LabLife ChemMaster
Chemistry Analyzer
User's Manual

Rev: 1.3e

RFCL LIMITED
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How to use this manual?

It's greatly appreciated you become the user of LabLife ChemMaster Chemistry Analyzer.

In order to get the best effect, you must be familiar with our instruments and their functions before performing the clinical diagnostic tests.

This manual is the operating guidance of LabLife ChemMaster Chemistry Analyzer of RFCL Company, which including the contents of instrument installation, daily test, quality control, and daily maintenance, etc. As to the users who uses external printer, please refer to the user's manual of external printer at the same time.

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

You may contact with your distributor if there is any problem.

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

Note: ***Indications, advices and suggestions. Italics are used to differ from each other.***

Warning! Warning indications must be obeyed, so as to ensure the normal operation of instruments and correct and real test results. Bold-face is used to make the difference.

Signals used on the packing box

Upward

Dampproof

Fragile

Stack

Warning and Safety Indications

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

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

- **Cut off the power source at once if there is abnormal smells or smokes, and pull out the power plug from the outlet. At the moment, you must immediately propose test applications to the distributors and the agents of our company. If it is continuously used under this condition, it may cause fire, electric shock or personnel casualty.**
- **Neither blood and reagent nor metal pieces of staple and pin should be dropped into the instrument; otherwise it would lead to short circuit or smoke and fire. If there is something abnormal, cut off the power source at once, and pull out the power plug from the outlet. At the moment, you must immediately propose test applications to the distributors and the agents of our company.**
- **Operators don't touch the electric circuit inside the instrument, especially wet hands, which may be easier to get electric shock.**
- **Rubber gloves must be put on while maintaining and checking the instrument, and prescriptive tools and spare parts should be used. After finishing the operation, please use disinfecting liquid soap to wash hands. Otherwise, the parts of skin that contact with blood may be infected, electrically injured or burned.**
- **Extremely be careful while dealing with samples. Rubber gloves must be put on, or it may cause infection. If the sample enters into eyes or wounds, use a great amount of water to wash at once, and accept the checkup of doctors.**

Reagent Application

- **If the reagent enters into eyes, use a great amount of water to wash at once, and accept the checkup of doctors.**
- **If drink the reagent at error, turn to the doctors immediately, and take a lot of water to vomit the reagent at the same time.**
- **If hand or skin is stained with the reagent, clear with water at once.**
- **The used tubes and other instruments should be properly disposed as the medical wastes or infective wastes. If the person is stained with blood, there is possibility of being infected by pathogens.**

Power voltage, connection and earthing

- **Be sure not to insert the plug into the electrical outlet of alternating current over 220V. Otherwise, it may cause fire or electrical shock.**
- **When the instrument is installed, three-core power cable accompanied with the machine must be used, and ensure it is well earthing. Otherwise, it may cause fire or electrical shock.**
- **Be sure not to damage the isolation protection peel of power line. Don not pull the power line with exertion or hang heavy things on it. Otherwise, it may cause broken circuit or short circuit, thus lead to electrical shock or fire.**
- **Power source must be cut off when connect the peripheral equipments. Otherwise, it may cause electrical shock or troubles.**

Specifications of Pharmaceutical affairs law: It is forbidden to refit the medical instruments.

Content

1. Brief introduction of instrument

1.1. Product introduction

1.1.1 Product name

Chemistry Analyzer

1.1.2 Model

LabLife ChemMaster

1.1.3 Product features

- Monochrome LCD, English menus.
- It has two test modes of single wavelength and double wavelength.
- Following test methods can be provided:

Endpoint method	（Endpoint）
Fixed time method	（Fixed time）
Kinetics method	（Kinetics）
Double wavelength	（Dichromatic）
Absorbance	（Absorbance）
Multi-calibration curve	（Multi- Calibration）

- It can perform sample analysis of serum, plasma, whole blood and urine, etc.
- Open for reagent, and there is no specific restriction.
- Internal printer can print English reports and programming parameters, etc.

1.2. Product structure and composition

It is composed of optical system, pipeline system, computer control system and software, etc.

1.3. Product applicability

It is for the clinical tests of body blood and the tests of all kinds of general biochemical criterion of other body fluids.

1.4. Instrument specifications

Resolution	0.001Abs (Display) , 0.0001 Abs (Internal calculation)
Light source:	Halogen tungsten lamp
Wavelength:	There are 5 filters inside: 340,405,500,546,620; Three more wavelengths can be added as optional.
Temperature control:	Ambient temperature,25,30,37℃
Flow-cell :	Flow-cell
Interface:	RS-232 bidirectional communication
Display:	Liquid crystal display
Print:	Internal printer
Work environment:	10℃-30℃,relative humidity≤70%
Storage environment:	-20℃-55℃; relative humidity≤93%
Weight:	7 kg
Overall dimensions:	360mm(L)×318mm(W)×160mm(H)
Power supply:	AC110/220V±10%, 50/60Hz±1Hz
Power input:	80VA
Fuse type:	Φ5×20
Fuse specification:	3.15AL250V

1.5. Instrument installation

1.5.1 Instrument Opening and Sealing

Open the instrument package, and take the materials used in transportation away.
Preserve the packing box and materials well, and it's convenient for you to repack the instrument someday in the future.
Take off the packing materials, and take the instrument out of the plastic package.
Check the articles inside the package box, and confirm the following should be included:

- LabLife ChemMaster Chemistry Analyzer
- User's manual
- Packing list
- Power line
- QC certificate

Note: The product accessories should be in accordance with the packing list. Please contact with the distributor when the accessories are found not right.

1.5.2 Select proper position for the instrument

Find a place without direct sunshine in your working place. The surface of the selected working table should be flat, and there is enough space for placing **LabLife ChemMaster Chemistry Analyzer**. The anterior edge of instrument should be near to the edge of working table. Avoid comparatively large shake of working table (For example, put hydroextractor on the working table).

Note: The work environment of instrument is that temperature is between 10℃-30℃and relative humidity is below 70%.

In order to guarantee the normal working of instrument, the following places are forbidden to be put on:

- Places with extreme changes of temperature.
- Particularly hot or cold places.
- Places full of dust.
- Places nearer to the electromagnetic devices that produce magnetic field.
- Places with direct sunshine.

1.5.3 Power supply requirement

- AC110/220V±10%
- 50/60±1 Hz
- 80VA

1.5.4 Connect instrument to power supply

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

Warning:

- **Alternating current power must be well earthed (near-ground voltage<5V).**
- **Alternating current power must be stable. It is prohibited to use power supply with high-power equipments together, and it's better to equip with voltage-regulated power supply.**
- **In the area with unstable voltage, please use UPS power supply to ensure the normal work of instrument.**
- **When power line is pulled out, you must hold plug itself, not the power line.**
- **If there is smoke, abnormal smell or strange sound of instrument, cut off the power at once, and contact with the distributor.**

1.5.5 Install flow-cell

As the shown in the following figure 1-1, turn the light source cover open by hands.

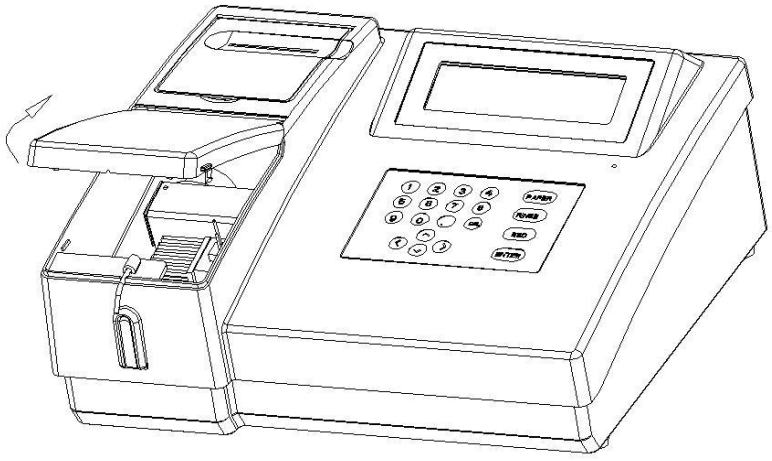


Figure 1-1 Open lamp cover

1) Take off the adhesive tape used to fix Flow-cell. .
2) Take off the wrapping materials.
3) Put the flow-cell into thermostatic bath.
4） Slightly insert the flow-cell in. Make the aspiration tube go through the fixing hole in the machine, and let it advanced extend.
5）Close the lamp cover.

