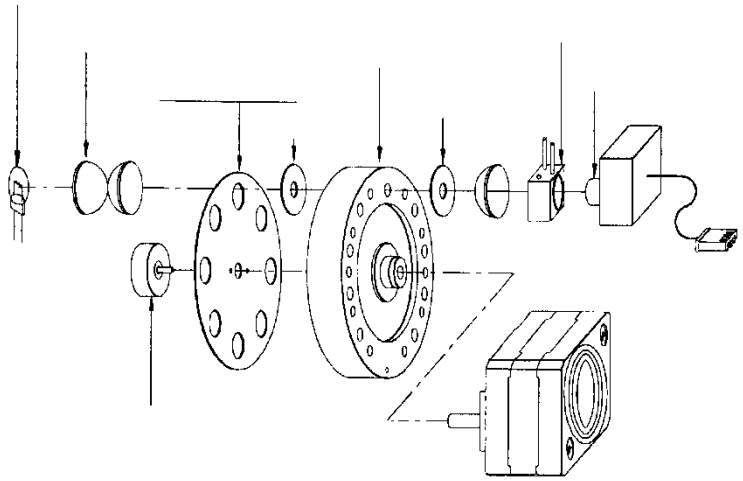
To guarantee the accuracy of the results, it is suggested to keep the volume of a sample no less than 3μL (10μL above is preferred) and the total volume for measurement no less than 400μL (500μL is preferred).

1.2.9 Spectrophotometer

The spectrophotometer of CliChem 200C Plus is constituted by several filters with high stability. The regulator of light source can compensate the impact caused by current heat drift and exterior diffused light.

The total volume of the flow cell is 70μL. The temperature is controlled by Peltier effect to 25°C(±0.5°C), 30°C(±0.5°C) or 37°C (±0.2°C). Each time before switching off the apparatus, confirm that the colorimetric basin is clean and full of distilled water.

Anytime before starting the testing, the apparatus will automatically check if the system is normal, rinse the flow cell and set each filter to zero position (WATER BLANK).



Optical circuit system

1.2.10 Drainage system

There is a drain hole on the bottom center of the apparatus, which connects to the waste container inside the apparatus.

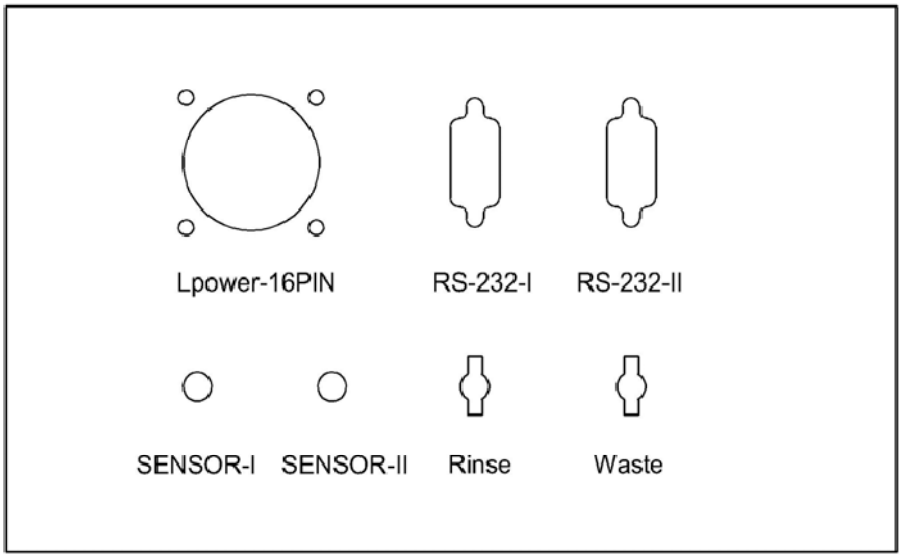
Under normal conditions, waste liquid will first be discharged into the waste container and then pumped into the waste liquid bottle by the peristaltic drainage pump. Therefore waste liquid will not flow out from the drain hole.

In case that any improper operation by the operator or any mistake in programming causes misoperation of the apparatus, waste liquid inside the waste container may overbrim and flow out from the drain hole on the bottom of the apparatus.

1.2.11 Schematic diagram for the position of rear outlet wire

Part 1

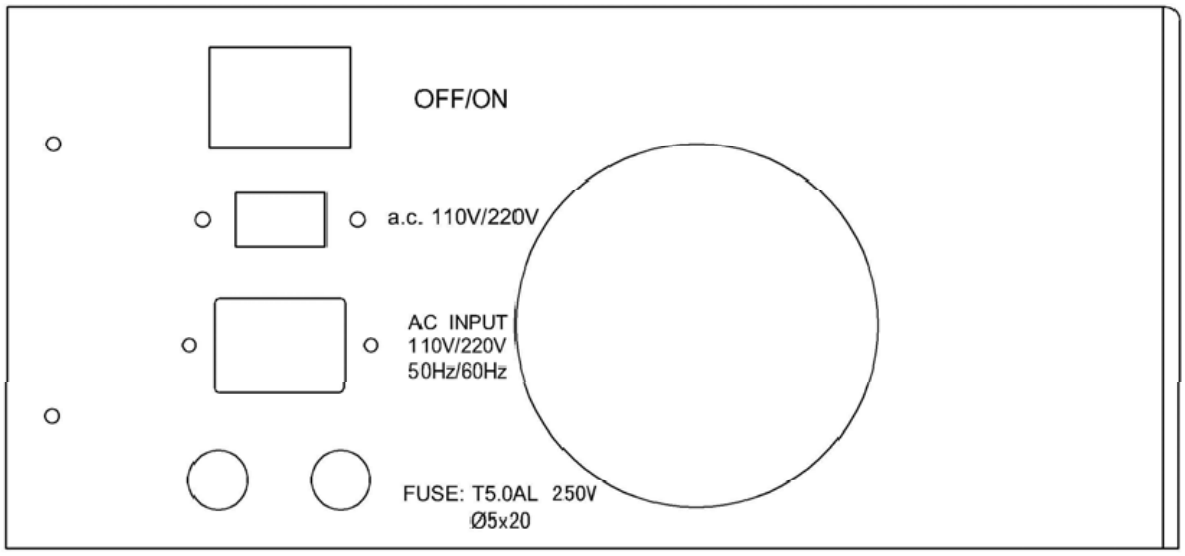
RS-232-I: Standard RS-232 port
RS-232-II: Standard RS-232 port
Rinse : Connection of rinsing pipe
Waste : Connection of waste liquid pipe
Lpower-16PIN : 16-pin power supply port
SENSOR-I : Connection of rinsing bottle sensor
SENSOR-II : Connection of waste bottle sensor



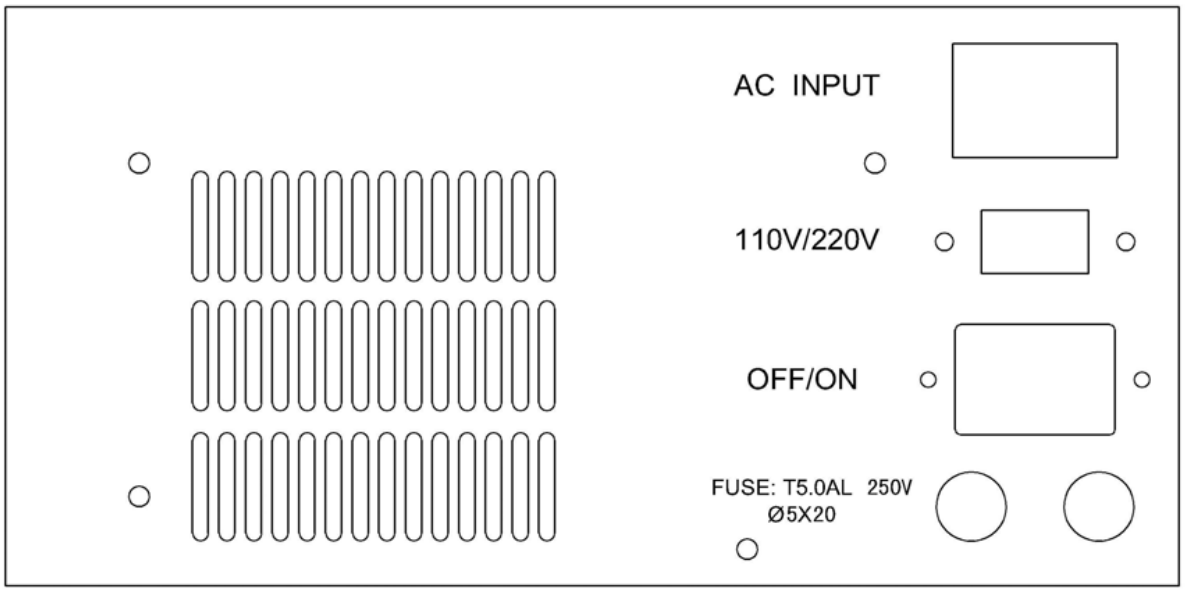
Part 1

Part 2
OFF/ON : Power switch
a.c. 110V/220V : 110V/220V potential switch.
AC INPUT 110V/220V 50Hz/60Hz : AC input port.
FUSE: T5.0AL 250V ∅5x20 : Fuse port.

Note: Please dial the 110V/220V potential switch according to your local voltage. Switch to 110V if your local voltage is 110V, and to 220V while it is 220V.

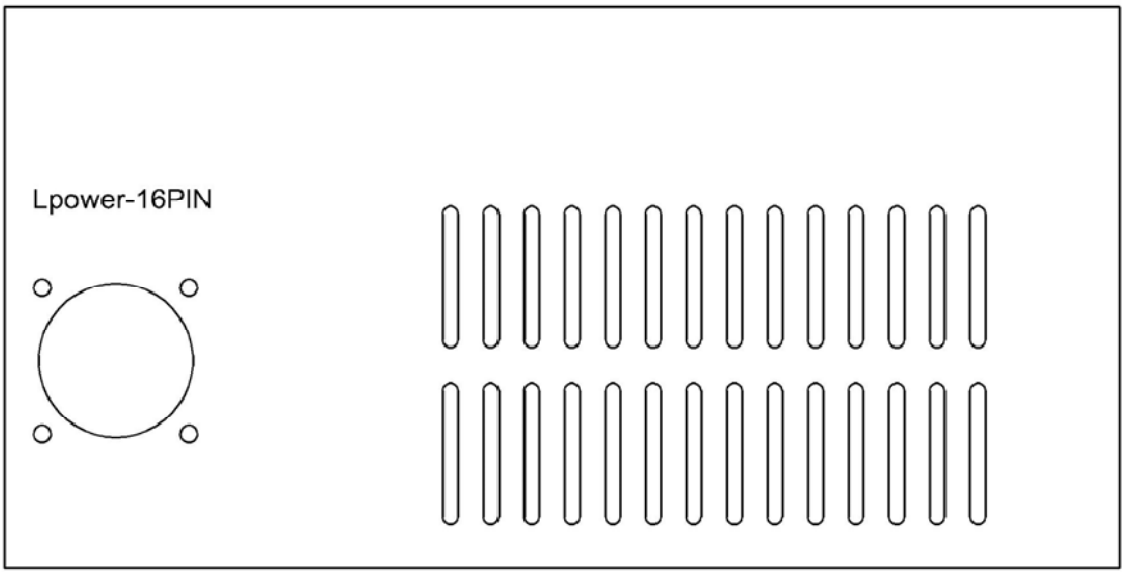


1.2.12 Outer power supply wiring schematic diagram
Front :
OFF/ON : Power switch
a.c. 110V/220V : 110V/220V potential switch
AC INPUT 110V/220V 50Hz/60Hz : AC input port
FUSE: T5.0AL 250V ∅5X20 : Fuse port

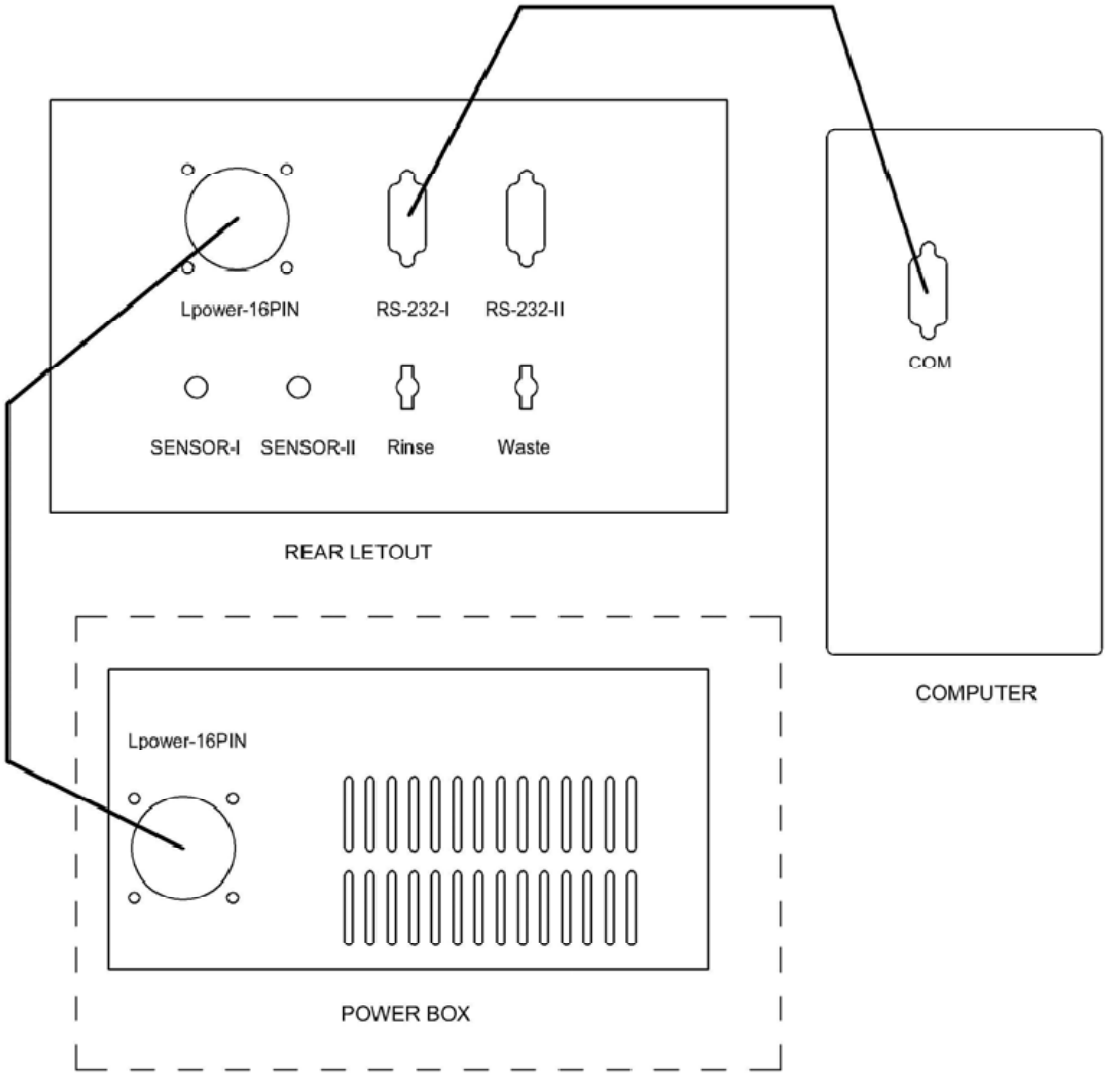


Back:

Lpower-16PIN : 16-pin power supply port



1.2.13 Connection



1.3 Technical parameter

Weight	65kg
Power supply	a.c.220V/110V，50Hz/60Hz
Fuse	T5.0AL 250V ,∅5X20
Analytical method	End-point method, two-point method, kinetic method
Filter	Eight pieces of optic filter （340，405，492，510，535，546，578，620nm）
Temperature control	Room temperature 25°C±0.5°C，30°C±0.5°C，37°C±0.2°C
Reagent position	36 positions
Volume of reagent	Recommended volume 300 - 500uL
Sample position	90 positions
Sample capacity	3-100uL（recommended value≥5uL）
Light source	Halogen lamp 12V, 20W
Linear range	0-2.500Abs
Sensitivity	Beyond 0.0005Abs
Operating environment	10 - 30°C，relative humidity≤70%

Chapter II Installation and Calibration of Apparatus

2.1 Unpacking of apparatus

Unpack the apparatus and remove all wrapping materials used for transportation. Please keep the packing containers and wrapping materials to facilitate your repacking the apparatus in the future.

1) Take out the apparatus from the package.

2) Remove all wrapping materials and take out the apparatus from the plastic packaging bag.

3) Check all items in the packing containers and confirm the following components available.

- Main body of CliChem 200C Plus
- User's Manual
- Packing list
- Warranty certificate issued by the dealer

Accessories: power cord, printer, printing cable, LCD, mouse, keyboard, RS-232 serial cable and spare fuse.
Optional accessories: outer power supply, power cord, interconnecting wiring.

Note: In case of any damaged part or noncoincidence with the packing list found, please contact the dealer.

2.2 Installation

CliChem 200C Plus Chemistry Analyser must be installed by professionals. The apparatus must be installed on a solid and clean operation desk and be sure to avoid shock, moistureness, intense magnetic field and direct sunshine. The operating environment should be maintained at a temperature ranging from 10°C to 30°C and a relative humidity ranging from 5% to 70% (free of condensation).
The power must be 220V/50HZ with proper ground wire. For a laboratory with voltage variation beyond ±10%, it is recommended to install an independent voltage stabilizer over 1000W. Since the apparatus is a precision instrument completely controlled by a computer, one UPS (Uninterrupted Power Supply) over 500W must be equipped.

Note:

- The AC power supply must be properly grounded (Null voltage less than 5 V).
- The AC power supply must be kept steady. It is forbidden for the analyser to share a same power supply with other large power electric appliances.
- While unplugging the power cord, be sure to hold the plug instead of the power cord.
- In case of smoke, abnormal smell or strange sound given by the analyser, please cut off the power supply immediately and contact the dealer.

Connect the apparatus to the power supply

1) Plug one end of the power cord into the power receptacle of the apparatus.

2) Plug the other end of the power cord into the receptacle of the AC power supply.

Connect the external printer

1) Confirm if both the printer and the apparatus have been switched off.

2) Plug one end of the printing cable with parallel ports into the socket of the rear parallel port of the printer.

3) Lock the plug by the steel wire buckle.

4) Plug the other end of the printing cable into the parallel printer port of the apparatus.

5) Connect the printer to the AC power supply by the power cord supplied.

Connect the monitor

1) Confirm if both the monitor and the apparatus have been switched off.

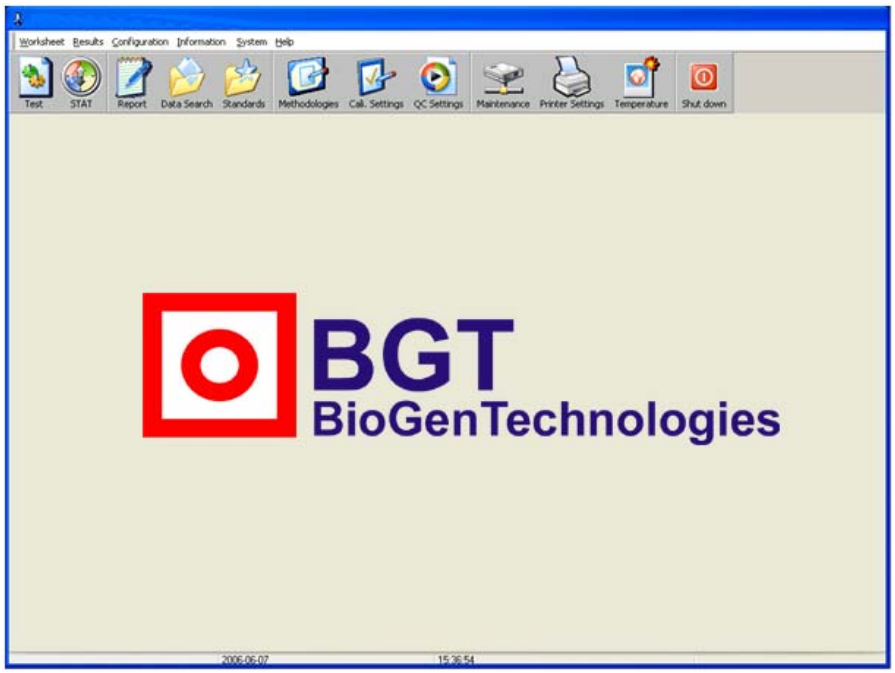
2) Plug one end of the monitor cable into the socket of the monitor interface on the rear of the apparatus.