Warning:

- **Please don't use hands to touch the surface of the light inlet window of Flow-cell, so as to avoid leaving the lipid of hands on the light inlet window and affecting the transmittancy.**
- **Ensure the aspiration tube is in the socket, otherwise, it will cause pressure and bend affecting the test effects. It's easy to result in inspiriting bubbles, and water blank will be high.**

1.6. Main structure

This part explains the structure of all the parts of **LabLife ChemMaster Chemistry Analyzer.**

1.6.1. Front view

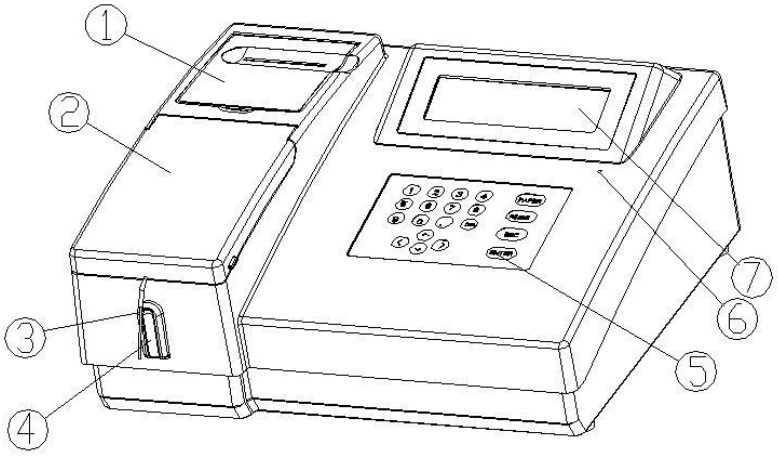


Figure 1- 2 Front view figure

① Printer cover
② Lamp cover
③ Aspiration tube
④ Aspiration key
⑤ Keyboard
⑥ Power source indicating light
⑦ LCD

1.6.2. Keypad

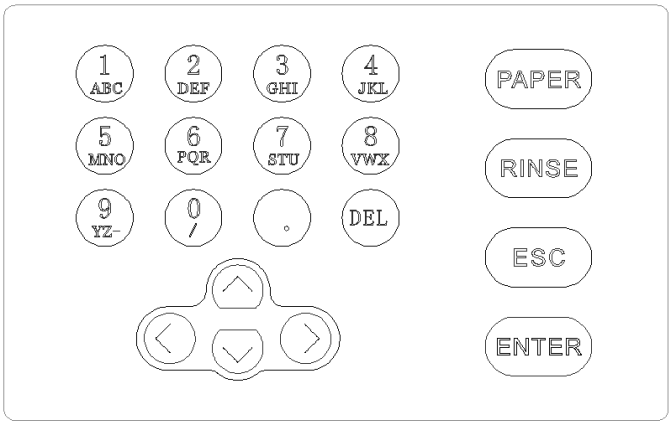
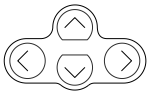


Figure 1- 3 Keypad



Direction key: Cursor moves in the screen of four directions, up, down, left and right.

Paper-feeding key: Feed paper by hand (It is also the shortcut key for parameter printing)

Rinse key: Clean the pipeline.

Exit key: exit the menu and cancel the operation.

Ensure key: To validate the input and save.

1.6.3. Back view

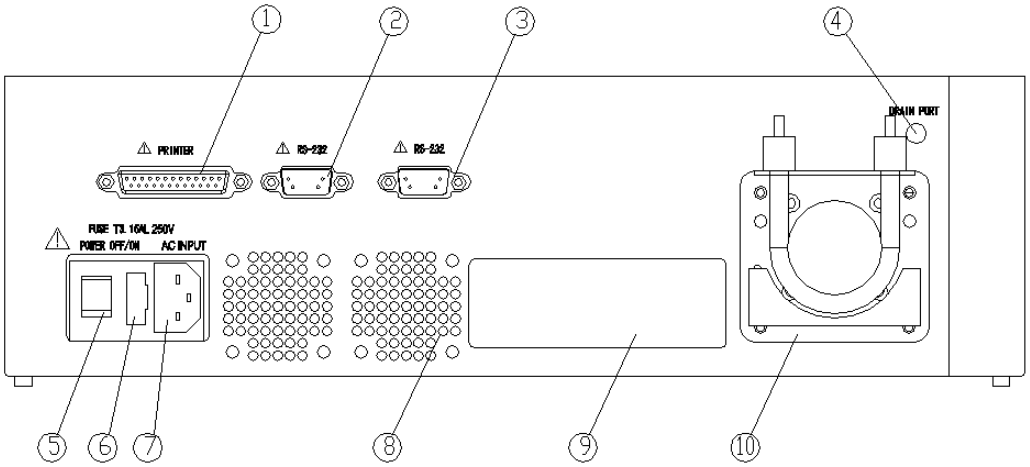


Figure 1- 4 Back view figure

1) Parallel port for printer	6) Fuse
2) RS-232 serial port	7) AC input
3) RS-232 serial port	8) Fan
4) Drain port	9）Backplate label
5) Power switch	10) Peristaltic pump

1.6.4. Internal printer

LabLife ChemMaster Chemistry Analyzer has internal special temperature sensitive printer.

1.6.5. Flow-cell and Cuvette

1）As shown in the following figure 1-５, open the lamp cover.

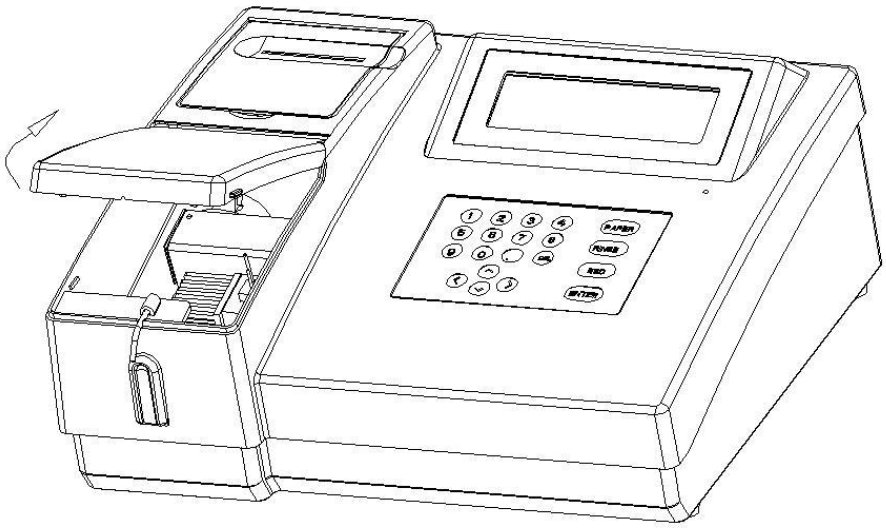


Figure 1-５ Open the lamp cover

Note: While turning the light source cover open, first you'd better emphatically press the protuberant block of the two sides of the cover, make both sides deform internally, and then open to the cover according to the direction of following figure.

2）Internal part of colorimetric system

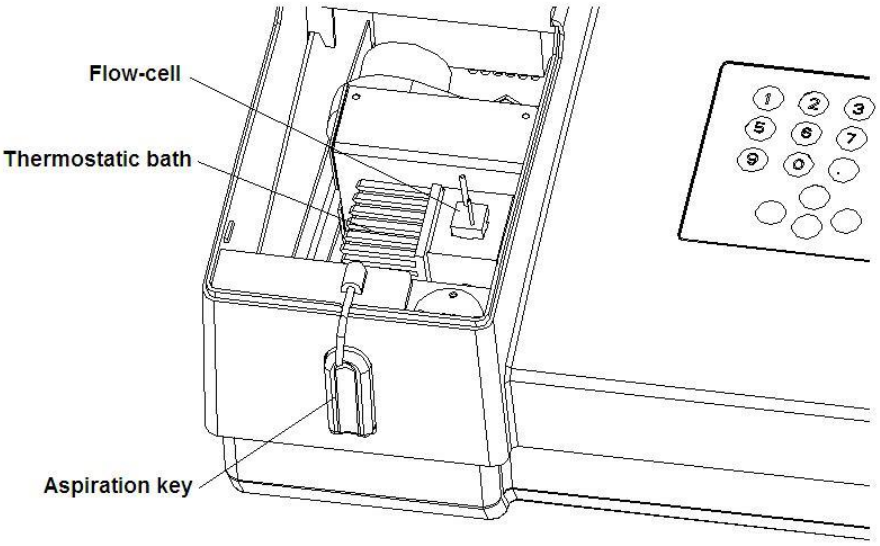


Figure 1- 6 Internal part of colorimetric system

- Thermostatic bath
- Flow-cell

3）Use cuvette system

①Take flow-cell out of thermostatic bath.

②Put the cuvette with samples into the thermostatic bath.

③All the test methods are the same with those of the test of flow-cell system.

1.6.6. Lamp and peristaltic pump

1）Open the lamp cover.

2）When changing lamps, pull off the connecting line of the lamp bracket and power source, rotate out the fixing screws on the lamp bracket, take out the lamp bracket, change a new one, put it as the original way, and rotate the tightening screws on the lamp bracket tightly. Connect the connecting line of light bracket and power source well.

3）Lamp and peristaltic pump, as the following figure:

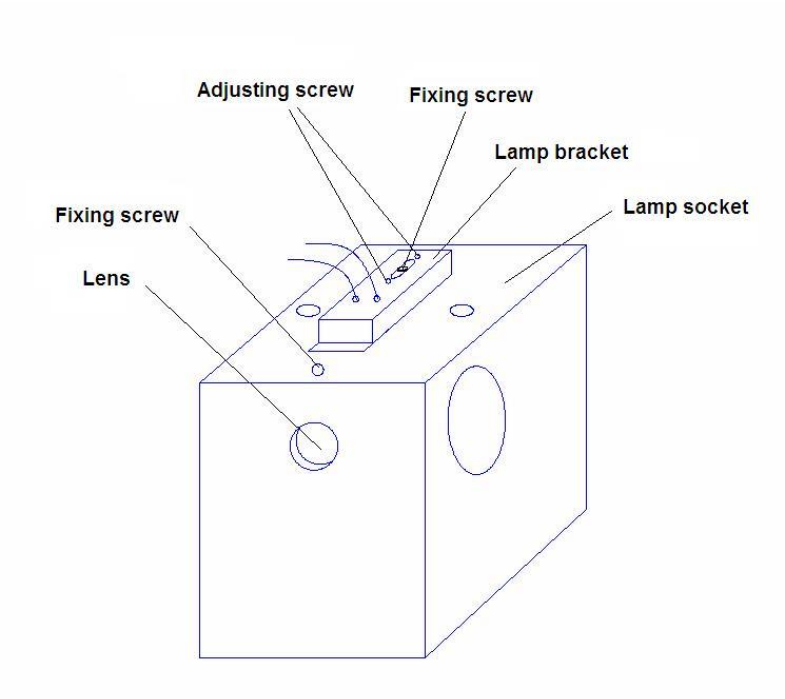


Figure 1-7 Light source system

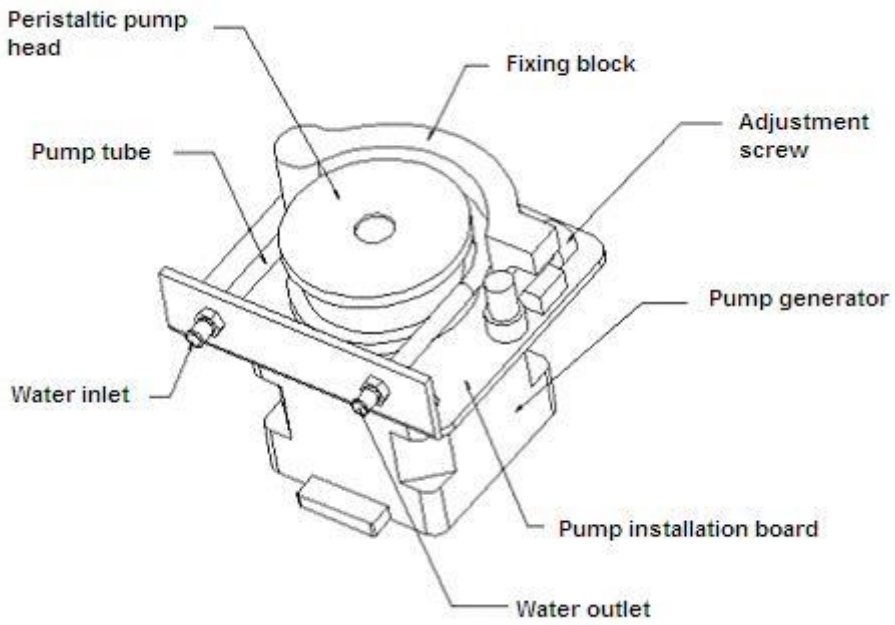


Figure 1-8 Peristaltic pump system

1.6.7. Principle structure figure (Only for reference)

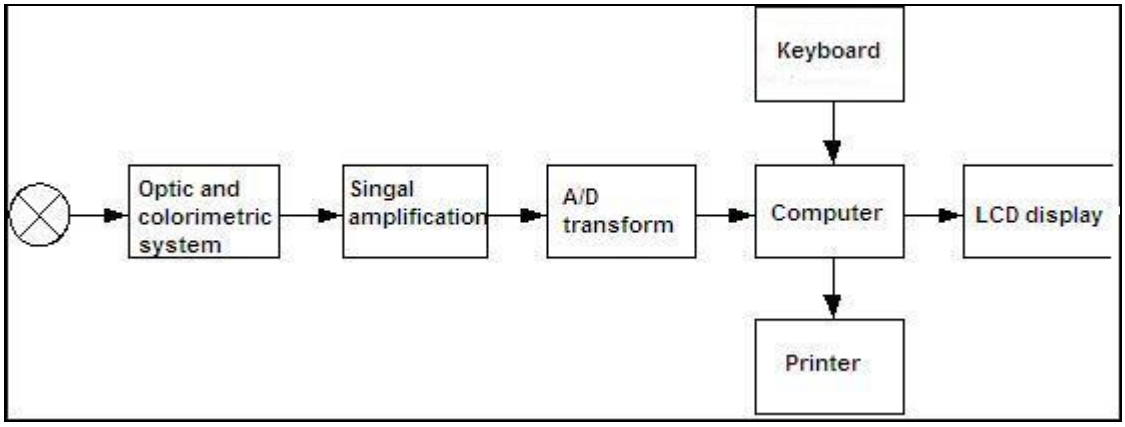


Figure 1-9 Principle structure figure

2. Operation

2.1. Power on

Open the power switch on the back of the instrument, several seconds later, a menu as 2-1 will appear in the screen:

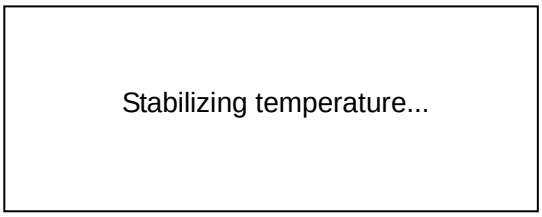


Figure 2-1 Temperature control

After waiting the temperature control procedure for about three minutes (select **ESC** key on the board, the system will stop temperature control, and directly enter the main menu of software), it will enter the main menu of system. As shown in figure 2-2.

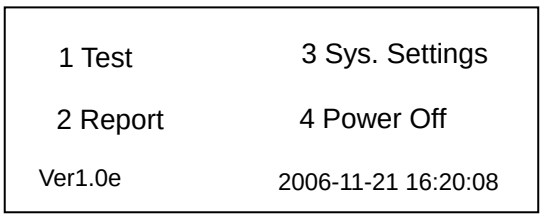


Figure 2-2 Main menu of system

2.2. Function introduction of main menu

1. Test: Edit the parameter settings, calibration settings and quality control settings of the test item, it will save the parameters automatically after ensuring, and enter the test process to perform item test.
2. Report: Perform the data administration function of the test system. Its functions include printing by test and patient numbers, deleting the test results, and searching the quality control information of the current month.
3. Sys. Setup: Set up the basic system operations. It includes printer settings, power on and off, time settings, externally connecting administration system to transmit all the test data of the current day.
4. Power off: It is mainly used to wash the tubes after tests. Consumers can directly cut off the power supply on the premise of ensuring the tubes are not needed to be washed (It is suggested to wash the tubes before exit).

2.3. How to operate the software?

The number in front of the item name is in accordance with the number key on the keypad, it means the serial number, as well as the key number of the corresponding operation (For example in the main menu if you press number key 1 in the keypad, system will enter test menu); ◄► on the right side of the name means to use the left and right keys on Keyboard to change the settings of parameters. ▲▼ In the menu refers to use the up and down keys on Keyboard to select the concrete menu item.

2.4. System settings

System parameter is used to set the most basic parameters of the instrument, e.g. date and time, etc. Press **key 3**, and enter the menu of system settings. As figure 2-3.