3) Connect the power cord of the monitor to the socket of the AC power supply.

2.3 Start and exit from the system

2.3.1 Start

Switch on the apparatus and then an interface of main window will be displayed.



Main menu

All commands of the main window are displayed on the top of the screen and each menu consists of its own command combination. Refer to the following contents for brief introduction to each menu.

1) Worksheet: edit test of samples.

2) Results: display and print the test results in different forms (patient report included); additionally display and print information related to quality control.

3) Configuration: the operator can program according to practical situations including edit standard, quality control, conditions required by the reaction, incubation temperature and data under etc.

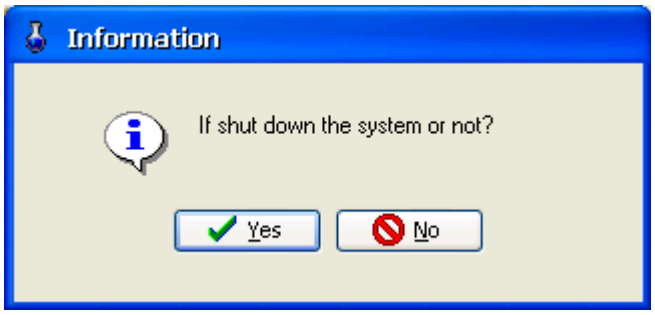
4) Information: system information and patient information are included.

5) System: set printer settings, set temperature and maintain the system.

There is a row of icons under the command line and each icon stands for a corresponding function key. There is a status bar on the top of the screen to display current date and time.

2.3.2 Shut down

Upon completion of the testing, the analyser must be shut down as per the following procedures. Click the button of "shut down" from the column of shortcut button and then a window will pop-up to warn.



Click “Yes” to exit the system normally and then shut down the computer control system. After shutting down the computer control system, power off the switch on the rear of the apparatus.

2.4 Calibration of apparatus

For each testing item, it is requested to calibrate the apparatus each day by testing the standard or quality control so as to ensure that the system can effectively test a patient's serum.

The standard, quality control or reagent blank can all be tested and verified. While testing samples, it is unnecessary to calibrate every day. However, for each item to be calibrated, the standard should be tested at least once. After a standard is determined, its value can be saved and the system can always apply this value to calculate the test result of this item until a new figure is saved upon updated calibration.

The fact whether or not the calibration is required regularly depends upon the stability and quality of the reagent and if the reagent batch number and suppliers need to be replaced. However, it is necessary to ensure the apparatus under normal testing status.

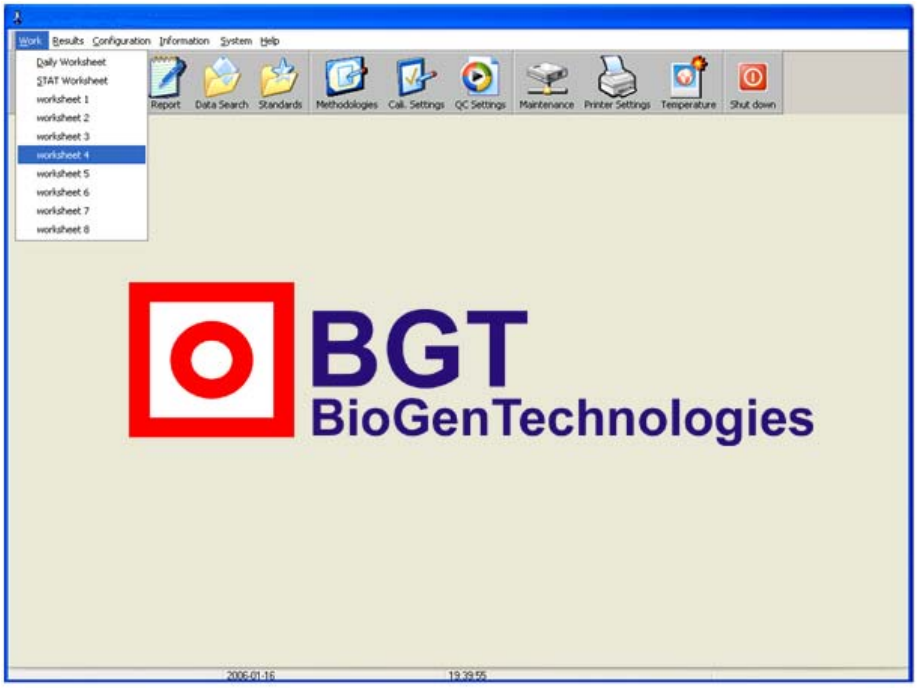
You can test standard and quality control in a separate worksheet ,or test them in the same worksheet with patient samples at the same time .Please refer to the next chapter.

Chapter III Routine Operation

3.1 Input of sample information

3.1.1 Select a worksheet

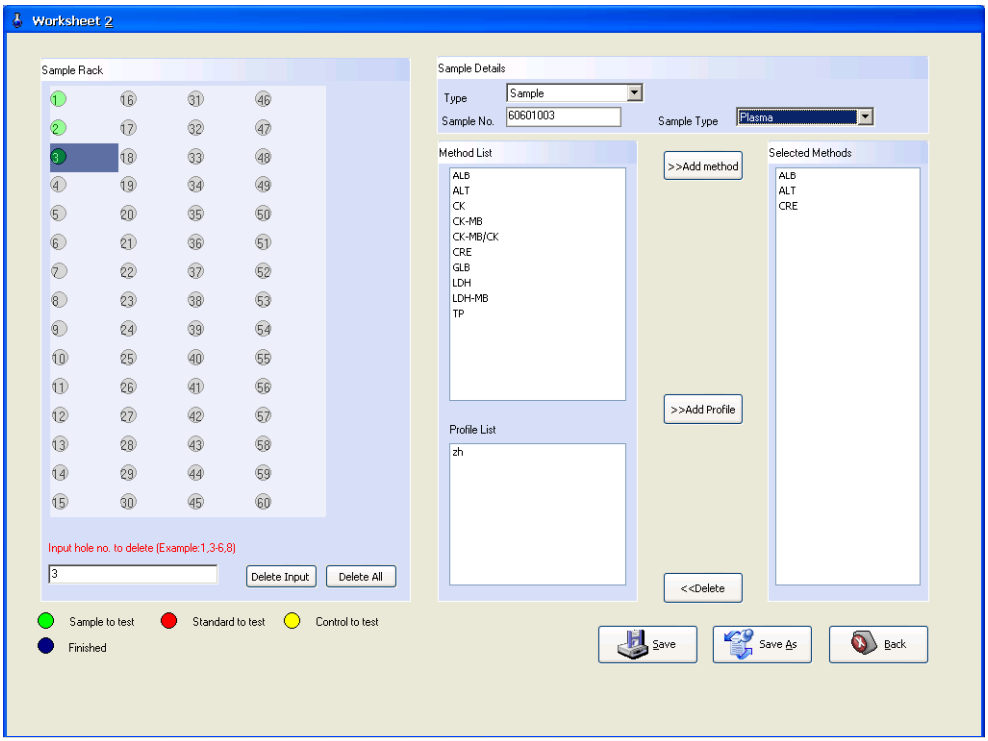
Start the system and activate the main menu. Click the worksheet menu and then a window for worksheet selection will pop-up.



Select a worksheet

There are 8 customer worksheets (users can edit the name of the worksheet) and 2 fixed worksheets (including routine worksheet and STAT worksheet). Select the desired worksheet by the mouse.

Note: Directly click the button of " STAT " to activate the STAT worksheet immediately.



Routine worksheet

Select a routine worksheet from “Worksheet” menu, all sample positions are displayed in the display box of a sample rack and each worksheet can edit 60 samples. The operator can select the sample position by the mouse. In each sample position, the operator can edit the information of each sample (Type, sample no, sample type and testing item, etc.).

3.1.2 Edit sample

Select an empty position on the sample rack and then the selected sample position will be displayed in a blue box.

1) Test Type: select the test type from “Standard”, ”Control” and “Sample”.

2) Sample No.: if the test type is “Sample”, input the serial number of a sample.

3) Sample Type: if the test type is “Sample”, learn the type of a sample to be tested

4) Method list: in the list of items available for selection, double click or press the button of "Add Test" upon selection to add an item.

5) Profile list: In the list of profiles available for selection, double click or press the button of "Add Profile" upon selection to add a profile. The system will automatically add the item in the profile to the list of selected items.

6) Selected methods: All tests selected for the current sample will be in the list named “Selected Methods”.

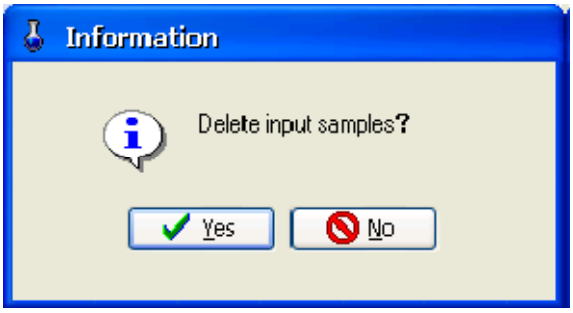
7) Save: save edited information and at this moment the sample will turn into green from dark gray.

8) Save as: input the number desired in the prompt box. The sample will be saved by the number you desire.

Note: The green icon ● indicates an edited sample.
The red icon ● indicates an edited standard.
The red icon ● indicates an edited control.

3.1.3 Delete a sample from a worksheet

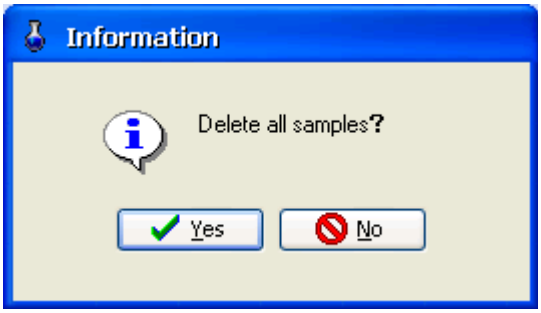
Move the cursor to a corresponding location and the selected sample position will be displayed in a blue box. Press the button of "Delete Input". Then a window will pop-up to warn:



Press Yes to confirm or directly press Enter to confirm. Press No to cancel.

3.1.4 Delete all samples from a worksheet

Activate the routine worksheet. Press the button of "Delete all" and then a window will pop-up to warn as follows.



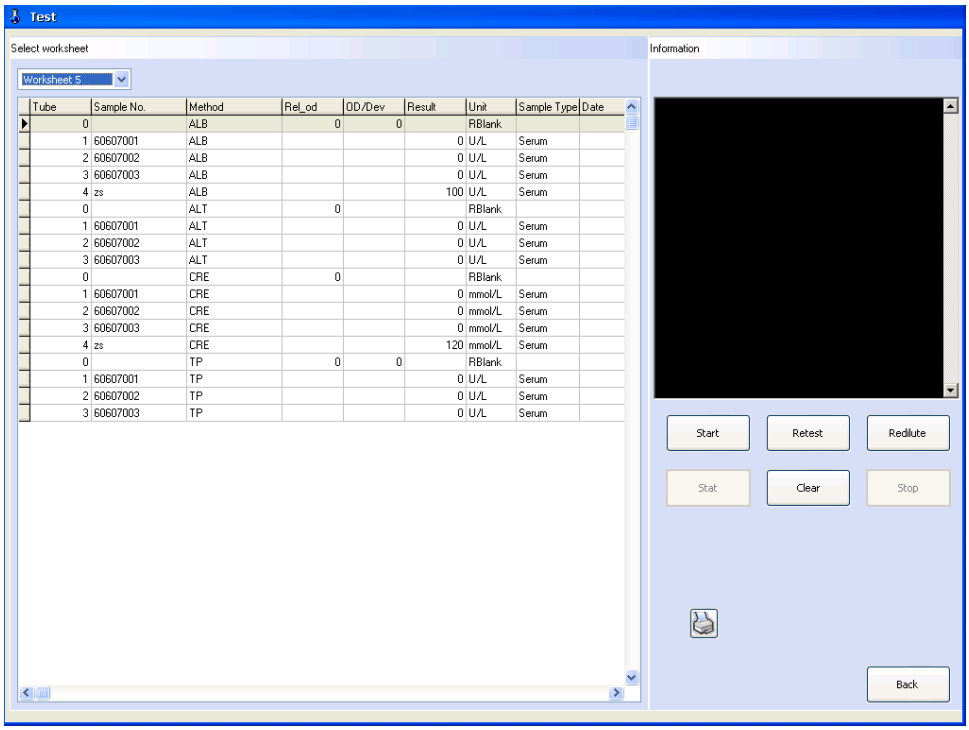
Press Yes to confirm or directly press Enter to confirm. Press No to cancel.

3.1.5. Revise an established worksheet

Due to some special reasons, it is requested to revise an established worksheet.
i) Remove or add a sample Follow the method stated in part 1 or 2 of this section.
ii) Remove or add a testing item of a sample Select the sample to be revised by the cursor and double click or single click the selected item in the list of selected items. Then click the button of "Delete Input" to remove the item, which is not to be tested. Then save.
Add a testing item of a sample: select the sample to be revised by the cursor and double click or single click the selected item in the list of items available for selection. Then click the button of "Add Test" to add the item desired. Then save.

3.2 Start routine testing

In the main menu., Press the button of "Test" and then a window for testing will be activated.

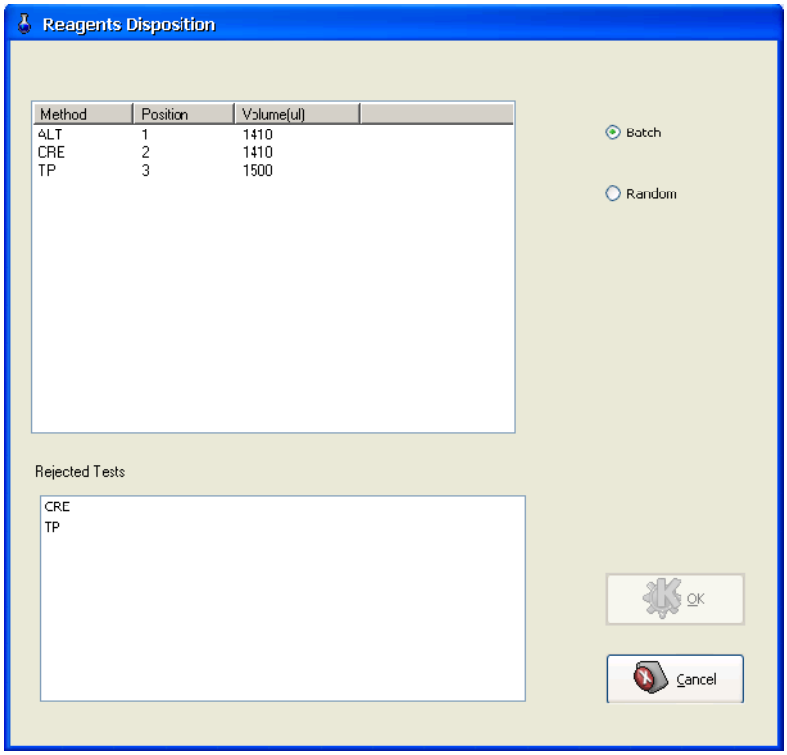


Tube	Sample No.	Method	Rel_od	OD/Dev	Result	Unit	Sample Type	Date
0		ALB	0	0		RBlank		
1	60607001	ALB			0	U/L	Serum	
2	60607002	ALB			0	U/L	Serum	
3	60607003	ALB			0	U/L	Serum	
4	zs	ALB			100	U/L	Serum	
0		ALT	0			RBlank		
1	60607001	ALT			0	U/L	Serum	
2	60607002	ALT			0	U/L	Serum	
3	60607003	ALT			0	U/L	Serum	
0		CRE	0			RBlank		
1	60607001	CRE			0	mmol/L	Serum	
2	60607002	CRE			0	mmol/L	Serum	
3	60607003	CRE			0	mmol/L	Serum	
4	zs	CRE			120	mmol/L	Serum	
0		TP	0	0		RBlank		
1	60607001	TP			0	U/L	Serum	
2	60607002	TP			0	U/L	Serum	
3	60607003	TP			0	U/L	Serum	

- Select worksheet: Select a worksheet which you wan to test from the list.
- Start: Start to test the selected worksheet.
- Retest: Retest the selected tests, which is marked with a black point .
- Redilute: If there are ‘OL’ results, which exceeded the linear range.
- You can click “Redilute” to redilute the tests.
- Stat: While testing a routine worksheet, you can click “Stat” to insert the tests of stat worksheet. When stat worksheet is completed, analyzer will continue to test the worksheet which has been interrupted.
- Clear: Clear the results of the selected tests, which is marked with a black point .
- Stop: While analyzer is working, you can click “Stop” the stop the process.

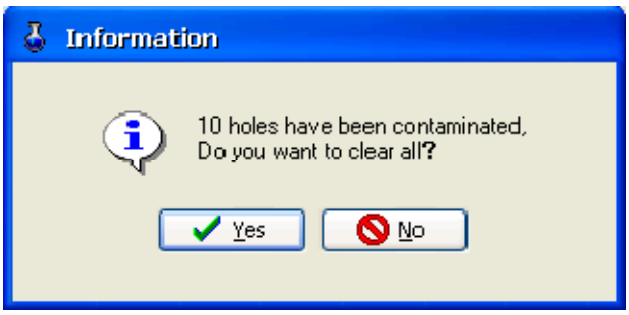
Select a worksheet from the list , press the button of "Start" and then a window for work confirmation will be activated. All items to be tested will be displayed in this window. Besides, the total volume and positions of reagent needed for each item will also be displayed.

3.2.1 Running



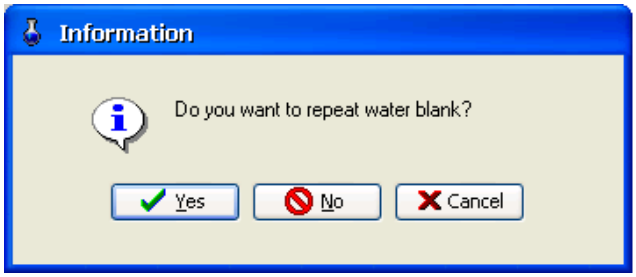
In case of incomplete allocation of reagent positions, a prompt box of "Please allocate all reagent positions" will pop-up as follows.

The system will prompt the number of clean reaction holes in the reaction tank and inquire if to replace.



Press “Yes” and all reaction plates must be replaced. The system will automatically start from the first clean reaction hole. Press No and no reaction plate will be replaced. The system will continue to use the rest clean reaction holes.

Check if the reagent positions on the reagent rack are correct and if the quantity of reagent is enough. Upon confirmation, press the button of "Start". Then the system will start to execute the testing.
Before the testing, the system will automatically detect the water blank once to adjust the photometer to zero and display the measurement value of 8 wavelengths. Meanwhile the system will prompt the operator if the water blank requests to be again measured. Press YES or NO to select.



By pressing YES, the system will automatically rinse the flow cell and then again measure the water blank and display the absorbency values of 8 wavelengths.
By pressing NO, the system will start to execute the testing and immediately display the total number of tests during this operation and the total time requested to complete the job. During the operation, the system will continuously display the test results and the remaining time before the completion of the operation.

By pressing Cancel, test will be stopped

Click the item displayed and all available information related to this testing will be displayed in a box on the right side of the screen.

1) Tube
2) Sample No.
3) Method
4) Rel_od
5) OD/Dev
6) Result
7) Unit
8) Sample Type
9) Date

All information during the operation of the information display system in the figure:

- Value of water blank
- Total number of tests
- Time before the completion of the testing cycle.
- Data and information during the testing etc.

Note: please confirm the following before the system starts to operate:

- If the reagent positions are correct
- If the sample positions are correct
- If 4 reaction plates are clean

With a program, the system can run the operation from beginning to end automatically.
Before the completion of the entire operation, it is requested to intervene in case of the following occasions.

- Replace clean reaction plates – if there are more than 120 tests for one operation

Upon replacement of 4 clean reaction plates, press OK to continue the operation. The operator should timely replace the sample rack or replenish
reagent and then again start the system operation. Any replacement (replacement of reaction plate, reagent rack and sample rack) must be duly completed. Otherwise the system will be kept under suspended state.

3.2.2 Stop system operation

During the testing process, you can stop the system. By pressing the “stop” button, the system will save the test results before stopping the job. (During testing water blank, you can press Alt +’q’ to interrupt)

3.3 Fix reagent position

In order to facilitate the operation, this apparatus is designed as an open-type system. Reagent positions can be allocated, yet for not more than 36 kinds of different reagent (double reagents included). In this way, for each operation, reagent positions for the same item will be fixed, this is greatly convenient for the operator.
Rack No.1: No. 1 reagent rack – 9 large reagent containers, or 18 small containers or 9 small containers and 9 second large containers can be accommodated. (including cooling)
Rack No.2: No. 2 reagent rack –9 large reagent containers, or 18 small containers or 9 small containers and 9 second large containers can be accommodated . (under room temperature). You can allocate all reagent positions or not. However, mixed allocation is not allowed (mixed allocation: partial reagent positions are allocated while the rest reagent positions are not allocated in the worksheet). Before system starts to test, it will check reagent positions. In case of mixed allocation, the system will request to re-allocate all reagent positions.

Note: For reagent positions not allocated, the system will automatically allocate all reagent positions before starting. The operator shall place corresponding reagent in compliance with positions allocated by the system.

3.3.1 Allocate reagent position

This will be described in the section of “Methodologies”.

3.4 Rework a worksheet

To rework a worksheet means to re-test a worksheet completely finished or partially finished instead of reedit sample information.
To retest some tests of a finished worksheet:

1. First, select the rows which you desire to retest.(Press Ctrl and click left button of mouse)
2. Then clear result of selected rows(Press Alt + ‘c’)
3. Run the worksheet again.(Do not clear the results of the worksheet)

To retest the whole worksheet

1. Back to the worksheet , click OK to start to run the worksheet again
2. Select Yes while system questions “Clear all result?”
3. Following process is the same as before.

3.5 Retest selected records

For a worksheet already tested, some tests result may be suspectable. You can select the rows which you desire to retest, and click button of “Retest”. Then these tests will be retested.

3.6 Redilute the ‘OL’ records

For a worksheet already tested, some tests may be marked with ‘OL’ due to exceeding the linear range. Click the botton of “Redilute”, all tests of ‘OL’ will be rediluted and retested.

Chapter IV Print Report

4.1 Print report

Click the button of "Report" in the shortcut tool bar to enter into the selection of report format as follows.

a) Print based on test

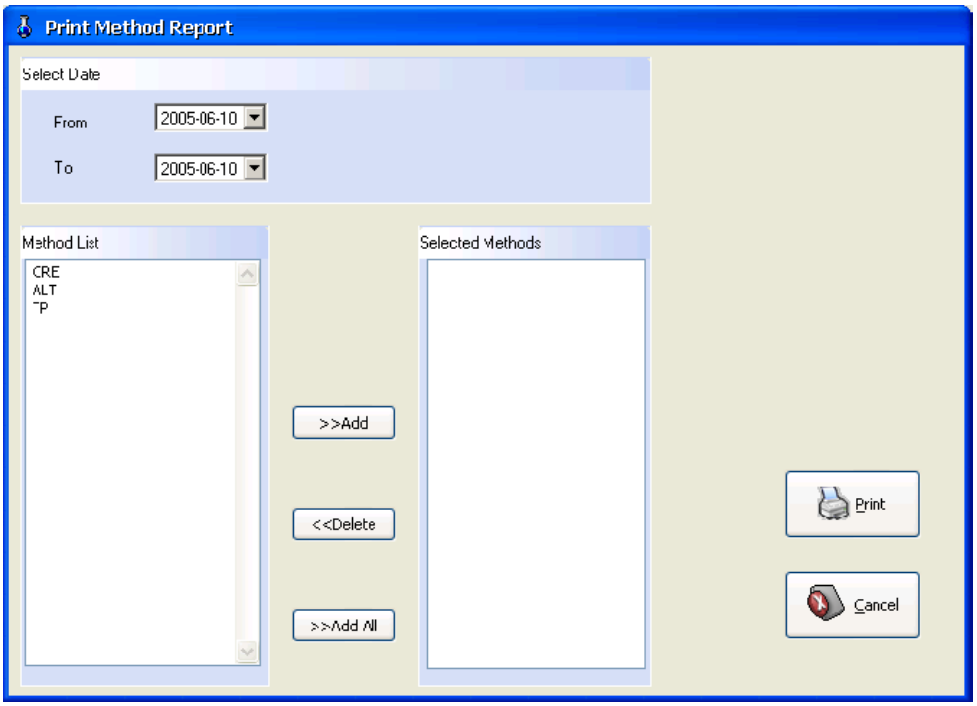
b) Print based on patient

c) Print history record

d) Expanded Report

4.1.1 Print by test

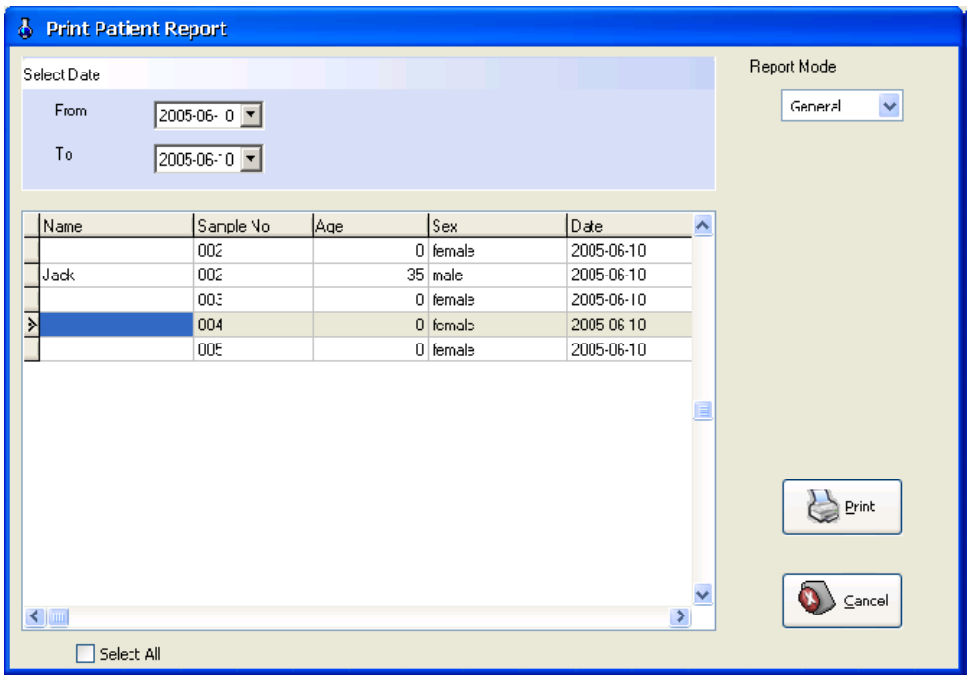
Select “By test” and press the button of "OK" to activate a window for printing based on item as follows.



Input the starting date and ending date. Select items to be printed from the list of items. Press the button of "Add" to add selected items to the list of items to be printed. Press the button of "Print" to print a report for a given period and designated items.

4.1.2 Print by patient

Select “By patient” and press the button of "OK" to activate a window for printing based on patient as follows.

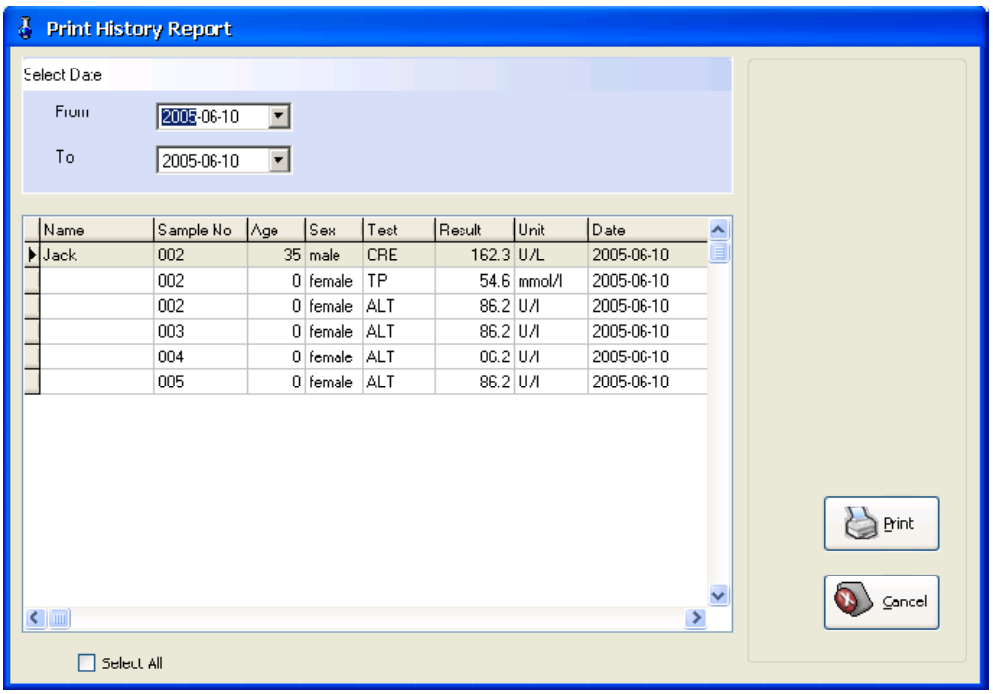


Input the starting time and ending time to inquire patient records within the designated period. Press the CTRL key and the left button of the mouse to execute multiple-selection printing. Or select the button of "Select all" on the lower left corner to select all patient records and print them.

If you fail to input the starting time and ending time, all patient records will be listed. Press the CTRL key and the left button of the mouse to execute multiple-selection printing. Or select the button of "Select all" on the lower left corner to select all patient records and print them.

4.1.3 Print history record

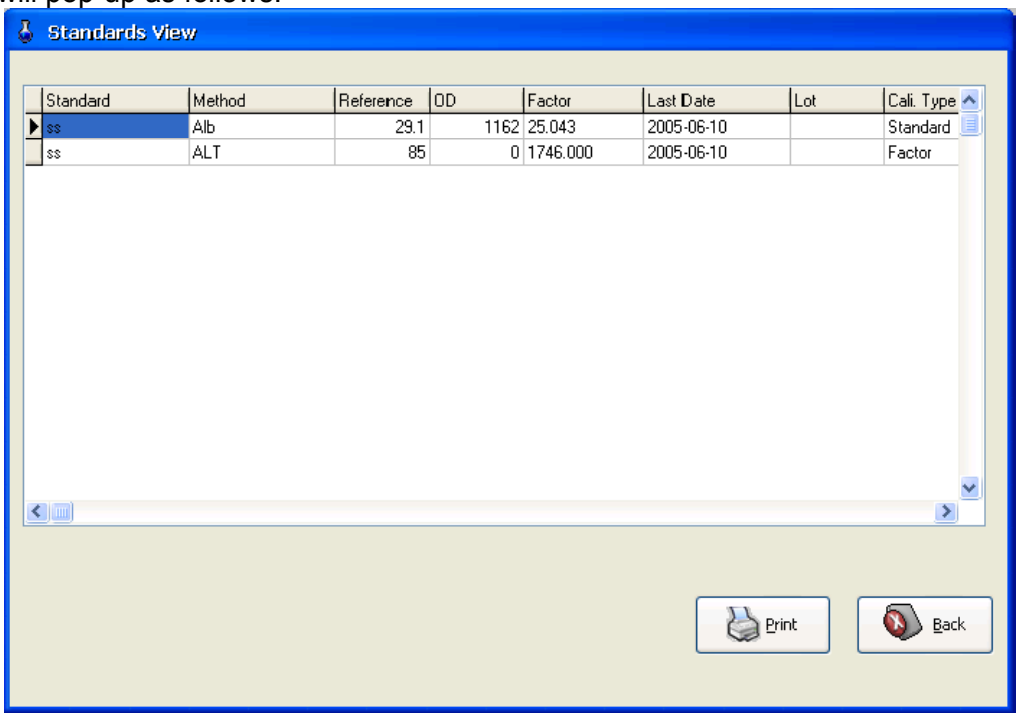
Select “History list”. After you press the button of to “OK”, a window for printing history record will pop-up as follows.



Input the starting time and ending time to inquire history records within the designated period. Press the CTRL key and the left button of the mouse to execute multiple-selection printing. Or select the button of "Select all" on the lower left corner to select all history records and print them.
If you fail to input the starting time and ending time, all history records will be listed. Press the CTRL and the left button of the mouse to execute multiple-selection printing. Or select the button of "Select all" on the lower left corner to select all history records and print them.

4.2 Standard inquiry

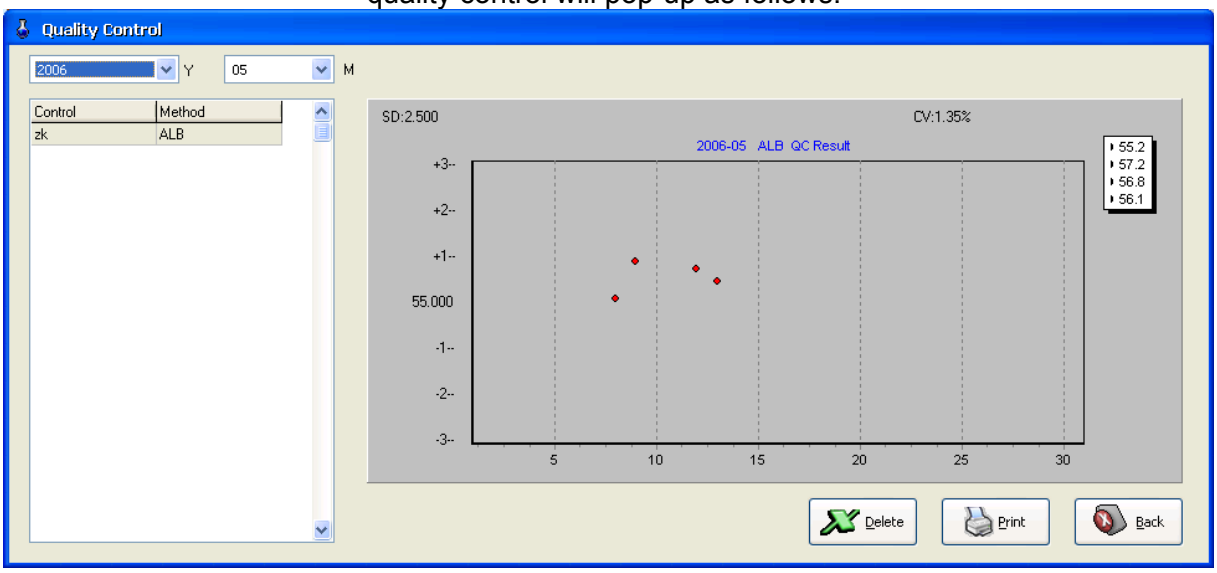
Under the menu of parameter setting, select “Standards” and then a window for standard inquiry will pop-up as follows.



All calibration result will be list in the table , you can also select one standard to print.

4.3 Inquiry of quality control

Under the menu of parameter setting, select “Controls” and then a window for inquiry of quality control will pop-up as follows.

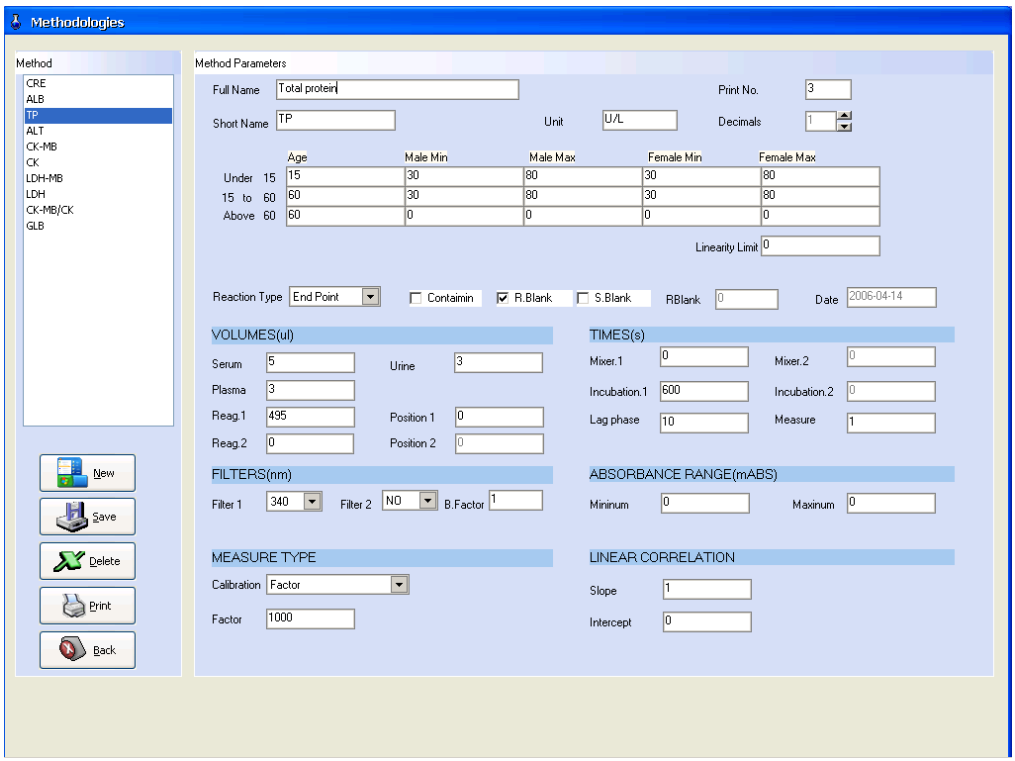


Select the quality control of a certain item of a certain month in a certain year, and the diagram of the quality control will be displayed on the right side as follows.
Press the button of "Delete" to delete the quality control results of the designated item.
Press the button of "Print" to print the quality control diagram of the designated item.

Chapter V Parameter Setting

5.1 Methodologies

Activate the menu of parameter setting and select “Methodologies” or directly click the button of "Methodologies" in the shortcut toolbar to edit a new testing item, amend or delete a certain item. All confirmed items are saved in the database and can be recalled at all times. Refer to the figure below.



Edit of testing parameters

The interface for input of item parameters is divided into three parts.

1. The left area is for various codes of items already edited.

2. The central area of the interface is the area of item parameters, which displays all parameters requested to be set for a certain item.

3. The lower left corner area of the interface contains five function keys, which are "New", "Save", "Delete", "Print" and "Back".

5.1.1 Edit a new testing item

Activate the menu of parameter setting and select “Methodologies” or directly click the button of "Methodologies" in the shortcut toolbar to enter into the window of parameter setting.