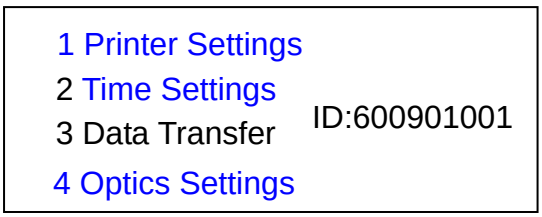


Figure 2-3 System settings menu

1. Print settings

In the menu of system settings, press **key 1**, the instrument will enter the following menu, as figure 2-4.

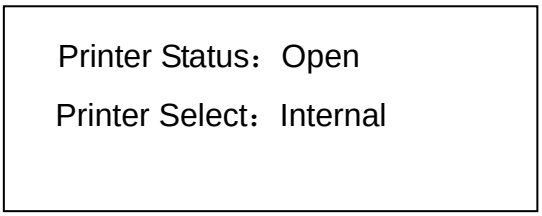


Figure 2-4 Printer settings

The instrument is equipped with an internal thermal-sensitive printer, and selects open and close by ◄► key on the board. At the same time, whether supporting instant print can be selected again during the test procedure. (As to the detailed settings, please refer to the print settings during the test procedure)

2. Time settings

In the menu of system settings, press **key 2**, and the instrument will enter the following menu, as figure 2-5.

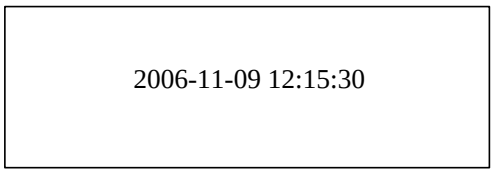
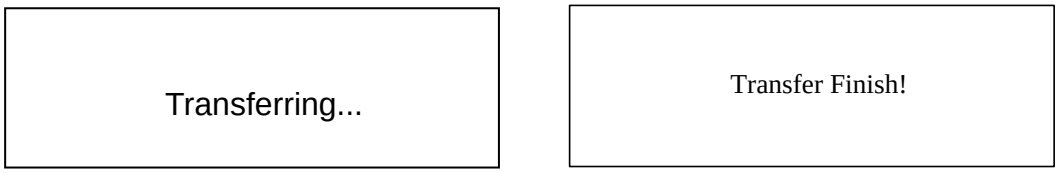


Figure 2-5 Time settings

Use ◀▶ key on the board to select the item needed to be changed, press Number key to change the current date or time, press **ENTER** key to save, press **ESC** key to turn back to the system settings menu.

3. Data transfer

In the menu of system settings, press **key 3** (before this operation, ensure there is communication cable inserted between the instrument and externally connected PC, and serial interface of the externally connected PC is under the receiving condition), the instrument will enter the following menu, as figure 2-6(a). While the menu of figure 2-6(b) appears, it indicates the data transferring is completed.

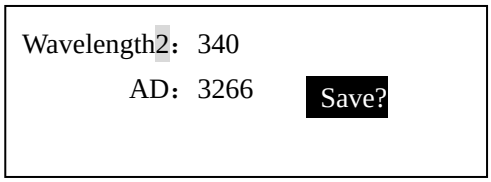


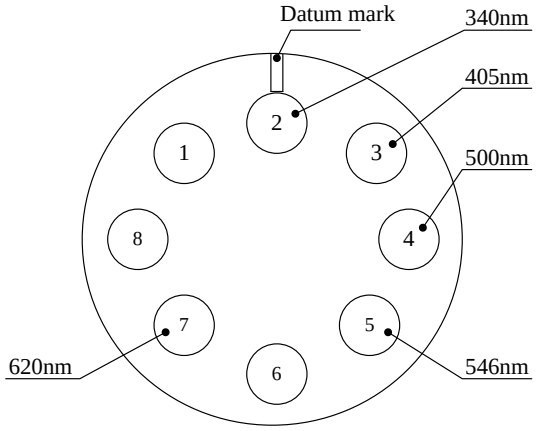
(a) Data transferring (b) Data transfer finish

Figure 2-6 Data transfer

4. Optics Settings

In the menu of system settings, press **key 4** to enter optic settings menu, as shown in figure 2-7 (a). The wavelength X is in accordance with the installation position of corresponding filters, as shown in figure 2-7(b).





（a）AD displaying menu (b) Layout of filter wheel (face the installation side)

Figure 2-7 Optic settings

1. Check the AD value

Press **RINSE** key to aspirate certain volume of distilled water (must fill the pipeline).Press left or right key（◀▶）to switch between wavelengths and check the AD value of current wavelength.

2. Save AD value

Because AD value will be taken as a fiducial value for calculation, it can not be saved discretionarily. Only when the filters are replaced or it always prompts "Retest" during water blank test, you need to save the AD value again.

First, press **RINSE** key to aspirate distilled water (must fill the pipeline)，press left and right

key（◄►）to switch wavelength.
Then, waiting for the AD value stable, press **ENTER** Key to save the AD value of current wavelength, the prompt "Save?" will disappear.

Note：

- ***This operation will affect the test performance, so just used to determine whether to replace lamp or the "redo" repeated appear at water blank.***
- ***Make sure enough water in flow cell at this operation, aspirated by key "RINSE".***
- ***Press key "ENTER" will only store the AD value of current filter, and other filters still hold the line.***

2.5. Sample test

Sample test includes item settings and item test. Item settings includes test method, item name, unit, temperature, wavelength, blank, delay time, test time, and aspirate volume, range of normal reference value, factor, standard and quality control, etc. Item test is composed of blank test, standard test, quality control test and sample test, etc.

2.5.1. Item parameter settings

2.5.1.1 Select test item

Figure 2-8 is the main menu of item selection, the first line is status column, and the following three lines indicate item name and its corresponding serial number in orders. You can use direction key, number key or name search to select items, the details is as following:

Index：2			123
1 ABS	**2 ALT**	3 AST	4 LDH-L
5 ALP	6 LDH-P	7 GGT	8 CK-NAC
9 HBDH	10 AMS	11 ACP	12 CK-MB

Figure 2-8 Item selection menu

1) Select by direction key: Select items by up, down, left and right keys, the selected item will be highlighted, and its corresponding number will display at the top-left of the screen.
2) Select by input: The input methods are displayed at the top-right of screen, they are "123" and "ABC" respectively, and use **.** key to switch. "123" means number input, numbers can be inputted directly at the moment, it will automatically select

the item according to the serial number, and display with highlight. "ABC" manifests character input, input the characters according to the indication of Keyboard, and it will display at the middle-top of screen. After finishing the input, press **ENTER** key to automatically select the corresponding item (if there is no corresponding item, there is no response).

2.5.1.2 Item parameters confirmation

Select a test item, press **Enter** Key to enter the menu of item parameters confirmation, as shown in figure 2-9, Press ◄► Key to select "QC" "STD", "Edit" and "Ok", press **Enter** to enter corresponding programs.

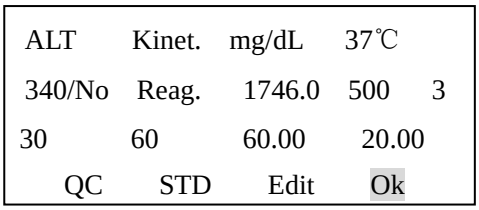


Figure 2-9 Menu of parameters confirmation

The meaning of each parameter is as following:

1st row: Item name, Test method, Unit, Temperature

2nd row: First /Second wavelength, Blank type, Factor, Aspirate vol., Decimal digits

3rd row: Delay Time, Test Time, Norms high, Norms Low

4th row: QC settings, Standard settings, Parameter settings, Enter test menu

Press ◄► Key to switch between "QC", "STD", "Edit" and "OK", press **Enter** Key to enter corresponding programs.

2.5.1.3 Item parameters editing

At the menu of parameters confirmation, select "Edit", press **ENTER** key, and the parameter setting of corresponding item will be performed, as figure 2-10.