1. Input various parameters.

2. Press the button of "Save".

3. After checking the parameters and confirming no error, the system will save them and then a new item has been added.

Note: In case that the system detects any wrong parameter during the process of saving, it will prompt to re-input the parameter, which has been detected to be incorrect, and will prompt to save again.

While editing the parameters of a certain item, be sure to fill in all spaces on the interface with necessary information in accordance with the requirements indicated on the reagent cover of the item. The cursor can move to different spaces through moving the mouse. Contents to be filled on the interface include:

1. Full name

2. Short name

3. Print No.- This No. determines the print order of tests in the patient report.

4. Unit- Measurement unit

5. Decimals- Decimal digits of measurement result

6. Range of normal reference value - For normal reference value, input required values respectively based on different sexes and age sections. In case of any column not input, the system will not provide services. After all normal reference values are input, the system will send a warning signal if the value of any sample is beyond the stipulated range during the operation of the apparatus.

7. Linearity limit- Input the linear range of this item

8. Reaction type- Test method -Select End Point Method, Fix Time Two-point Method and Kinetic rate Method by the arrow key

9. Contamin - If the reagent is contaminant, tick the box before the option by the space key. Then during the testing, the system will automatically double to rinse the colorimetric basin.

10. S.Blank - For items requesting sample blank, tick the box before the option by the space key.

11. R.Blank - For items requesting reagent blank, tick the box before the option by the space key.

12. Volume of sample - Input the sample volume (5-60 uL) for Serum, Plasma and Urine.

13. (Volume of reagent 1) Input the volume of reagent 1 (100-500).

14. 14) (Volume of reagent 2) If necessary, input the volume of reagent 2.

15. (Position of reagent 1) If allocate, input the position of reagent 1 (1-36), otherwise, input 0

16. (Position of reagent 2) If allocate, input the position of reagent 1 (1-36), otherwise, input 0

17. Mixing time 1 - After filling in reagent 1, it is necessary to mix by a mixer and the time can be set as one second (not applicable for single reagent).

18. Incubation time 1 - It is the incubation time (in second) after reagent 1 is filled while double reagents are applied.

19. Mixing time 2 - It can be set as one second.

20. Incubation time 2 - It is requested to be input only when double reagents are applied. It is the incubation time from the time in second when reagent 2 is filled to the time when the reagent is inspired to the flow cell for color comparison.

21. Delay time - It is the time for equalization in the flowing colorimetric basic. It is 5 seconds for End Point method and 20-30 seconds for Kinetic rate method.

22. Time for measurement and reading - It is 1 seconds for End Points method and 30 seconds for Kinetic rate method.

23. Wavelength -The system can provide eight wavelengths available for selection.

24. Wavelength 2 - If dual-wavelength method is requested, then wavelength 2 can be selected. The second wavelength system can provide eight wavelengths available for selection.

25. Absorbency range of reagent - Input the maximal and minimal values of reagent blank in mAbs (micro-absorbency) so as to control the reliability of the reagent used.

26. Measure type – Select the calculation method, if select “Factor”, factor is required to input

27. Linear correlation – Input the intercept and slope (only used if test results need to be corrected). Generally the intercept is 0 and the slope is 1. After inputting the slope and intercept, all results will be calculated based on the new slope and intercept. Because the variation of slope and intercept will affect many parameters and the final results, do not change it randomly.

Upon the completion of input of all above parameters, press the button of "Save" to save all edited contents.

5.1.2 Amend parameters of a certain item

Activate the menu of parameter setting and select “Methodologies” or directly click the button of “Methodologies” in the shortcut toolbar to enter into the window of parameter setting. Select the item to be amended in the left list and move the cursor to different parameters by the mouse. Upon the revision, press the button of "Save" to save the revision.

5.1.3 Delete a certain item

Activate the menu of parameter setting and select “Methodologies” or directly click the button of “Methodologies” in the shortcut toolbar to enter into the window of parameter setting. Select the item to be deleted (the selected item will be highlighted in blue color) and then press the button of "Delete" to delete.

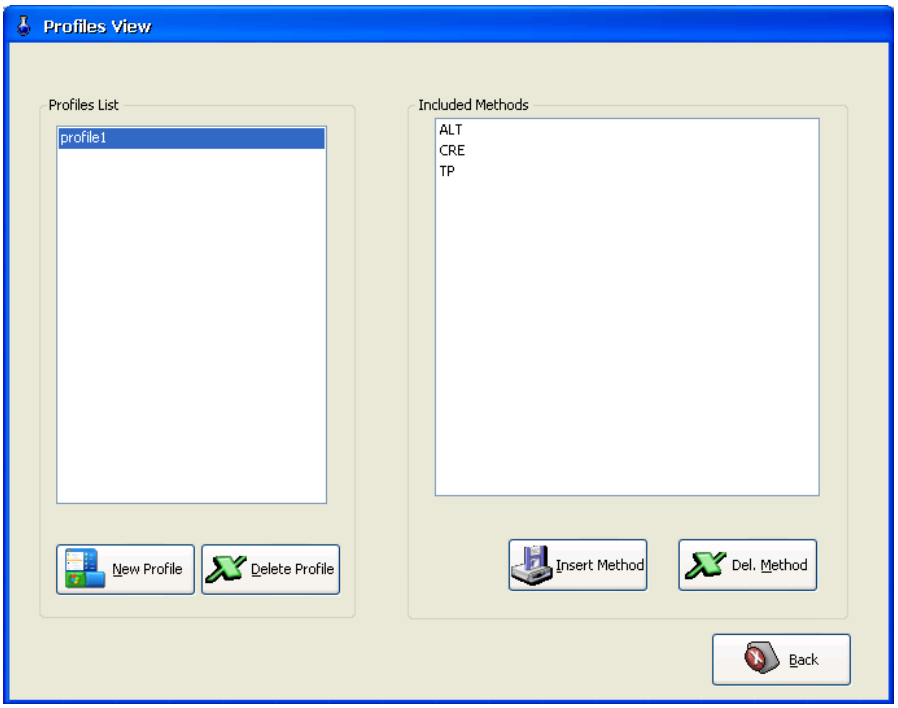
5.1.4 Print a certain item

Activate the menu of parameter setting and select “Methodologies” or directly click the button of “Methodologies” in the shortcut toolbar to enter into the window of parameter setting. Select the item to be printed in the left list. Press the button of "Print" to print all set parameters of the item.

5.2 Profile

The profile refers to a group of significant testing items requested to be tested during the diagnosis of a certain disease and the combination of this group of testing items is called a profile.

Activate the menu of parameter setting and select profile setting to enter into a window of profile setting. A window is activated as follows.

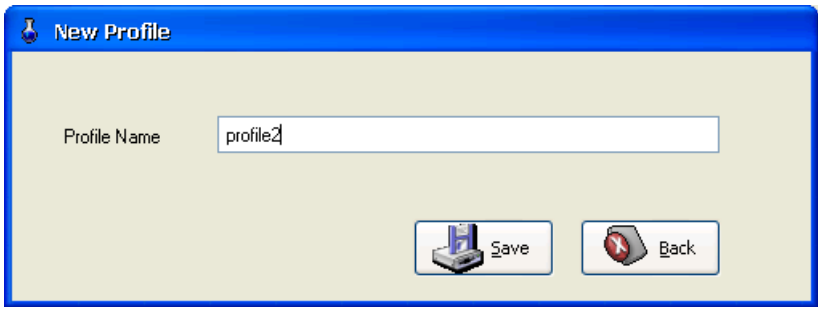


The list of edited profiles is displayed on the left side of the window. Select the desired profile and then all items contained in the profile are listed in the box on the right side. There are five function keys below the window including newly add a profile, Delete a profile newly, add a item, Delete an item and Exit.

5.2.1 Edit a profile

The procedures to edit a new profile are as follows.

1. Edit a new profile Press the button of "New Profile" and a window will pop-up.



2. Input the name of the new profile (not more than 6 characters)

3. Double click the desired item in the left list of items or press the button of "Add" upon selection (the selected items are covered by a blue rectangle). Then the right list will display the selected item.

4. Save Press the button of "Save" to save.

5.2.2 Amend a certain profile

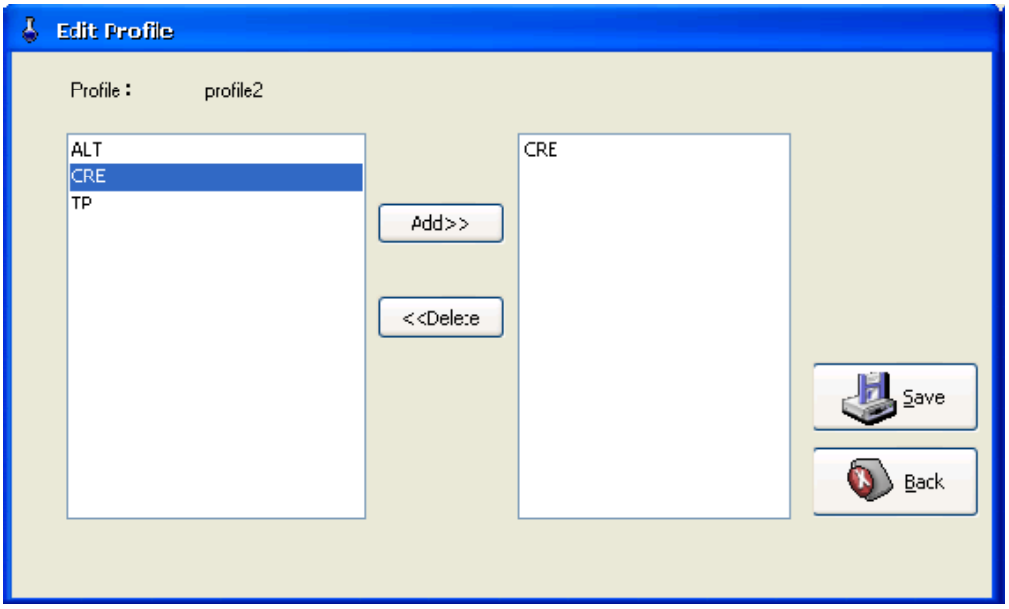
To amend a certain profile means to add or remove some testing items.

a) Add testing items

Activate the menu of parameter setting and select profile setting to enter into a window of profile setting. Select the profile to be amended.

1) Select the profile to be amended.

2) Click "Insert Method" and then a window will pop-up for adding a new item as follows.



3) Select the item to be added in the right box and click the button of "Add" to add the selected item to the right list.

4) Press the button of "Save" to save.

5) The operation in step 3) can be repeated many times to add more items.

b) Delete testing items

1) Select the profile to be amended.

2) Then select the item to be deleted in the right list.

4) Click the button of "Delete" and then the selected item is deleted.

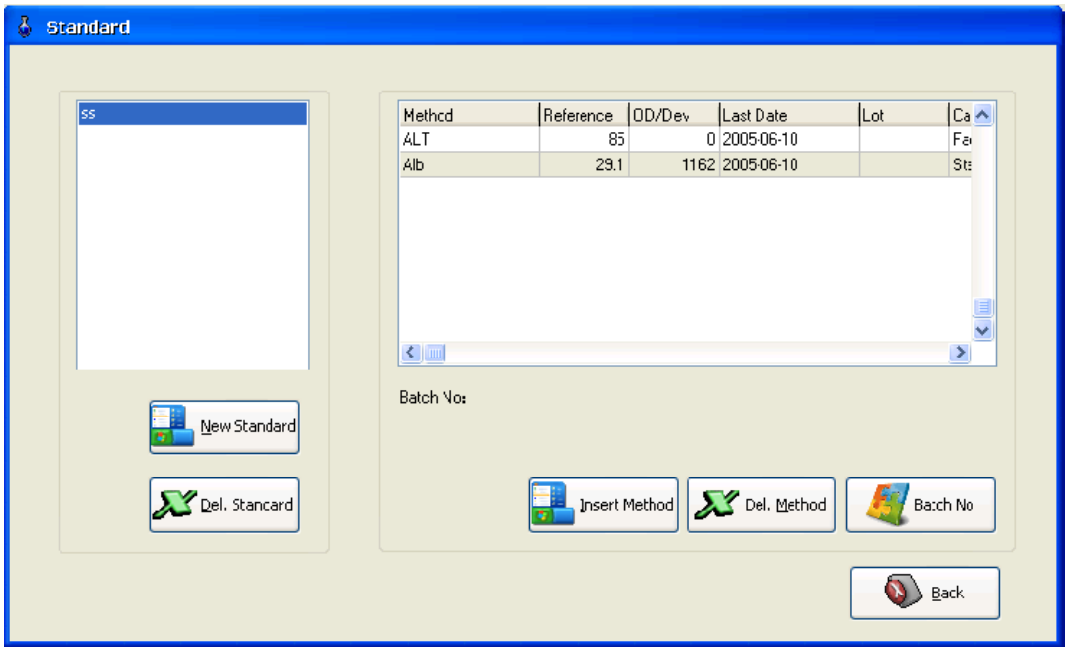
5.2.3 Delete a certain profile

Activate the menu of parameter setting and select profile setting to enter into a window of profile setting. Select the profile to be deleted in the left list. Press the button of "Delete Profile" upon selection. Then a message-box will pop-up to request your confirmation. Press “OK” to delete and press “Cancel” to cancel.

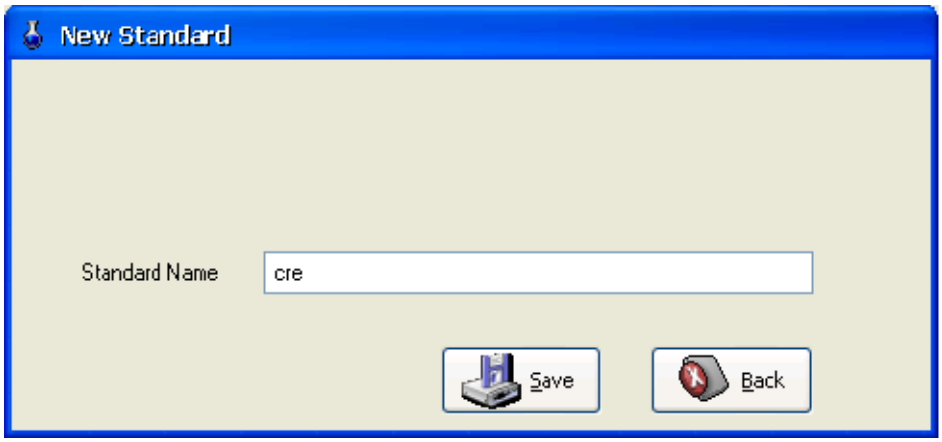
5.3 Standard

I. Edit a new standard

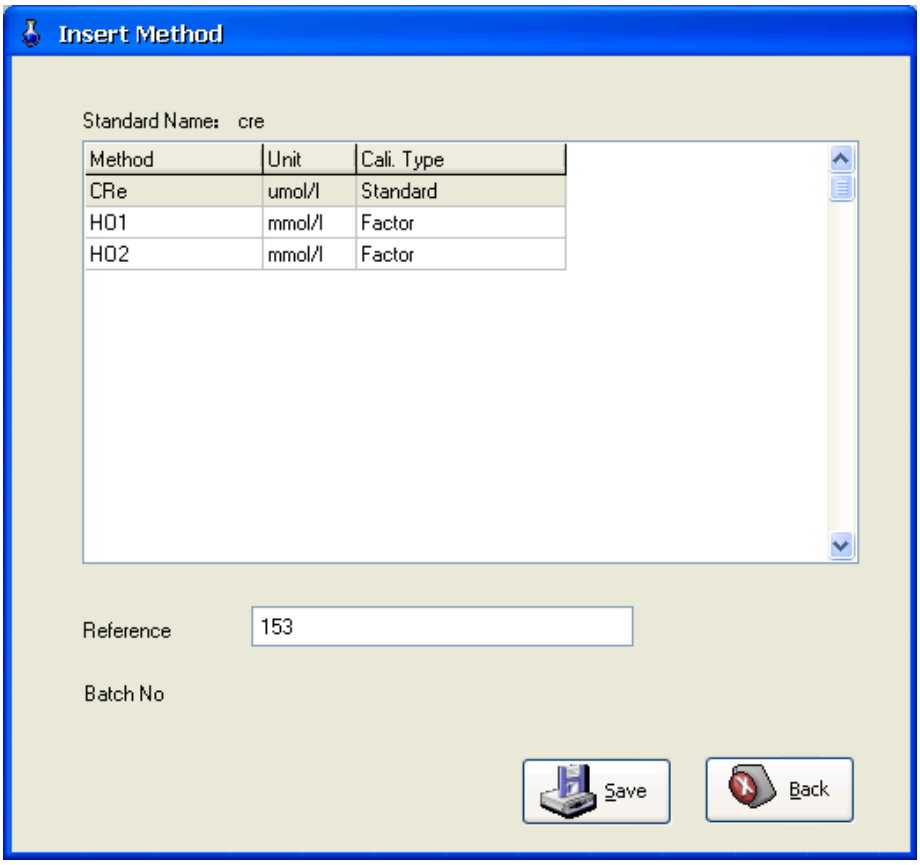
Activate the menu of parameter setting and select standard setting or directly click the button of "Cali. settings" in the shortcut toolbar to enter into the window of standard setting. Then a window will be activated as shown in the figure below.



All standards of the system are listed in the left box. Select the standard desired and the standard of the corresponding calibration item is displayed in the right area (relevant items). While editing a new standard, press the button of "New Standard" and then a new window will be activated.



Input the name of a new standard. Each standard must have its own name, which cannot be the same as others. After inputting the name of a new standard, press the button of "Save" to save. Then a new window will be activated. Select items, which request this standard for calibration.



Upon the selection of desired items, input the concentration value of the standard (the unit of concentration has already been defined while inputting item parameters). Press the button of "Save" to save. For a compound calibration substance, continuously input the standard value of each item and then save is finally exit.

Note: If the standard contains no item, the system will automatically delete the empty standard when to exit.

If any standard belongs to a part of a certain calibration curve, it cannot act as the calibration for another item. The batch number is not very important if only single standard is applied. However, if a calibration curve is applied, the batch number will become very important. During the edit of all standard points on one calibration curve, each standard value must be input. Furthermore, be sure to confirm that all standards must belong to a same batch number.

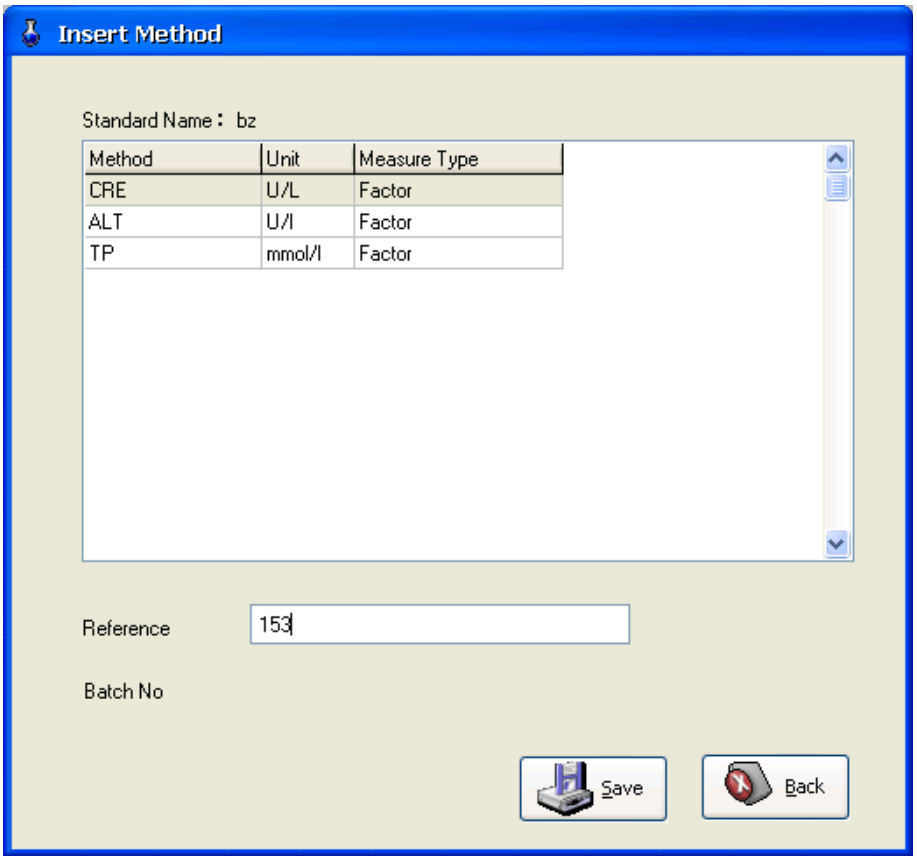
II. Input the batch number

Select the standard in the left list and the selected standard will be covered by a blue rectangle. Then press the button of "Batch number" and a new window will be activated.
Input the batch number and press the button of "Save" to save. Then exit.

III. Amend a standard

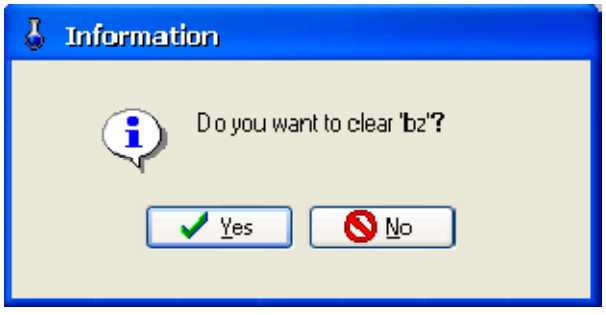
The amendment of a standard only allows to add or remove an item, which will conduct calibration based on this standard, and does not allow to amend the standard concentration of a certain calibration item. In order to amend the concentration of a standard, it is a must to first delete this calibration item and then reedit the item and input a new standard concentration.
In the window shown in the figure below, move the cursor to the name of the standard to be amended.

To add a calibration item, press the button of "Insert Method" and a window for selection of calibration items will pop-up.



Select a calibration item to be added. Input its standard value and save it. This operation can be repeated many times to add more items. Finally press the button of "Back" to exit.
To remove a calibration item, select the standard in the left list. Then the calibration items of this standard will be displayed in the right list. Select the calibration item to be deleted and press the button of "Delete an item" to delete.

IV. Delete a certain standard
Activate the window of standard setting. Select the standard to be deleted in the left list and press the button of "Del. standard". Then a window will pop-up for confirmation.

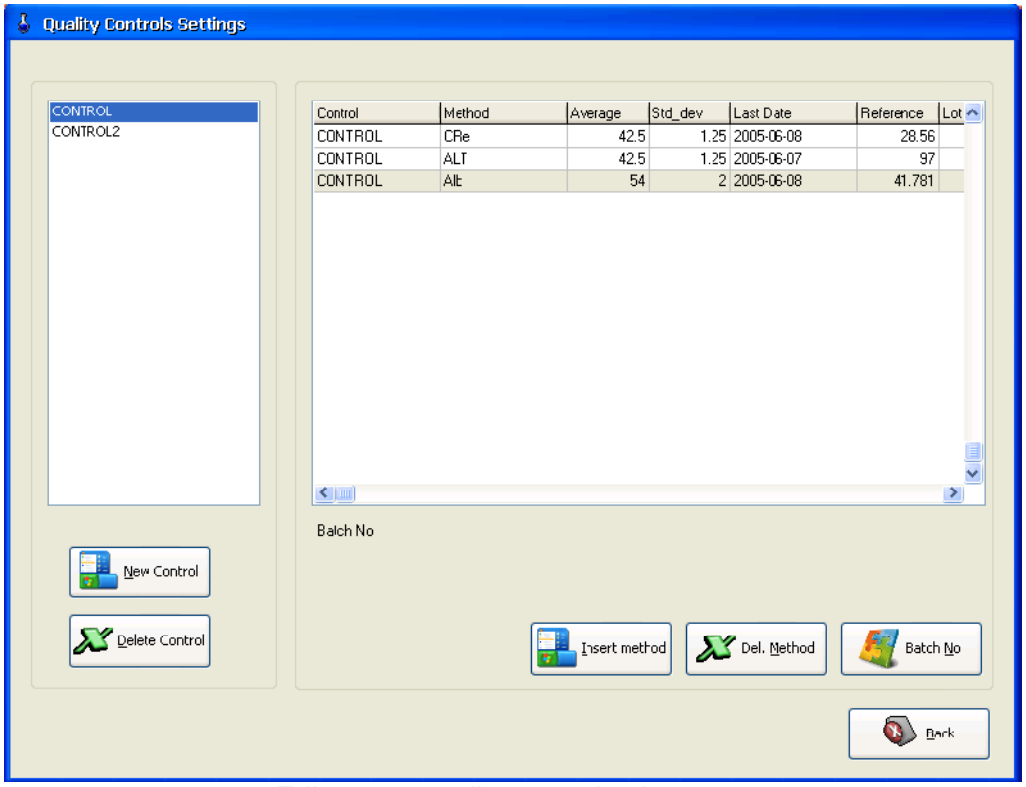


Select Yes to delete the selected standard and select No to remain it.
Please note that when a certain standard is deleted, the system will automatically delete the calibration items set in all worksheets (all items of compound calibration substance).

5.4 Quality control

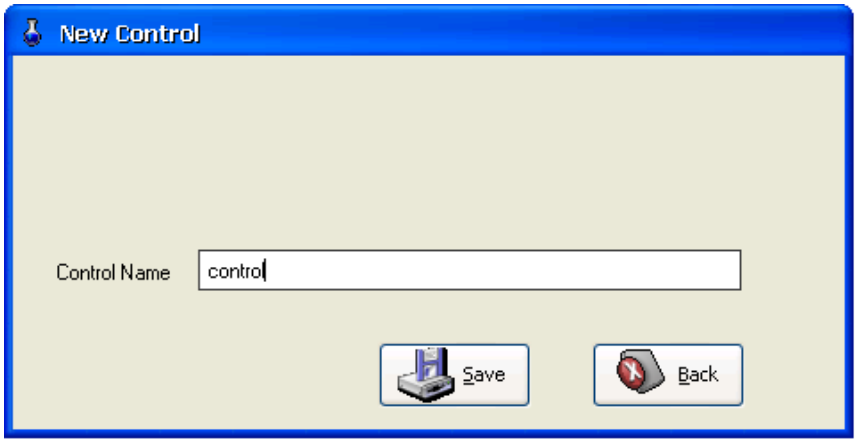
I. Edit a new quality control substance

Activate the menu of parameter setting and select quality control setting or directly click the button of "QC settings" in the shortcut toolbar to enter into the window of quality control setting shown in the figure below.



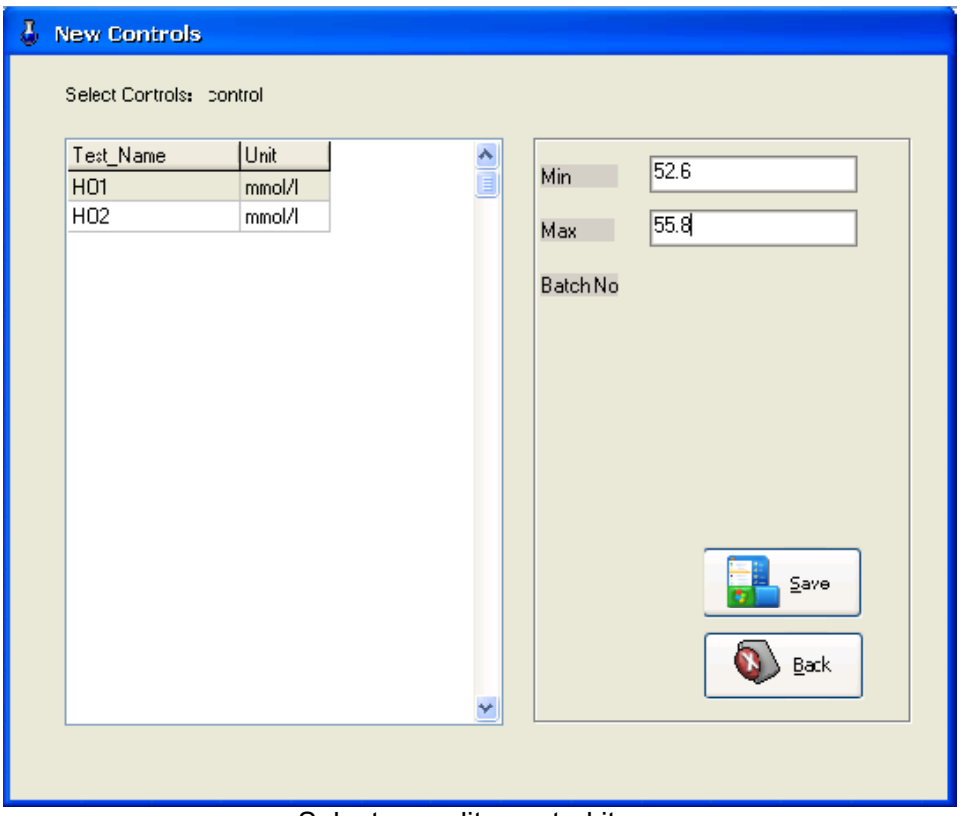
Edit a new quality control substance

The list of edited quality control substance is displayed on the left side of the activated window. Move the cursor to select the name of the control
substance desired. The information of all quality control items related to the control substance is listed in the right box.
To edit a new quality control substance, press the button of "New Control" and then a window will be activated.



Input the name of a new control substance

Input the name of a new control substance. The name of each control substance must be unique and two different control substance cannot share a same name. After inputting the name, press the button of "Save" to save. A window will be activated as follows.



Select a quality control item

All testing items stored in the system are displayed in the left area. Move the cursor to activate the testing item, which will use this control substance for quality control. Input corresponding values, such as the maximum value and minimum value. The system will automatically calculate the average values.
After the input of all information, save it.
For a compound calibration substance, continuously input the value of quality control of each item and then save it finally press the button of "Back" to exit.

II. Amend quality control
The amendment of quality control can only add or remove the quality control items of the control substance and cannot directly amend the value of quality control of a certain testing item. To amend the value of quality control, first delete the testing item and then re-add and input a new value of quality control.

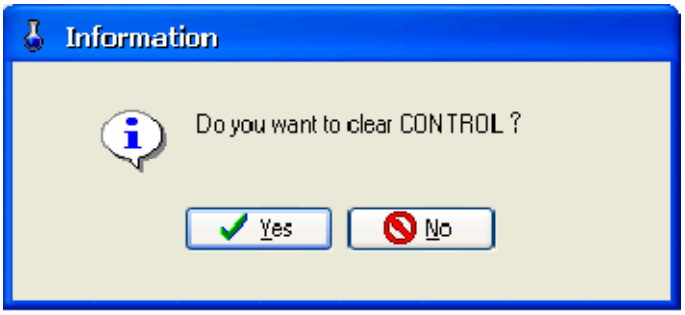
a) Add testing items
Activate the window of quality control. Select the control substance to be amended. Then press the button of "Insert Method" and a window for selection of quality control items will pop-up.
Select the testing item to be added. Input the value of quality control and save it. For a compound calibration substance, continuously input the value of quality control of each item and then save is. Finally press the button of "Back" to exit.

b) Remove testing items
To remove quality control items, activate the window of quality control. Select the control substance to be amended in the left list of control substance and then the testing items

contained in the control material will be displayed in the right list. Select the item to be deleted and click the button of "Dele. Method" to delete.

Delete a control substance

Activate the window of quality control. Select the name of the control substance to be deleted and press the button of "Del. Control". Then a window shown in the figure below will pop-up to warn.

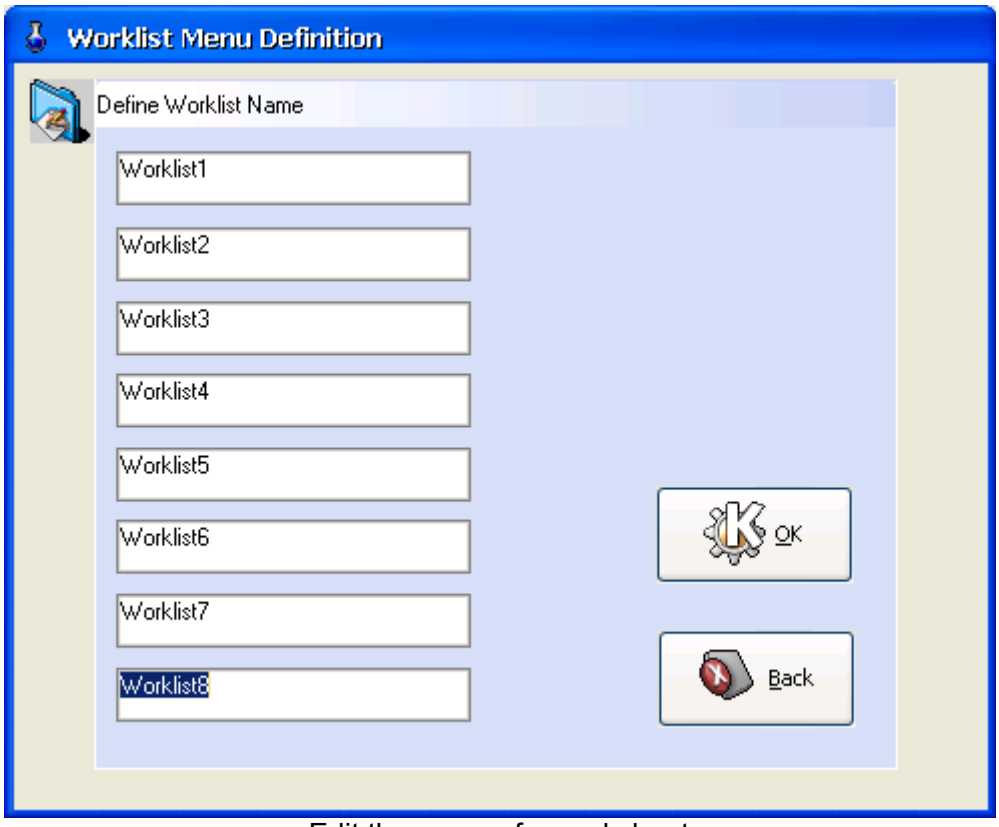


Press “Yes” to delete and press “No” to cancel.

If a certain control is deleted, the system will automatically delete the quality control items of this control set in all worksheets (all items of a compound control substance).

5.5 Set the name of a worksheet

Activate the menu of parameter setting and select worksheet defining. The system allows editing 8 different worksheets.



Edit the name of a worksheet

Note: Each worksheet can be indicated by its name or figures.

Amend the name of a worksheet

To amend the name of a certain worksheet, make amendment by input in the corresponding input box. Upon the completion of amendment, press the button of "OK" to save.

Chapter VI Information

6.1 System Information

The setting of system information can conduct operations such as adding or deleting upon the sender, checker, assessor and department.

1) Add or delete a sender

Select the option of “Sender” and input the name of the doctor. Press the button of "Add" to add the new sending doctor into the list. Or press the button of "Delete" to delete the sending doctor from the list.

2) Add or delete a checker

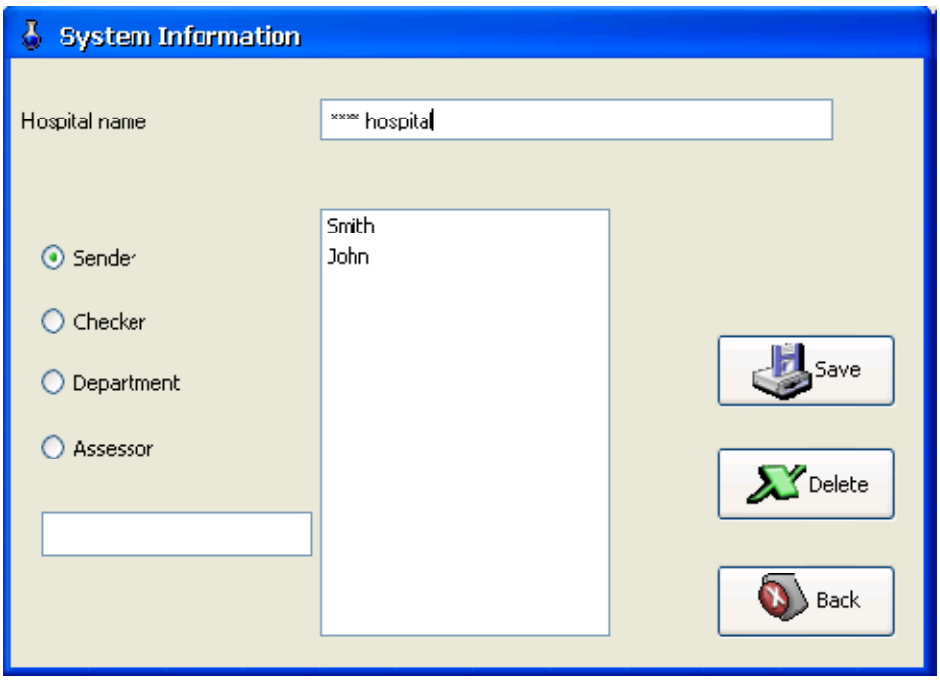
Select the option of “Checker” and input the name of the doctor. Press the button of "Add" or "Delete" to add the new testing doctor into the list. Or press the button of "Delete" to delete the testing doctor from the list.

3) Add or delete an assessor

Select the option of “Assessor” and input the name of the doctor. Press the button of "Add" or "Delete" to add the new auditing doctor into the list. Or press the button of "Delete" to delete the auditing doctor from the list.

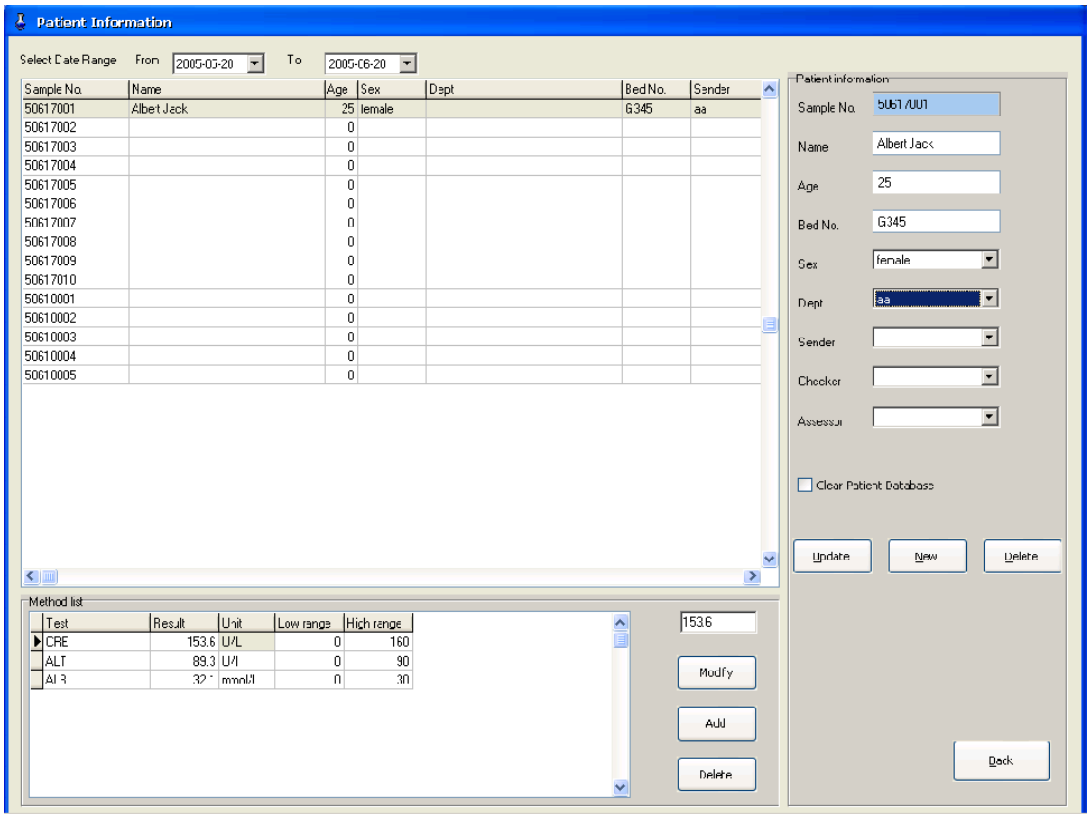
4) Add or delete a department

Select the option of “Department” and input the name of the department. Press the button of "Add" to add the new department into the list. Or press the button of "Delete" to delete the department from the list.