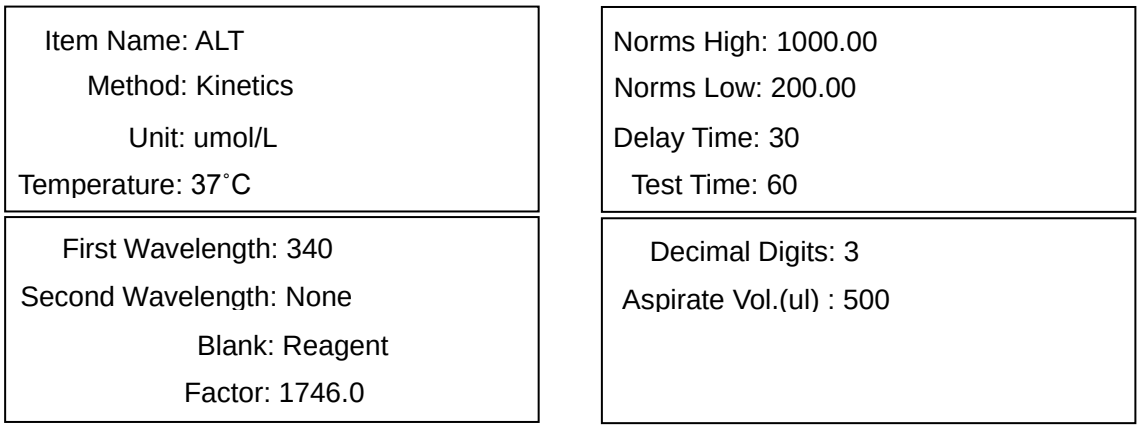


Figure 2-10 Parameter editing menus

Basic operation method:

1) Select the item which needs to be edited; moving cursor by press ▲▼ on the

keyboard, the selected item will be highlighted to display.

2) To edit the settings. As to the selected item, if the right side displays ◄►, it means to edit by ◄► key. If the right side displays ►, it indicates to enter the next editing menu by ► key. If the selected item has decimal point, it means decimal points can be inputted; otherwise, only integer can be inputted.
3) Quick turning page method. When the current page is ensured not to be revised, directly press **ENTER** key to enter the next page or item test process.
4) Item parameter print. In the menu of item parameter settings, if parameter selection is completed, press **PAPER** to print this item parameter.
5) Press **ENTER** key at the last page of item settings to automatically save the parameter settings, and enter item test process.

Set all the parameters:

1) Item name: The system permits setting 60 test items, including 47 fixed items. Users can define items from 48 to 60.
2) Method: Select test method, including endpoint method, two points method and kinetics method. Choose the method by ◄► key.
   a） Endpoint method: Endpoint method refers that the reaction reaches the endpoint after a period of time by mixing reagents and sample (i.e. the color of reaction fluid will not change, or the absorbance of reaction fluid will not change). At the moment, test the absorbance value of the reaction fluid, concentration of reaction solution can be gotten according to Lambert-Beer Law. The kits of some test items require using dual wavelength to test, and in this way, some interference factors can be erased. This instrument provides dual wavelength test method.
   b） Kinetics method: Kinetics method refers to use photometer to continuously test the absorbance value of reaction fluid after mixing reagents and sample. When the absorbance value begins linear changes, test its variance ratio. On the basis of Lambert-Beer Law, concentration of reaction solution can be obtained.
   c） Two points method: Two points method test is a special case of kinetics method test, i.e. when absorbance value begins to change in linear, measure the absorbance difference value of the two points in the linear part, and thus concentration of reaction solution is obtained.
3) Unit: Select the test result unit, including 9 selectable units of mg/dL, mg/L, g/L, umol/L, mmol/L, mol/L, U/L , IU/L and blank, etc. Choose the unit by ◄►key.
4) Temperature: Select test temperature, including 4 selectable temperatures of ambient temperature, 25, 30 and 37, etc. Choose the temperature by ◄► key.
5) First wavelength: Choose the test dominant wavelength according to the kit requirements, including 5 selectable wavelengths of 340nm, 405nm, 500 nm, 546 nm and 620 nm. Choose the dominant wavelength by ◄► key.
6) Second wavelength: Select the test secondary wavelength according to the kit requirements, and the system will flexibly implement dual wavelength method by

setting secondary wavelength. It includes 6 selectable secondary wavelengths of 340 nm, 405 nm, 500 nm, 546 nm, 620 nm and none. When single wavelength is used to test, secondary wavelength must be set as none. Choose secondary wavelength by ◄► key.

7) Blank: Select the blank testing, including none, reagent blank and sample blank. Choose the blank type by ◄► key. In the endpoint method test, reagent blank and sample blank can be selected according to the consumer requirements. Two points method test can choose reagent blank, and kinetics method has no blank settings.
8) Factor: Input the calculative factors, negative and positive value can be switched by ◄► key. The system supports direct inputting factors and determining calculative factors by system calibration (standard test).
9) Norms high: The inputted result is the value of norms high of the judgment evidence.
10) Norms low: The inputted result is the value of norms low of the judgment evidence.
11) Delay time: Input the delay time of the test process. The delay time is the time from the tested fluid entering flow-cell to the start of actual test.

Note:

- ***In order to make the test samples balance temperature and eliminate tiny bubbles in the flow-cell, a certain time delay is necessary.***
- ***Most endpoint method tests, time delay is 5 seconds;***
- ***Kinetics method below 25℃, time delay should not less than 10 seconds;***
- ***Kinetics method below 30℃, time delay should not less than 12 seconds;***
- ***Kinetics method below 37℃, time delay is no less than 15 seconds.***

12) Test time: Input the reaction time of the test procedure (endpoint method does not need this parameter).
13) Decimal Digits: The reserved digit after the decimal point of result. The maximum is 4.
14) Aspirate volume: The aspirated solution amount of peristaltic pump. This parameter indicates the amount of imbibed fluid to be tested each time. In order to ensure the accuracy of test, aspirate volume is generally more than 400uL. (General items should set as 500μL; the aspirate volume of reagents with great pollution can be increased to 700μL).

After setting all the parameters, press **ENTER** key to automatically save parameters and return to the menu of item parameters confirmation, press **ESC** key to return without saving. Therefore, correct standard parameters must be inputted.

Note: Generally, the aspirate volume of 500uL can ensure the cross contamination ratio below 1%. The aspirate volume can be increased or reduced, and it is concretely regulated by the number input on keyboard.

2.5.1.4 Standard settings

At the menu of parameters confirmation, select "STD", press **ENTER** key to enter the settings menu of standard parameter according to the indications, as figure 2-11.

Method: The calculation methods of standard test are linear regression and non-linear regression respectively. Choose by ◄► key.

No. of Std: The number of standard preparations used in the standard test process. The maximum is 8 to calibrate.

Repeat Times: The repeat times of the test of each standard preparation.

concentration: Standard preparation concentration used in the standard test process.

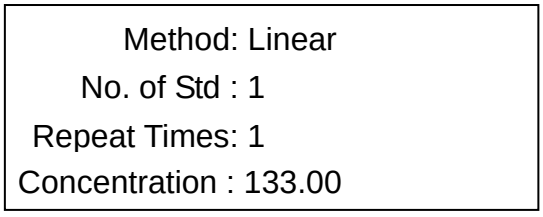


Figure 2-11 Standard parameter setup menu

Note:

- ***When non-linear regression is selected, the number of standard should be more than 3, otherwise calibrate according to the linear regression method;***
- ***When more than two standards are selected, the repeated number is uniformly managed according to single time;***
- ***When more than three standard concentrations are inputted, it must be inputted by progressive or degressive method; otherwise the calibration is not successful. During the treating process of standard parameter, the system will indicate the third started standard concentration range, as figure 2-12. The system will judge the progressive or degressive tendency automatically according to the order, and the third started concentration range will be indicated at the right side.***

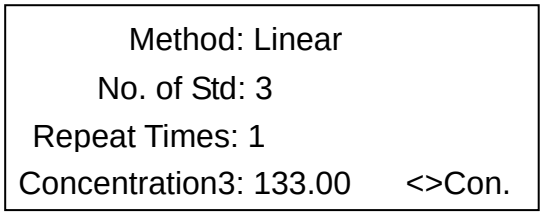


Figure 2-12 Standard concentration menu

After setting all the parameters, press **ENTER** key to automatically save parameters and return to the menu of item parameters confirmation, press **ESC** key to return without saving. Therefore, correct standard parameters must be inputted.

2.5.1.5 QC settings

At the menu of parameters confirmation, select "QC", press **ENTER** key to enter the

settings menu of quality control parameters according to the indications, as figure 2-13.
Control: The system can set two quality control preparations. Select by ◄► key (in the settings menu of quality control parameter, press ◄► key to select quality control preparations in cycle).
Average Value: Standard concentration of quality control preparation.
SD: Standard deviation of quality control preparation.
Batch number: Corresponding batch number of quality control.