6.2 Patient Information

The setting of patient information provides two functions:



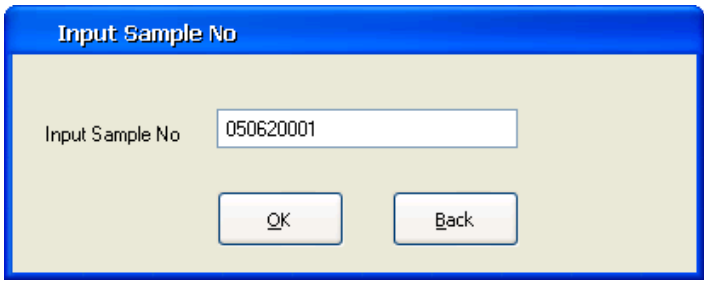
Edit the patient information

1) Update patient information

First select the date range if you need to edit the patient information or test results of some day, then select a row of the patient list, the corresponding information will be shown in the right list. If you want to rewrite it ,just input the new information of each item and click the button of “Update” .

2) Insert a new patient

Press the button of “New” in the right band, a window will be displayed.:



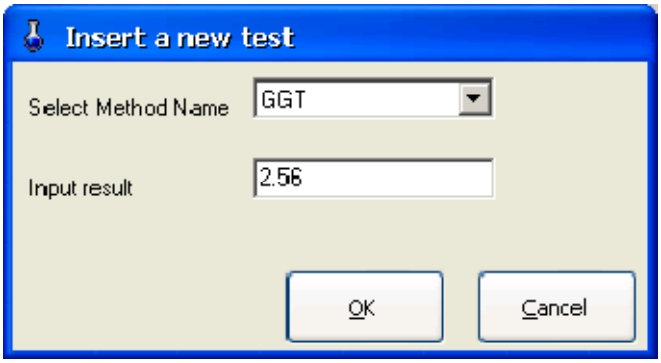
Input the sample No. which you want to insert, and it will be added to the patient list of today. Then you can update its information or insert a new test result for it.

3) Delete patient records

If you want to delete a patient, please select the row and click the button of “Delete”. If you want to clear all patient records, just mark the check box of “Clear patient database” and click the button of “Delete”.

4) Insert a new test result

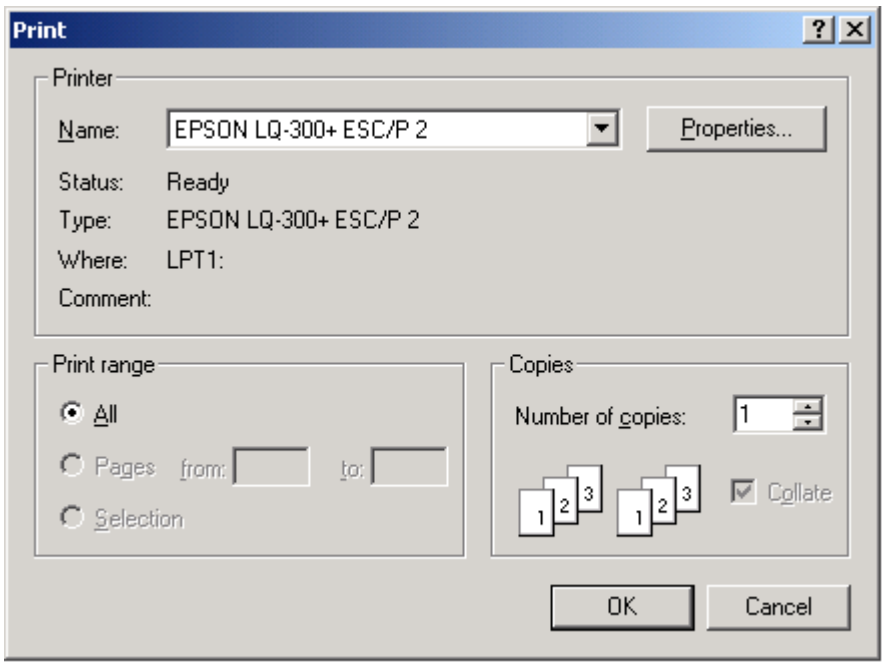
Click the button of “Add” in the method list band, you can insert a new test result for the selected patient.



Chapter VII System Setting

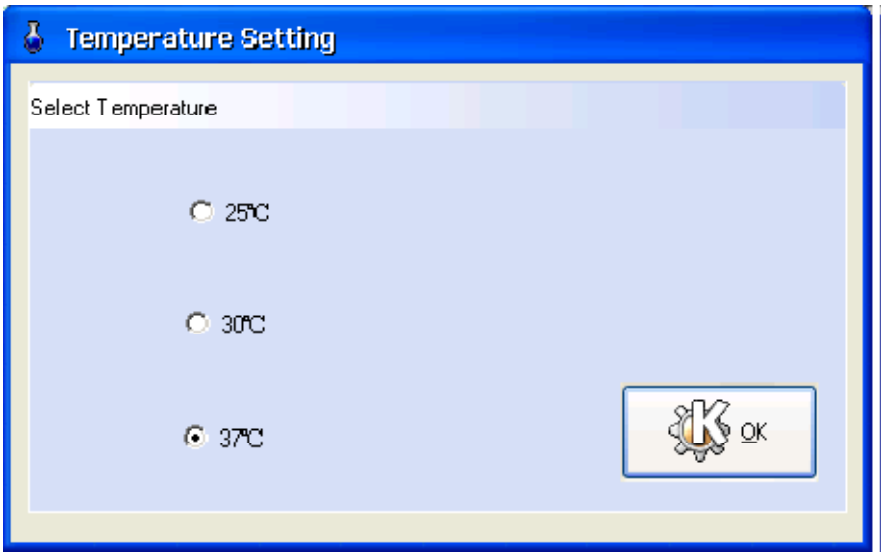
7.1 Setting of printer

Set up the printer.



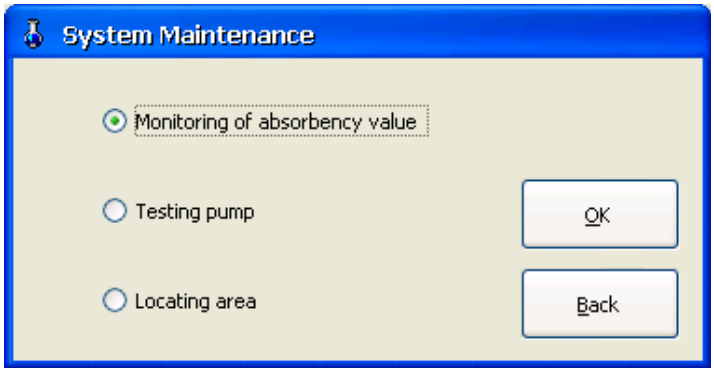
7.2 Setting of temperature

The working temperature refers to the actual incubation temperature in the reaction tray and the temperature of reactant liquid inside the flow cell. Activate the menu of system setting and select temperature setting. Select the proper reaction temperature and press "Confirm".

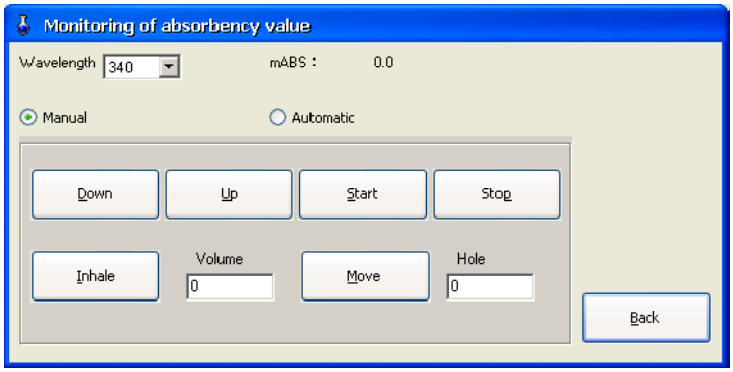


Setting of working temperature

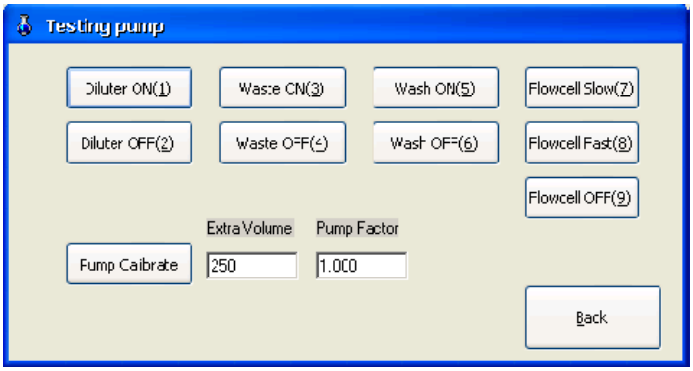
7.3 System maintaining



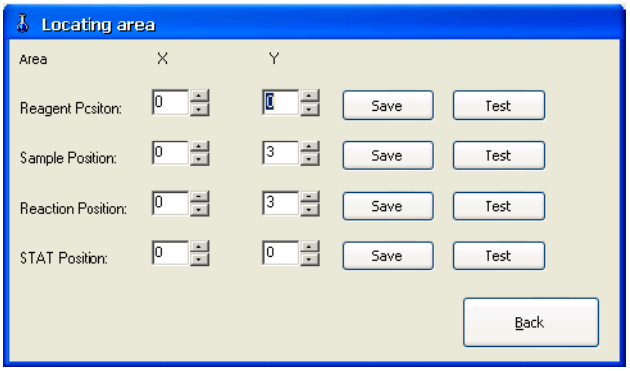
1) Monitoring of absorbency value Select a wavelength to be monitored. Upon the selection, the change of the absorbency value will automatically be displayed.



2) Testing pump



3) Locating area



Chapter VIII Work Flow

8.1 Operation

This chapter describes the preparation and operation of the system. Switch on the analyser. The system will begin self-checking and then enter into the main interface. Refer to Chapter III.

8.2 Parameter setting

First, you should make sure that the settings of each method in “Methodologies” is ok. Then, go to “Cali. Settings” to revise standard parameters.
Only after you finish above settings, you can start following operation next.

8.2 System calibration

Before testing the samples, be sure to calibrate the system first. The standard substance can be used for calibration.
For items to be calibrated, it is unnecessary to test the standard each day. However, it should be tested at least once. Determine the calibration curve and relevant data will be stored until new data are stored upon the next calibration.
For nonlinear items, the quality control substance can be used for calibration. The calibration can be conducted once in each day or once in several days. The value of quality control has been stored by the system. The purpose of daily calibration is to make comparison with the stored data.

8.4 Execution of worksheet

Switch on the apparatus and activate the main menu. Select a worksheet which you want to test.The screen will display the sample positions on the sample rack from No. 1 to 60. Refer to chapter III for the edit of sample information.
Before editing a new worksheet, be sure to delete the original sample information in the worksheet.
Upon completing the edit of the worksheet, press the button of "Start to test" to start the operation. Then the window will be activated to confirm reagent positions.

8.4.1 Check before operation

1. The serial number and position of each sample on the sample rack.

2. Check the reagent requested by daily testing and confirm that it has reached the room temperature before the testing. Confirm if the position of the reagent container on the reagent rack is in compliance with that displayed on the screen.

3. Check if cleaning solution is fully filled.

4. Check if the waste liquid bottle has been emptied.

5. Check if 6 clean reaction plates have been replaced.

6. Check if the positions of two probes are correct.

8.4.2 Confirmation of starting

The system will automatically execute each step of the edited testing. Each operation can accommodate 60 samples and 36 different kinds of reagents. The screen will display the total number of tests, test results (micro-absorbency, final results) and the remaining time before the completion of testing.

After the testing for the first batch of 60 samples is completed, the operator should duly replace the reaction plate (such information is displayed on the screen). The system will continue to operate as per the edited program without being affected.

8.4.3 Check of normal operation

During the operation, the system will continuously monitor the operation conditions. In case of any abnormal condition, the system will prompt or warn, such as no reagent or no sample available.

8.4.4 Stop of normal operation of system

While the apparatus is under operation, the operator can press the button of "Stop" to stop it. (During testing water blank, you can press Alt +'q' to interrupt)

8.4.5 Retest

Refer to "**3.5 Retest selected records**".

8.4.6 Redilute

Refer to "**3.6 Redilute the 'OL' records**".

Note: The original results for tests reworked have no backup copy and they cannot be remained after being covered.

8.4.7 Operating cycle

Upon starting, the system will automatically rinse the pipelines, dilutor and aspiration probes. Then it will clean those two probes in the rinsing tank, clean the colorimetric basin and all pipelines. For contaminant reagent, the system will automatically conduct the cleaning cycle twice. After cleaning the colorimetric basin, the system will automatically detect the water blank for 8 wavelengths and calibrate to adjust the photometer to zero. The cycle for sampling is as follows.

1. The sampling probe is immerged into a reagent bottle to inspire reagent of fixed volume and a bit of air.

2. The probe moves to the cleaning basin for cleaning.

3. The sampling probe will inspire the sample and a bit of air.

4. The probe again moves to the cleaning basin for cleaning.

5. The sample and reagent are transferred into a hole on the reaction tray.

6. As the mechanical arm returns back to the cleaning basin, the probe and the mixer are cleaned.

7. Distilled water is filled into the flow cell to clear residual sample remained inside.

8. The aspiration probe will inspire 80μL reactant liquid and a bit of air, which will be filled into the flow cell to rinse the colorimetric basin so as to avoid contamination caused by different samples.

9. The aspiration probe will inspire rest reactant liquid into the flow cell to make measurement.

10. The mechanical arm will again return to its original position (cleaning basin) to clean the probe. Then the cycle of sampling will again start.

Generally, the mixer is requested only when dual reagent is applied.

8.5 Summary of operation

8.5.1 Switch on.

Turn on the pourer switch and preheat for 20 minutes (the preheating time can be properly prolonged in case of low room temperature).
Calibrate the apparatus.

8.5.2 Establish a worksheet.

Each worksheet can accommodate up to 60 samples. In case of more
than 60 samples for once operation, other worksheets can be used (worksheet 2, 3, etc.). Please confirm the following points before operating the apparatus.

1. If the sample is placed on the sample rack.

2. Prepare enough reagent for daily operation. Confirm that the reagent reaches the room temperature before the apparatus is started.

3. Place the reagent on the designated position.

4. Check if the cleaning solution bottle is full of deionized water.

5. If the waste liquid bottle has been emptied.

6. Place six clean reaction trays on the incubation plate.

7. Check if each probe is exactly on its position.

8.5.3 Start operation.

Start operation system.
All operation conditions, the absorbency and final results of the samples will be displayed on the screen. The system will continuously detect abnormal conditions and display on the screen. If the system sends a warning signal as "ticktack", it means that the distilled water, reagent or sample is almost exhausted, or the waste liquid bottle is almost full. The remaining time for operation of the apparatus will also be displayed on the screen. So the operator can leave the worktable during this period and come back in a proper time to replace the reaction tray (if necessary). After the apparatus finishes the tests of 120 samples, it will prompt the operator on the screen to replace the reaction tray. Upon the replacement, press OK and then the apparatus will automatically continue the operation.
Any unreliable test result can be retested.
Upon the completion of operation, the system will automatically clean the pipelines and the probes will automatically return to original positions.
The system will automatically save the testing results and the operator can print reports as required.

8.5.4 Shut down.

Before shutting down the apparatus, be sure that the daily maintenance has been finished. Exit from the system and shut off the power. Clean the exterior of the apparatus and cover it with a dust shield.

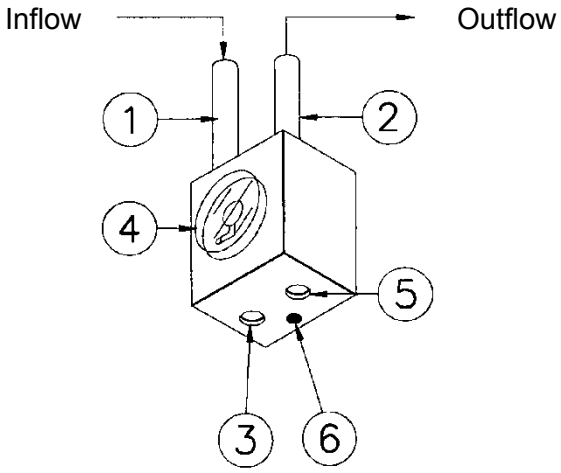
Chapter IX Maintenance

9.1 Components

9.1.1 Flow cell

The flow cell installed inside the apparatus is made of stainless steel materials. It has high technical precision, rapid temperature rise and accurate constant temperature. The temperature conversion is performed by Peltier and can guarantee the interior temperature of the flow cell to be constant rapidly.
Feature:

- Volume：50uL - Diameter of window：7.5mm
- Optical path: 10mm - Weight: 10 g



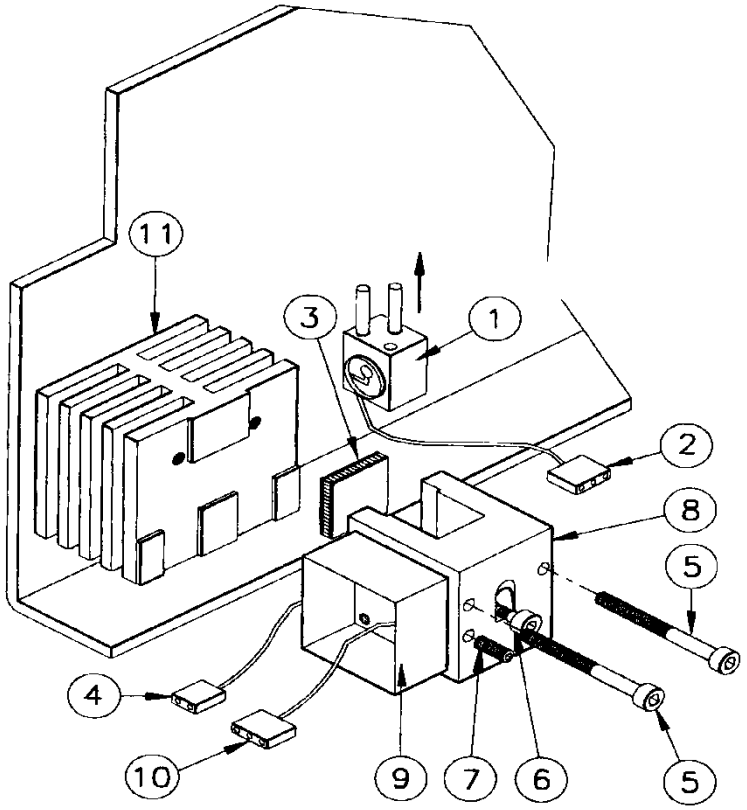
Flow cell

1. Inlet of colorimetric basin
2. Outlet of colorimetric basin
3. Temperature sensor
4. Colorimetric window
5. Temperature sensor
6. Fixing screw

9.1.2 Cleaning of Flow cell

Upon the completion of the testing, the system will automatically rinse the colorimetric basin once. In order to avoid bacteria's multiplication inside the flow cell, it is suggested to clean the flow cell by detergent for glassware in each week.
Procedures:

1. Start the system.
2. Immerse the probe into cleaning solution. Press the button of the manual pump and then pump cleaning solution into the colorimetric basin (press the button and hold for ten seconds).
3. Keep cleaning solution into the colorimetric basin for 15 minutes.
4. Repeat steps 2 and 3 once.
5. Rinse the colorimetric basin with cleaning solution for one minute and then exit.



Cleaning of the colorimetric basin

1 Flow cell	2 Plug (connect to J6)	3 Peltier
4 Plug (connect to J6)	5 Screw	6 Spring regulator
7 Fixing lock	8 Fixing block	9 Preamplifier
10 Plug (connect to J2)	11 Radiator	

9.1.3 Replacement of Flow cell

1. Switch off the apparatus.
2. Open the rear cover of the apparatus.
3. Remove the inlet and outlet pipes on the flow cell.
4. Unscrew the screw and draw out the flow cell. Pay attention to the wiring of the temperature sensor.
5. Release the temperature sensor and take it out carefully.
6. Install the temperature sensor on the new flow cell carefully.
7. Apply some heat conduction grease on the side of the colorimetric basin in direct contact with Peltier.
8. Check if the transparent side of the colorimetric basin is clean.
9. Adjust the position (height) of the colorimetric basin and secure by the fixing lock.
10. Re Connect the pipes as per the original arrangement. Inspire distilled water by the manual aspiration button.
11. Check the value of water blank for each wavelength (to repeat water blank while start the test of a worksheet).

9.1.4 Replacement of waste liquid pipe

Remove the pipe between the flow cell and the peristaltic pump and replace it by a new pipe with the same size and length. While replacing the pipe, be careful not to damage the flow cell.

9.1.5 Replacement of aspiration pipe

Remove the pipe connecting the probe to the flow cell and replace it by a new pipe with the same size and length.

9.1.6 Replacement of photometer lamp

1. Shut down the system.
2. Open the rear cover plate of the apparatus.
3. Unplug the pins of the photometer lamp P1 on the PCB (A0068001) board.
4. Unscrew the positioning knob (two circles).
5. Unscrew the lock knob and dismount the photometer lamp (be careful!).
6. Install a new photometer lamp and screw the positioning knob (do not tighten). Be careful not to make your hands touch the bulb (use plastic film to wrap the bulb). Plug the pins P1 of the bulb into the socket J8 on the PCB (A0068001) board.

7. Power on the apparatus and execute “Maintenance” - “Monitoring of absorbency value”.

8. Select the testing of filters.

9. Select 340nm wavelength and the screen will display the averange value of water blank, which is continuously measured and read.

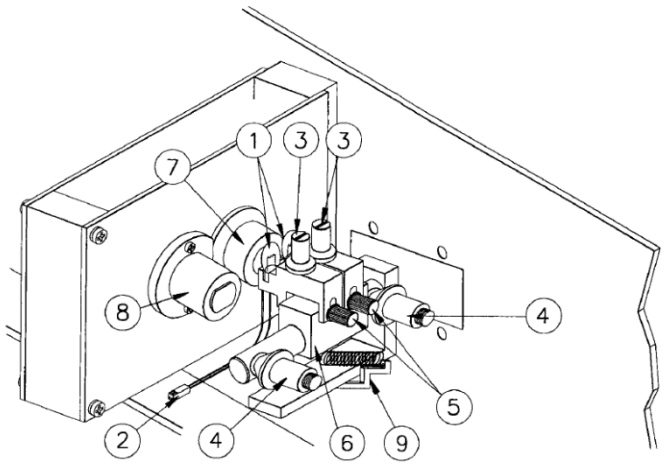
10. Press the button of manual pump and then pump distilled water into the flow cell.

11. Observe the value displayed on the screen while adjusting the positioning knob until the value reaches the minimum value (the minimum value should be less than 300 mAbs).

12. Tighten the lock knob and close the rear cover plate.

13. Exit from the system.

Note: Please prevent the lamp from directly irradiating your eyes while you are adjusting the position of the photometer lamp, because 340nm UV-light will hurt your eyes.



Photometer lamp

1 Photometer lamp
2 Pins of photometer lamp
3 Vertical positioning knob
4 Level regulator
5 Lock knob
6 Lamp hanger
7 Lens
8 Motor
9 Horizontal commutator of photometer lamp

9.1.7 Peristaltic pump

Replacement of peristaltic pump tubing (connecting to the flow cell)

1. Open the rear cover plate and the peristaltic pump can be seen at the left side. Refer to the figure below.

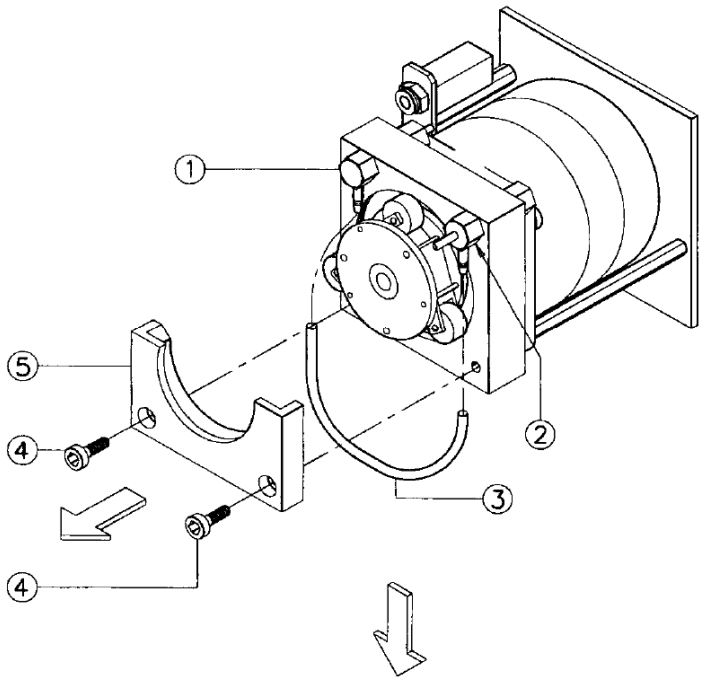
2. Remove the two screws by a inner4-hexagon spanner.

3. Remove the mounting plate .5

4. Dismount the pump tubing and replace it by a new pump tubing with the 3 same size.

5. Reinstall and restart the system. Observe if the operation is normal.

Replacement of peristaltic pump tubing (cleaning system)
There are three peristaltic pumps on the right side on the rear part of the apparatus. The replacement of the pump tubing is the same as above-mentioned method.



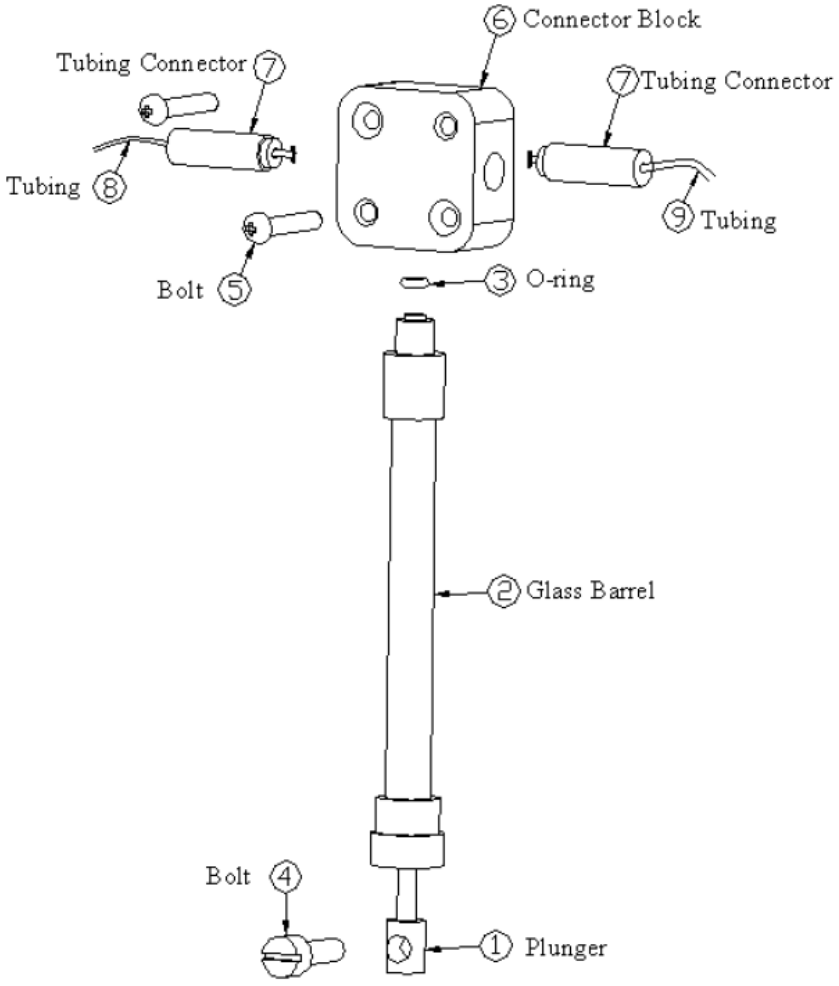
Replacement of peristaltic pump tubing
1 Inlet 2 Outlet 3 Peristaltic pump tubing 4 Screw 5 Mounting plate

9.1.8 Dilutor

Replacement of syringe

Remove the syringe from the plate of the dilutor. Unscrew the syringe and 2 the piston . Install a new syringe and a new piston. Check if the gasket seal 1 has been placed.

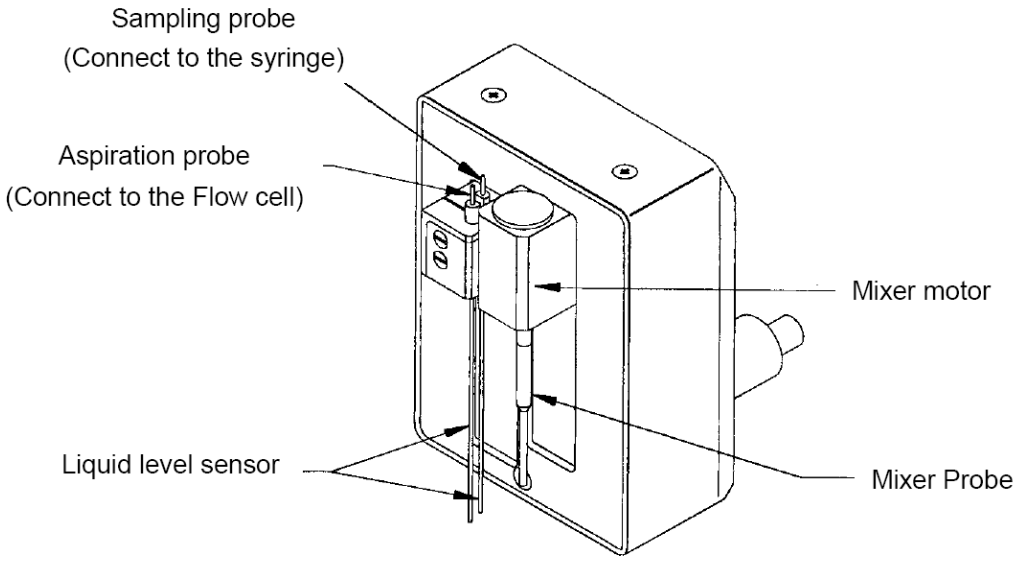
Note: please do not disassemble the dilutor randomly (unless the dilutor has leakage or is broken).



Dilutor

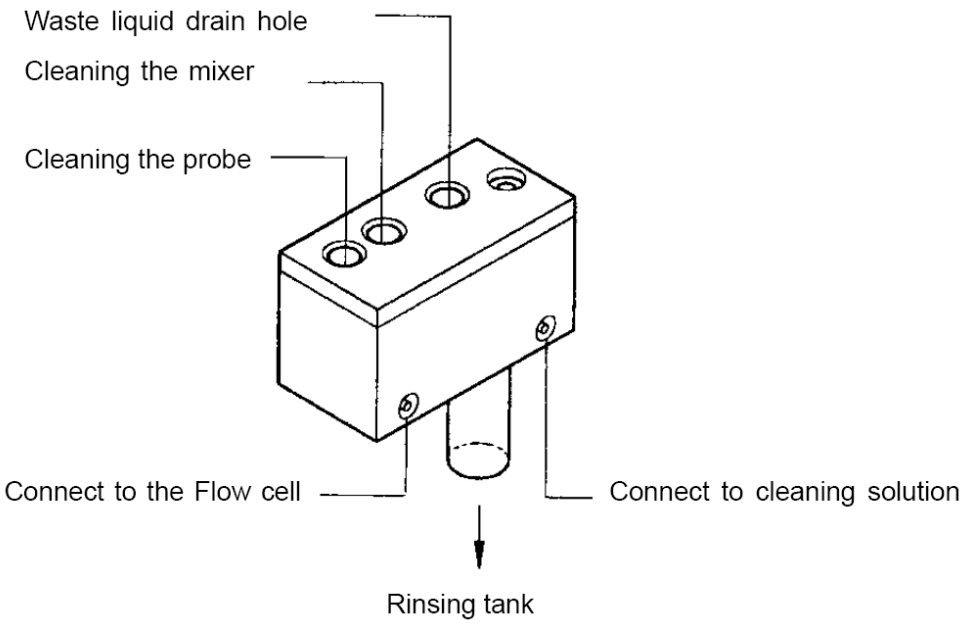
Maintenance of dilutor
Apply a small quantity of lubricant upon the screws of the dilutor every five or six months. Professional operators should pay attention to scheduled maintenance.

9.1.9 Probe
Please replace the tubing If necessary.
Disconnect the tubing from the probe and replace it by new one. Besides, please be careful not to damage the tubing during connection. Before replacing, be sure to check if the diameter and length of the new tubing are the same as those of the original tubing.



9.1.10 Rinsing tank for probe

Clean the rinsing tank once in every month. Fill bleacher diluted as 5:1000 into the rinsing tank and keep for 15 to 20 minutes. Then rinse out.



9.1.11. Open the rear cover of the apparatus.

1. Shut off the power supply and remove all accessories on the rear of the apparatus, such as the power cord, printing cable, printer power cord and so on.
2. Remove the fixing screws on the rear cover.
3. Take away the rear cover backward.

9.2 Maintenance

9.2.1 Daily maintenance

1. Empty the waste liquid bottle.
2. Fill up the cleaning solution bottle.
3. Check if the printer has adequate printer paper.
4. Clean with detergent.

9.2.2 Weekly maintenance

1. Clean the flow cell with "Tween 20 Solution".
2. Apply two droplets of lubricant on the screws of the dilutor.

9.2.3 Biannual maintenance

1. Replace the peristaltic pump tubing.
2. Cleaning of rinsing tank: Fill in several milliliters of diluted bleaching agent (5:1000).
3. The designed minimal service life of the bulb of the photometer is 2000 h. The bulb should be replaced at the appointed time.

9.3 Optional parts and spare part

S.N.	Code of spare parts	Spare parts and specification
1	KG0030.01	Reagent Containers 32ml (10 in each package)
2	KG0027.01	Reagent Containers 15ml (10 in each package)
3	A00740.01	Plastic Sample cups (200 in each package)
4	A00741.01	Reaction Plates (100 or 300 (for testing) in each package)
5	KG0021.01	Photometer Lamps
6	A00852.01	Syringe and Piston No.4
7	A01115.01	Aspiration Probe
8	A01353.01	Sampling Probe
9	KG0025.01	Peristaltic pump tubing (4 pieces)
10	K10030.01	Kit tubing complete
11	KG0026.01	Mixer tip (2 pieces)
12	254.010.009	O-Ring for Syringe No.4
13	A00454.01	Piston for syringe N0.4
14	MA0092.01	Sample Rack (1-60)
15	MA0092.02	Sample Rack (1-30)
16	MA0091.01	Reagent Rack (1-18)
17	MA0091.02	Reagent Rack (19-36)
18	161.020.005	Tween 20 Solution

Chapter X System Fault and Troubleshooting

Fault symptom	Solution
The analyser cannot be started.	—Check if the plug is loose. —Check the fuse. —Check the voltage.
The bulb of the photometer cannot light.	—Check the power supply before replacing the bulb. —If both the computer and the apparatus can be normally started, then replace the bulb.
Program downloading is prohibited.	—Shun down the apparatus and restart it after 10 seconds.
The printer cannot be started.	—Check if the plug is loose. —Check the button ON /OFF. —Check the fuse.
The printer cannot print.	—Check if the connection is correct.
No liquid exists in the rinsing tank.	—Check if there is cleaning solution in the cleaning solution bottle. —Check if the peristaltic pump can be normally operated. —Check the tube for transfusion.
No liquid exists in the flow cell.	—Check if the peristaltic pump can be normally operated. —Check the connection between the aspiration probe and the inlet of the flow cell. —The aspiration tubing may be over long or short. —If the aspiration tubing is aged, then replace it. —The flow cell may be much dirty.
The Photometer has no display.	—Check if the bulb of the photometer can light. —Try to read by another wavelength.
The value of water blank is too high.	—Clean the colorimetric basin. —Check the cleaning solution. —Check the bulb of the photometer. —Check if the aspiration probe is blocked.
The repeatability of the result is poor.	—The reaction tray may be contaminated. Replace it by a new one. —The colorimetric basin has bubbles. Clean it. —Check the aspiration of the colorimetric basin. —The quantity of reagent may be less than 400ul. Increase the quantity. —Replace the bulb of the photometer. —The aspiration probe is not connected correctly. —The reactant liquid has been contaminated. —Check if there is enough samples.