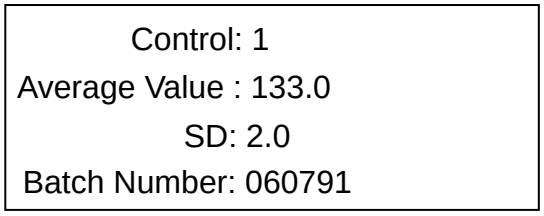


Figure 2-13 Menu of quality control parameters

After setting all the parameters, press **ENTER** key to automatically save the parameters and return to the menu of item parameters confirmation, press **ESC** key to return without saving. Therefore, correct quality control parameters must be inputted.

2.5.1.6 Parameter print
Under the menu of parameters confirmation or the menu of parameter settings, as figure 2-9 or figure 2-10, press **PAPER** key to print the parameter of the current item.
After finishing setting all the parameters and ensuring, select "Ok" at the menu of parameters confirmation, press **ENTER** key to enter item test process, thus it must be ensured to input the correct parameters. Pressing **ESC** key will turn back to the item select menu.
2.5.1.7 Item user-definition
The instrument can save 60 test items, including 47 fixing items and 13 user-defined items; meanwhile, item user-definition also can be implemented directly on the basis of 47 fixing items. The concrete user-defined methods are as following:

1) Move cursor to the "Name" column of parameter settings. At the moment, item name is highlighted, or displayed as cursor symbol (no item name);
2) Directly input item name according to the character index figure on keyboard, and the name includes 5 characters at the most. During the inputting process, it will automatically ascertain characters at the interval of 3 seconds, and indicate inputting next character;
3) During the inputting process, press **DEL** key to delete the inputted characters;
4) Set item parameters, press **ENTER** to automatically save the user-defined item name and parameters, and enter test process.

2.5.2. Item test

After setting item parameters, press **ENTER** key to automatically save parameter settings, and enter item test process. First, the system will switch light filter according to the set

wavelength, and equip with other information. The output information is as figure 2-14. The switching time is very short, generally, several seconds, and automatically enters temperature control.

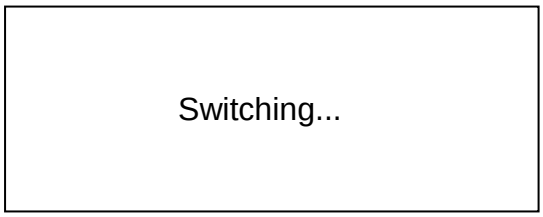


Figure 2-14 Item switch indication

After finishing item switch and information equipment, the system will enter temperature control, as figure 2-15. Temperature control time is set on the basis of the temperature difference before and after item switch. It's usually within several seconds to 3 minutes. Press **ESC** key to cancel temperature control and enter blank test.

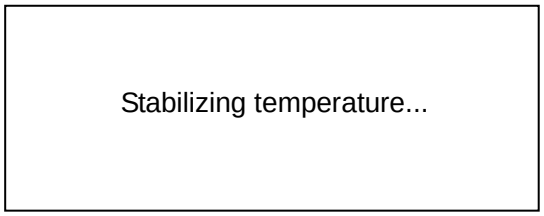


Figure 2-15 Temperature control condition

2.5.2.1 Blank test

After finishing item switch and temperature control, the system automatically enters blank test process. According to the settings information of parameter, the system will select whether performing reagent blank. When the blank settings in the parameter settings menu selects no blank or sample blank, blank test will just perform water blank. When reagent blank is selected, blank test will perform water blank and reagent blank.

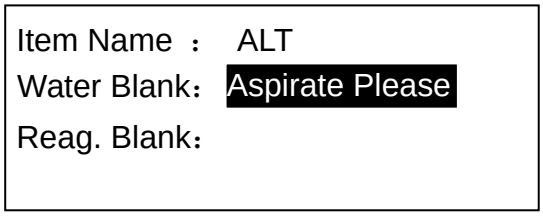


Figure 2-16 Blank test

As figure 2-16, perform water blank first, and indicate "Aspirate please" in the column of water blank. Prepare distilled water and press aspiration key, the system will automatically test, and output the results of water blank. When the value of water blank is too big, it will indicate "Aspirate please Retest" and the real-time AD value will show below, as figure 2-17. At the moment, water blank must be done again. If it still indicates "Aspirate please Retest" after many times of repeat, it is suggested to check whether the light path is

loosen.

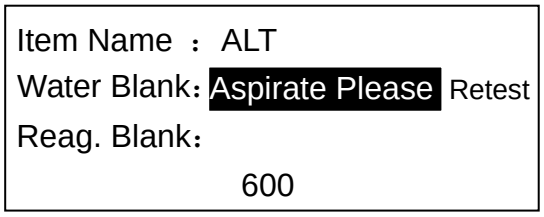


Figure 2-17 Water blank abnormality

After testing water blank, it will automatically enter reagent blank, aspirate reagent according to the indications, test the system, and output the results.

After testing reagent blank, no key is needed to be pressed, the system will automatically enter test selection menu waiting for several seconds, as figure 2-18. Cursor points to "Test sample" in absent condition, and select by  key. Press **ENTER** key to enter the corresponding test process, and press **ESC** key to return to this test selection menu in the corresponding test menu.

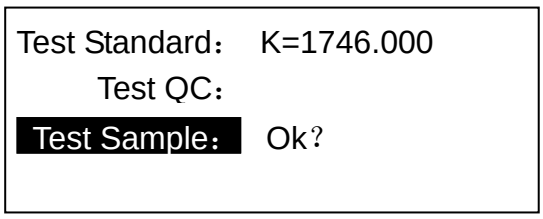


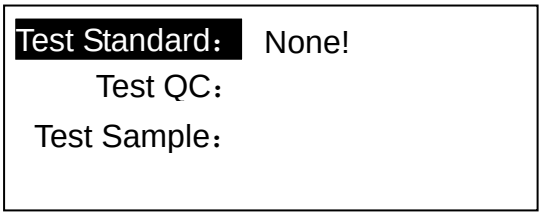
Figure 2-18 Test selection menu

2.5.2.2 Standard test

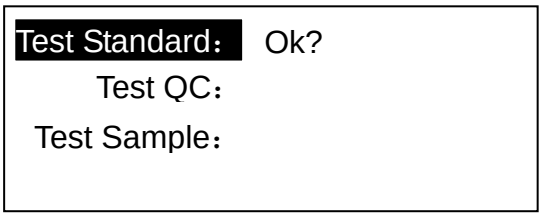
System is able to obtain the standard factors through two methods. One is inputting factors while setting parameters, at the moment, "K=xxx" will be displayed in the test selection menu, as figure 2-18. The other method is getting standard factors by standard test. This section will introduce the basic process of standard test in details.

1) Test selection

Under the test selection menu, move cursor to "Test Standard", and the typeface is highlighted at the moment. System judges whether the settings of standard parameter is correct. If the settings are wrong, it will display "None!", which means standard test is not needed or wrong, as figure 2-19(a). If the settings are correct, it indicates "Ok?", as figure 2-19(b), ensure whether standard test is to be performed. If it is ensured, please press **ENTER** key to enter test procedure, otherwise moving cursor to select other tests, or press **ESC** key to return to the main menu.



(a) Standard parameter has errors



(b) Standard parameter is correct

Figure 2-19 standard test selection

2) Test operation

After entering standard test procedure, standard test menu as figure 2-20 will appear. Among them, "Test" displays the item name of current test. "STD" displays the serial number of current standard fluid, and the corresponding concentration value is shown on the right side. For example, "Con.: 133.00", please ensure whether the solution with the same concentration is inputted before aspirating standard fluid. "Status" manifests the test process schedule and test results. "Aspirate please", "testing…" and "save?" are displayed one by one in the middle-down area of menu. The concrete test procedure is the same with item test process; please refer to the specific operation of item test.

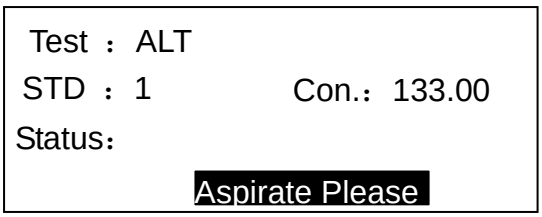


Figure 2-20 standard test menu

3) Test saving

After aspirating the corresponding standard fluid according to the steps, system will calculate standard factors at real time. The calibration K and b values will be displayed in the column of "test result", and it will indicated "save?" in the condition column of system. Press **ENTER** key to save the calibration result, and all the following item tests are calculated on the basis of this calibration result till resetting standard factors or recalibrating and saving, as figure 2-21. Press **ESC** key to cancel the saving, and directly enter item test process. Meanwhile, all the following item tests are calculated according to the factors before calibration. If it is needed to calibrate again, please select "Standard Test" in the test selection menu to perform calibration. As figure 2-18.