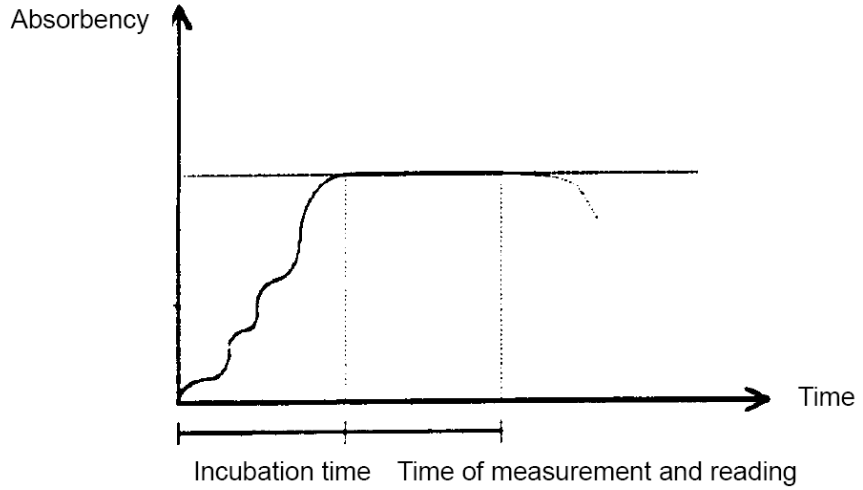
	—Check if there is enough reagent.
The aspiration capacity of the flow cell is not constant.	—Check if the aspiration probe is blocked. —The peristaltic pump tubing may need to be replaced. —Check if the reaction tray is under perfect condition and place it into position.
The quality control does not fall within the target range.	—Check the availability of the quality control liquid and confirm that it has not been contaminated. —Check if parameters need to be amended for the item setting. —Retest by other methods. —Check the flow cell and the incubation temperature. Retest by new reagent or quality control.
The colorimetric basin has bubbles.	—The tubing connecting the aspiration probe and the flow cell may have been damaged or the connection is not correct. —The pipeline is too short or too long. —Confirm the connection is correct.
The syringe contains bubbles.	—Check if the piston is airtight and free of air leakage. —Clean the syringe by "Tween 20 solution" (2 drops in a liter of distilled water). —Replace the O-ring inside the syringe. —Check the pipeline connected with the syringe.
Samples are contaminated.	—Due to improper connection, the sampling probe shows leakage. —Properly clean the probe or replace it by a new one probe. —Clean the rinsing tank. —Confirm that no liquid is remained on the probe. —Check if cleaning solution is fresh and has not been contaminated. —Clean the flow cell. —During the item setting, apply double rinsing. —The reaction tray is dirty and needs to be replaced. —The sample cup is dirty and replace it by a new one.
The incubation chamber is not warm.	—Check the temperature setting and adjust the temperature to 37.°C

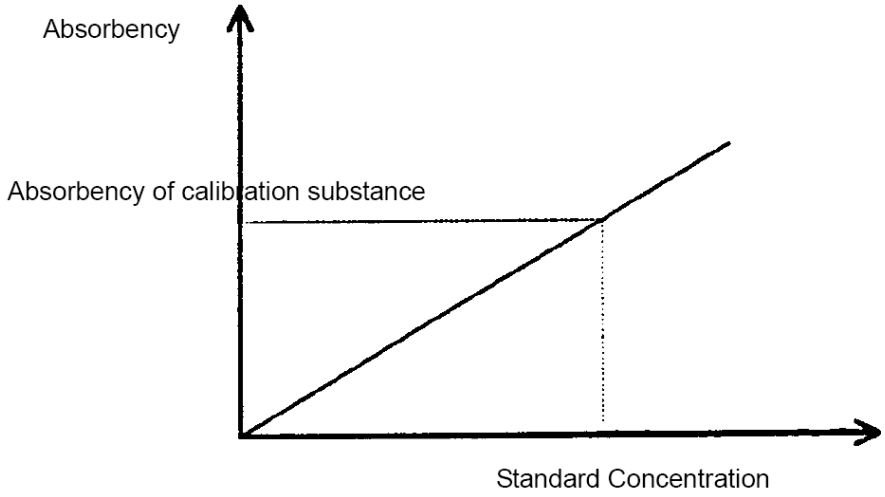
There is fluid seepage below the analyser.	—Check if the waste liquid drainage pipe has been inserted into the waste liquid bottle. —The waste liquid bottle is full. —The rinsing tank is blocked.
The edited item has not been executed.	—Check if there are valid calibration results —Check if reagent position are all allocated

Chapter XI Calculation

End-point method

The reaction curve shown in the figure below is a standard End-point method reaction. After the incubation period, the reaction develops to a phase with the darkest color, which is also the end point. Within a reaction time, the solution has constant color and keeps the status of the darkest color. Therefore this period is suitable to read the absorbency. The reaction is in strict compliance with the Lambert-Beer law and the result can be calculated based on the standard or factor.





End-point method

1 Based on standard

$$CONC_{sample} = \frac{O.D._{.sample} - O.D._{.reagent\ blank}}{O.D._{.standard} - O.D._{.reagent\ blank}} \times CONC_{standard}$$

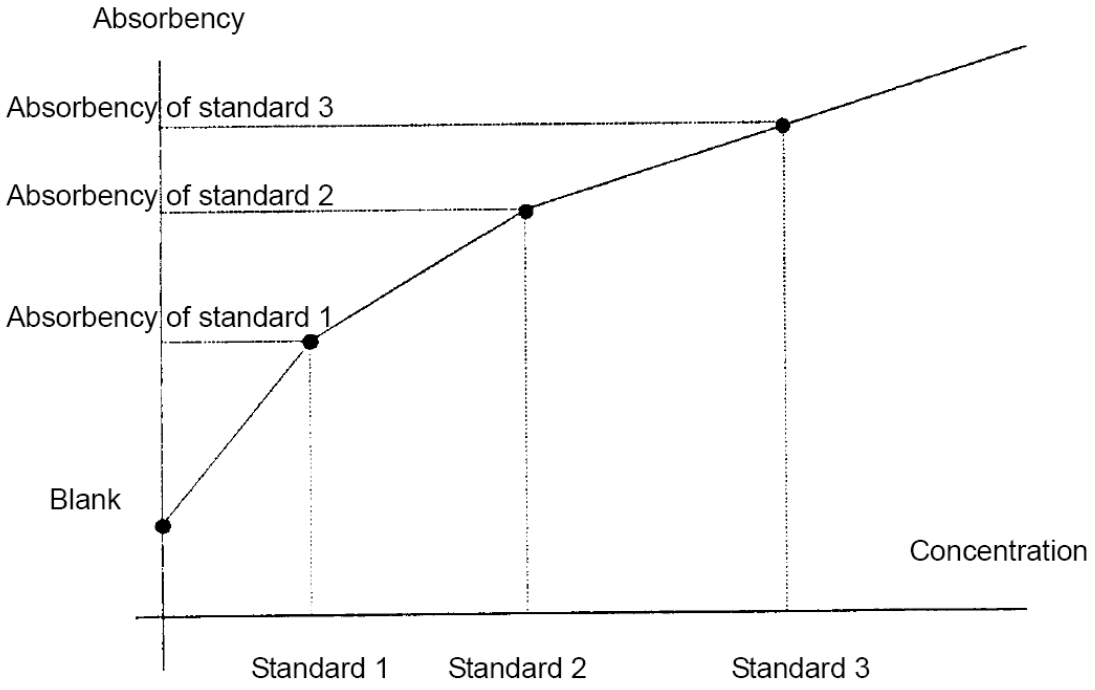
2 Based on factor

CONC. sample = (Abs. sample — Abs. reagent blank) ×factor

End-point method for calculation based on multi-standard method

This method also belongs to the conventional End-point method except that the calibration of the standard curve is based on a series of standards (up to 9 standards with different

concentration values) instead of a single standard. Refer to the following figure. The testing result can be read from the curve.



Calibration based on multi-standard

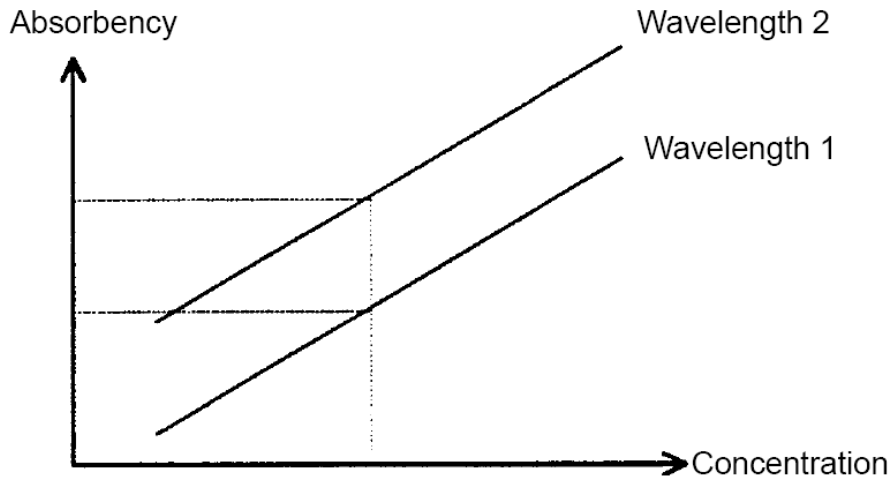
Dual-wavelength method

Dual-wavelength method is an End-point method applying two different wavelengths to make measurement. This method has an advantage that it can eliminate some undesirable disturbances. If applying this method,

the final result will be calculated by the difference between the absorbency values of two wavelengths. Refer to the following figure.

Δ A =A wavelength 1 — A wavelength 2

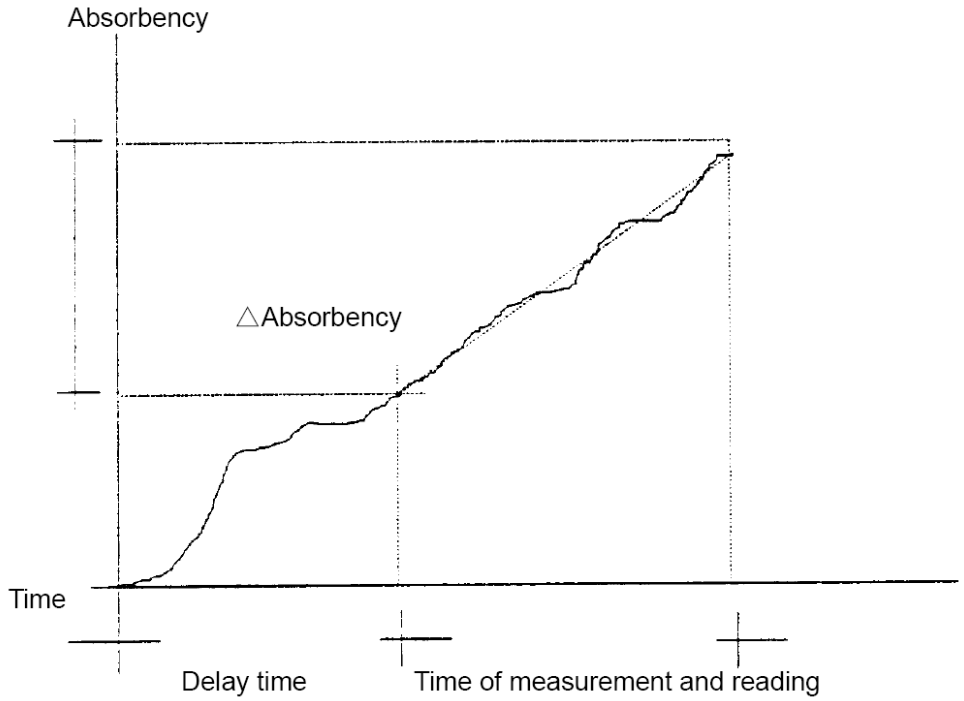
CONC. sample = (A sample Δ— A reagent blankΔ) × Factor



Dual-wavelength method

Rate method

Rate method is to continuously measure the enzym activity within a period (generally one minute). With reading one time in each second, the total time of reading in 60 seconds will be 60. The system will obtain a reaction curve and minimize the variance of each measured value. The following figure is a typical example of rate method. The operator can select to make calculation based on the factor or standard.

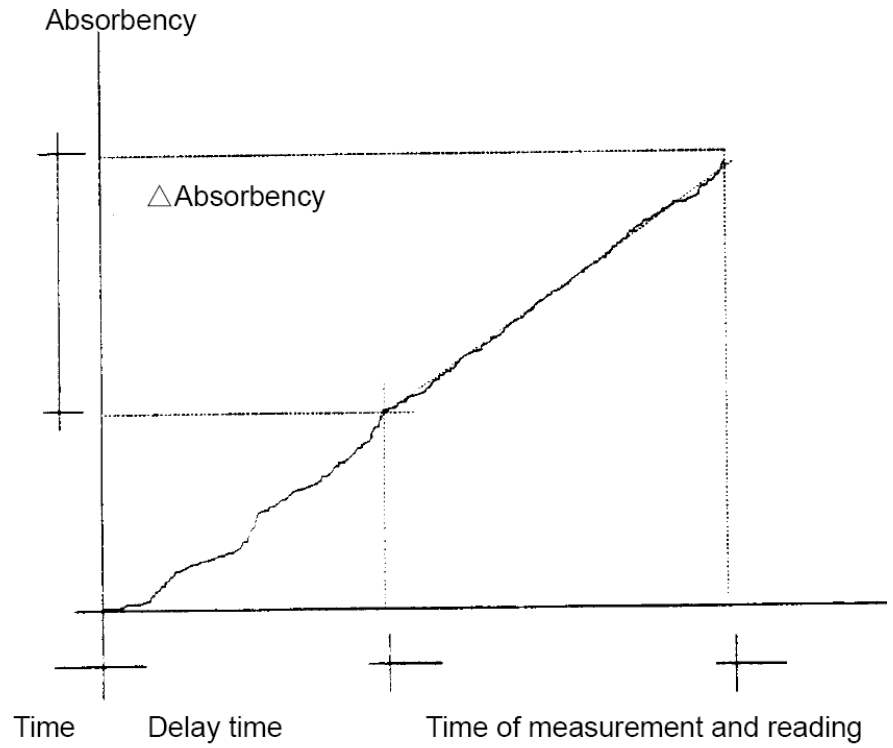


Rate method

Activity of sample =ΔA (within 60 seconds) × Factor
Factor = 1000 × Total volume /(Measurement time × Diameter of the flow cell × Coefficient × Volume of the sample)

Two-point method

Two-point method refers to consider the straight line connected between two measuring points as the calculation basis. After the incubation period, read the absorbency values for two points successively. The value of each point is the average value of certain absorbency values quickly read within the time range. The testing can take distilled water or reagent as the blank. Either the standard or the factor can be used as the calculation basis.
The following is a typical example.



Two-point method

Calculation：ΔA=A1-A2

1 Based on standard

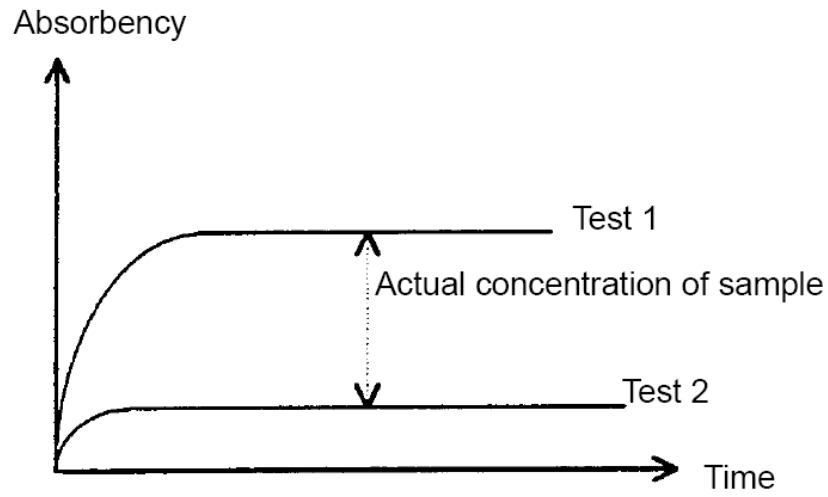
$$CONC_{sample} = \frac{\triangle A_{sample}}{\triangle A_{standard}} \times CONC_{standard}$$

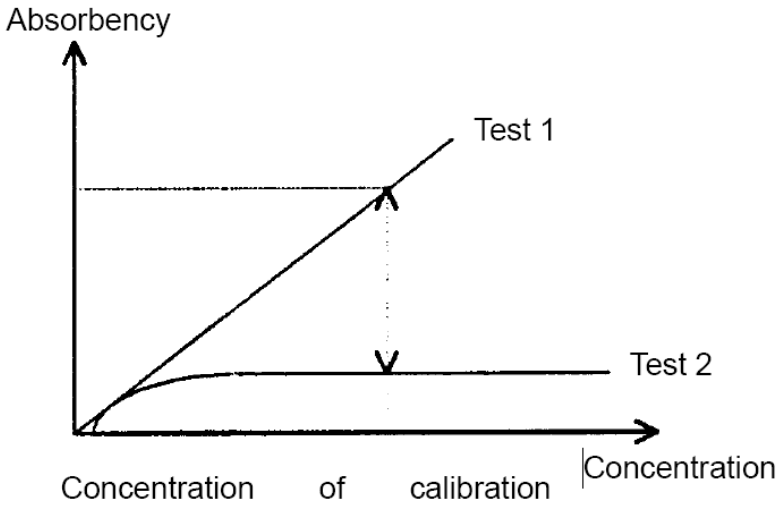
2 Based on factor

$$CONC.\ Sample = \triangle A_{sample} \times Factor$$

Differential method

Differential method, in fact, is a kind of End-point method too. For this method, a sample will be analyzed twice. In the first time, the sample will react with the reagent and the reactant liquid will be measured. In the second time, the sample blank, id est the mixture of the sample and distilled water or reagent 1 will be measured.





Differential method

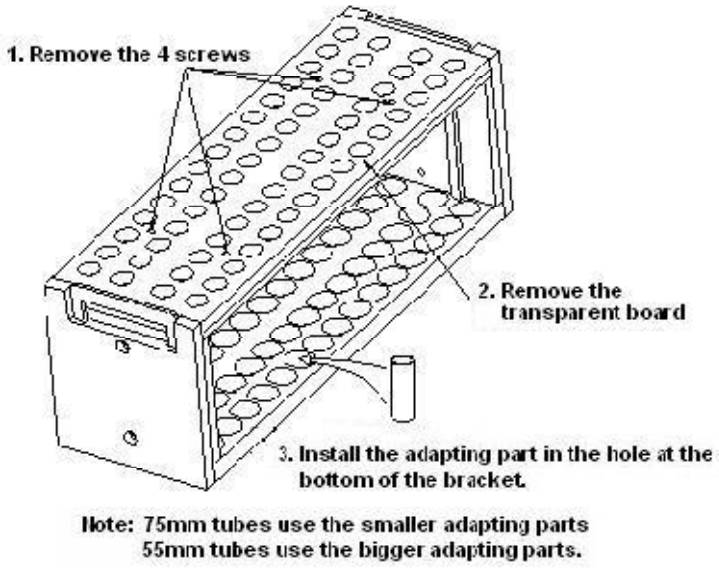
$$CONC_{sample} = \frac{\triangle A_{sample}}{\triangle A_{standard}} \times CONC_{standard}$$

$$\triangle A = A_{Test\ 1} - A_{Test\ 2}$$

While applying differential method, two kinds of completely different reagents will be used. In fact, there are two different tests conducted. One is the sample blank and the other is a real testing experiment. However, the final actual volume of both must be the same.

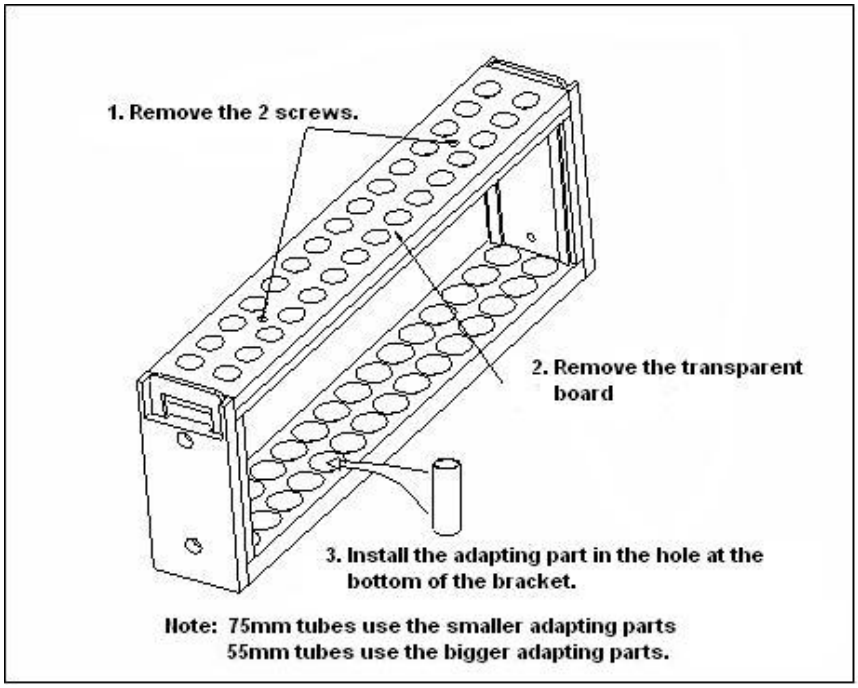
Annex I: How to make original tubes compatible with CliChem 200C Plus
Instructions: It is supported by CliChem 200C Plus automated chemistry analyzer to test with original tubes, but first you must install some adapting parts made of rubber on the sample and STAT positions.
Note: Only 12*15, 12*75 and 13*75 mm original tubes are supported by CliChem 200C Plus chemistry analyzer. To meet the requirement of test, the sampling volume should be above 3ml. Please refer to the following pictures for detailed instructions.

1．For sample position, refer to picture A



Picture A

2．For STAT position, refer to Picture B



Picture B