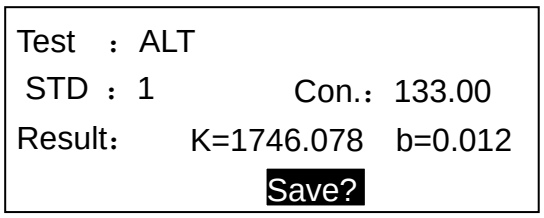


Figure 2-21 standard test saving

2.5.2.3 Quality control test

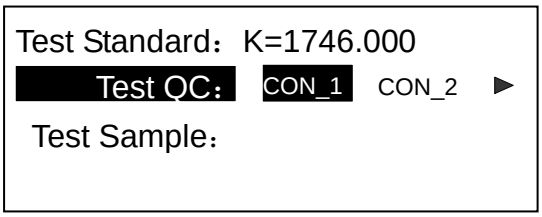
1) Test selection

In the test selection menu, move cursor to "Test QC", and the typeface is highlighted at the moment. On the right side, it displays that the system can select quality control preparation, and chooses by ◀▶ key on the extreme right side.

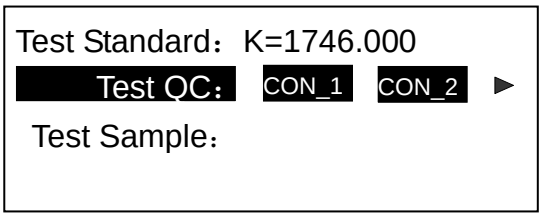
System supports single quality control and double quality control, select by ◀▶ key, and make the selected quality control preparation highlighted, as figure 2-22(a). When double quality control is chosen, continuously press ◀▶ key till two of the quality

control preparations are highlighted together, as figure 2-22(b).

Ensure the selected quality control preparation, press **ENTER** key to enter the menu of quality control test, as figure 2-23.



(a) Select single quality control



(b) Select double quality control

Figure 2-22 Quality control test selection

2) Test operation

After entering the process of quality control test, the menu of quality control test, as figure 2-23, will appear. Among them, "Test" displays the item name of current test. "QC" shows the serial number of the current quality control solution, and the corresponding quality control batch number is manifested on the right side. For example, "Batch: 070691", please ensure whether quality control preparations with same batch number are inputted before aspirating quality control solution. "Status" displays the progress of test process and test results. "Aspirate please", "testing…" and "save?" are displayed one by one in the middle-down area of menu. The detailed test procedure is the same with item test process; please refer to the specific operation of item test.

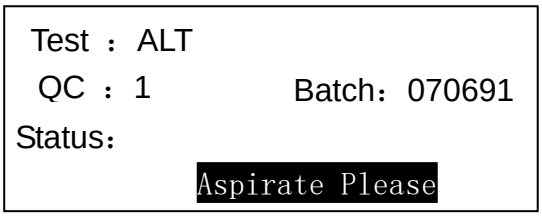


Figure 2-23 Quality control test menu

3) Test saving

After aspirating the corresponding quality control solution according to the steps, system will calculate the results on real time. Quality control results are displayed, and quality control conditions are judged in "Result" column ("C>2SD" means quality control result is larger than the value of two SD, otherwise, this information will not be displayed), and it is indicated "save?" in the system condition column. After ensuring quality control is effective, press **ENTER** key to save quality control results. When double quality control is selected, test the two quality control preparations in order. Aspirate corresponding quality control solution according to the indication, and valid quality control results are saved (Only one quality control result of the same item and same batch number is saved everyday), as figure 2-24. Press **ESC** key to redo quality control. After quality control test, system will automatically skip to the test selection menu and point to item test, as figure 2-18.

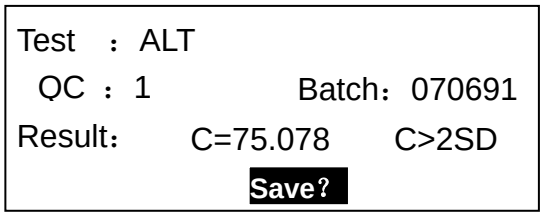


Figure 2-24 Quality control test saving

2.5.2.4 Sample test

In the test selection menu, cursor points to "Sample Test" in absent condition, and it is displayed by highlight. Press **ENTER** key to enter sample test procedure.

1) Test operation

When sample blank is selected during the parameter settings, sample blank is performed first before sample test, as figure 2-25(a). When no blank or reagent blank is chosen, it has already been finished during the former blank test, and it will directly enter test menu, as figure 2-25(b).

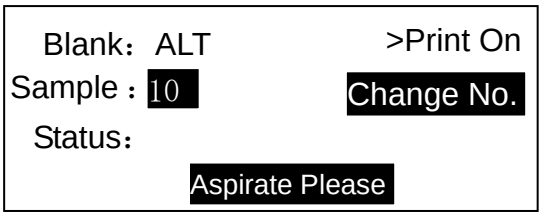
"Blank" and "Test" will display the item name of current test. "

">print on" or ">print off" on the right upper corner of the window means to open and close the online print function by ▶ key, which refers to immediately print results after finishing the test. It only can be changed on the condition of waiting for aspirating fluid.

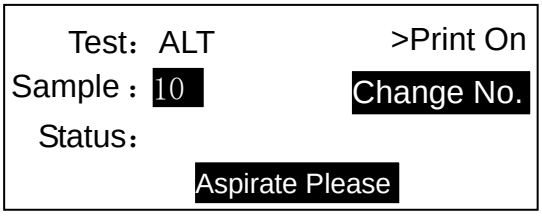
"Sample" displays the next sample number to be tested, it can be changed before the test, and it will indicate "Change No." by highlight on the right side of the corresponding column. It is suggested to ensure whether the number is correct before the test, otherwise, the former test result will be automatically overlapped by the same item and same number.

"Status" displays the progress of test process, and "Result" indicates the test absorbance and concentration.

"Aspirate please", "Testing…" and "Printing…" are displayed in order in the middle-down part of the condition column, please inject the sample or wait for the test according to the indications. When "Overlapped?" appears after testing, it means that this item already has the test result of the same sample number on the same day. Press **ENTER** key directly to overlap the existed result; Input a new sample number then press **ENTER** key, it will be saved as a new sample.



(a) Sample blank



(b) Sample test

Figure 2-25 Sample test menu

2) Test process

Take no sample blank (select no blank or reagent blank) as an example, the procedure and related operations are introduced in details. If sample blank is selected, sample blank will be performed before each item test, and automatically enter sample test to wait for aspirate the test sample. Its operation is completely the same with that of the sample test.

a） Confirm sample number (the displayed sample number is the number of the sample to be tested), and open or close online print function by ▶ key, as figure 2-25.

b） On the condition of "Aspirate please", prepare the test sample, press aspiration key to imbibe sample preparation. System will imbibe the fluid according to the set aspirate volume, and automatically enter test process. "Testing……" will be displayed in the condition column, and the test progress is indicated by seconds in "Status" column, as figure 2-26.

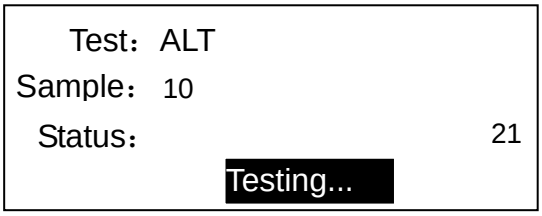


Figure 2-26 Sample test condition

c） After finishing test, the test results are automatically saved (If this item already has the test result of the same sample number on the same day, "Overlapped?" will appear and waiting for responding. Press **ENTER** key directly to overlap the existed result; Input a new sample number then press **ENTER** key, it will be saved as a new sample). Meanwhile, the sample number will increase one automatically as the number of next test sample, which is provided to the consumers to revise. "

d） Print the results. If online print function is selected, open or close by ▶ key under the condition of waiting for imbibing fluid.

e） When the current sample test and print are completed, the sample number will increase one, and enter the condition of waiting for fluid aspiration of next sample test.

f） Perform according to the indications, it can continuously test samples. When quality control, calibration or exit is needed during the test procedure, press **ESC** key to return to the test selection menu, and choose the related operations.

3. Report

Report is mainly in charge of the test results and the quality control test of the current month. Meanwhile, perform the basic functions of data search, print and delete, etc.

In the main menu of system, press **2** key to enter administration menu, as figure 3-1. They are sample report, item report and control report respectively, and the corresponding function modules are entered by number key **1**, **2** and **3**.

Sample report: Search the test results according to the date and sample number;
Item report: Search the test results according to the date and item number;
Control report: Search the quality control results according to the month, item number and batch number of quality control.

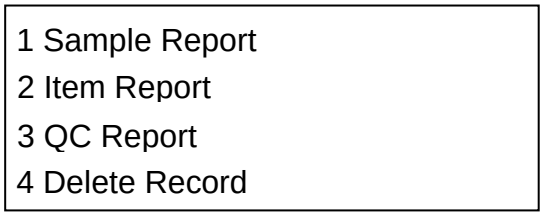


Figure 3-1 Administration function selection

Note: LabLife ChemMaster can save 2200 test results at the most. System has data renew ability by itself. When the test data exceeds the system storage capacity, system will automatically delete parts of the old data. At the same time, system will have the related indications during the renewing procedure. Please wait for a moment, it can automatically complete, and start test again.

3.1. Sample report

Input time range and sample number to search for the test results. Input start date and end date respectively, meanwhile, the end date must behind the original date or the same day. Input the sample number to be searched in "Sample No". "-" means from A number to B number, and B must not be less than A at the same time. When A equals to B, single sample will be searched. As figure 3-2, it will search the test results of sample 1, 2 and 3 tested on November, 9th, 2006.

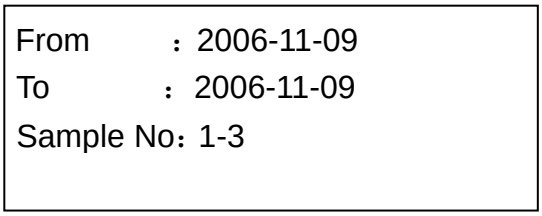
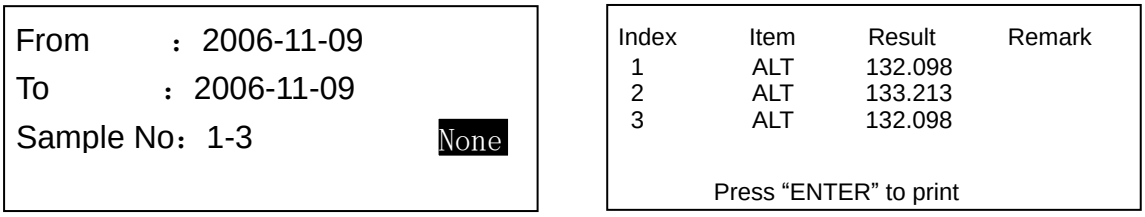


Figure 3-2 Sample report search

After inputting time range and sample number, press **ENTER** key to search the results met the conditions. If no related record is searched, "None" will be displayed on the right-down of the window, as figure 3-3(a). If the related record is searched, all the condition satisfied records will be displayed, as figure 3-3(b).



(a) No record (b) Condition satisfied records

Figure 3-3 Sample search condition

In the display window of searched results, as Figure 3-3(b), several following modes of shortcut key are defined:

- Page up/down: A single page only can display 3 records, and the records of more pages can be displayed by turning pages with  key.
- Print: Press **ENTER** key to print all the searched results.
- Delete: Press **DEL** key to delete all the searched results.
- Return: Press **ESC** key to turn back to the search window.

Note: The "remark" in display and print report: Normal condition is no display. "H"----Test result higher than the maximum reference value, "L" ---Test result lower than the min reference value.

3.2. Item report

Input time range and item number to search the test results. Input start date and end date respectively, meanwhile, the end date must behind the original date or the same day with the start date. Input the searched item number in "item No", and display the item name corresponding to the number on the right side at real time. Otherwise, input the characters in character mode when "ABC" appears on the upper-right side of screen. Key **.** is used to switch number and character input mode. As Figure 3-4. It will search for all the results of ALT item tested on November, 9th 2006.

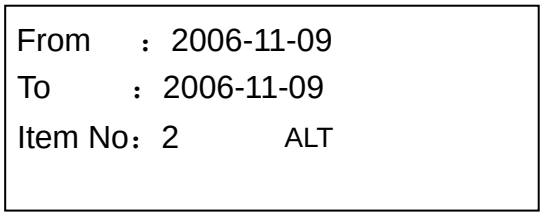


Figure 3-4 Item report search

After inputting time range and item number, press **ENTER** key will search the condition

satisfied records. If no related record is searched, "None" will be displayed at the lower-right of the window, as Figure 3-5(a). If the related records are searched, all the satisfied records will be displayed, as Figure 3-5(b).

(a) No record (b) Condition satisfied records

Figure 3-5 Item search condition

In the display window of searched results, as Figure 3-5(b), several following modes of shortcut key are defined:

- Page up/down: A single page only can display 3 records, and the records of more pages can be displayed by turning pages with key.
- Print: Press **ENTER** key to print all the searched results.
- Delete: Press **DEL** key to delete all the searched results.
- Return: Press **ESC** key to turn back to the search window.

Note: The "remark" in display and print report: Normal condition is no display. "H"----Test result higher than the maximum reference value, "L" ---Test result lower than the min reference value.

3.3. QC report

Input month, item number and quality control batch number to search the results of quality control. Input test date, input the searched item number in "item No", and display the item name corresponding to the number on the right side at real time (input characters in character mode switched by key **.**). Input the required quality control batch number in "Batch No". As Figure 3-6. It will search for the quality control results of ALT item with the batch number of 070691 on November, 2006.

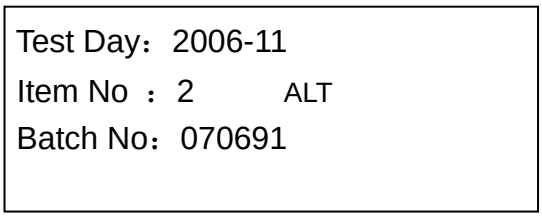
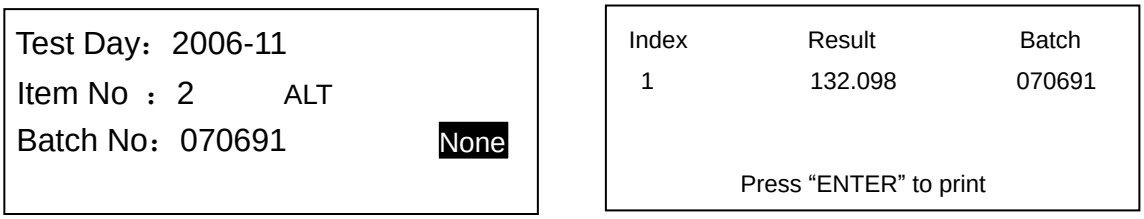


Figure 3-6 Control report search

After inputting month, item number and quality control batch number, press **ENTER** key will search the records meet the conditions. If no related record is searched, "None" will

be displayed at the lower-right of the window, as Figure 3-7(a). If the related records are searched, all the satisfied records will be displayed, as Figure 3-7(b).



(a) No record (b) Records meet conditions

Figure 3-7 Quality control search condition

In the display window of searched results, as Figure 3-7(b), several following modes of shortcut key are defined:

- Page up/down: A single page only can display 3 records, and the records of more pages can be displayed by turning pages with key.
- Print: Press **ENTER** key to print all the searched results.
- Delete: Press **DEL** key to delete all the searched results.
- Return: Press **ESC** key to turn back to the search window.

Note: The "remark" in display and print report: Normal condition is no display. "H"----Test result higher than 2SD, "L" ---Test result lower than 2SD.

3.4. Delete Record

All test result and control result of the equipment can be cleared with this command, or delete test result and quality control respectively, as Figure 3-8.

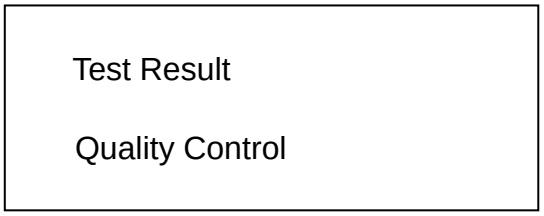


Figure 3-8 Quality control search condition

Here will delete all the test results or quality control results. One record can be deleted respectively as described at section 3.2 or section 3.3.

4. Power off

After finishing all the tests, turn back to the main menu, press **key 4** to perform the power-off program. When the screen displays as Figure 4-1, press **ENTER** key (if press **ESC** key, it will not be power off, and return to the main menu).

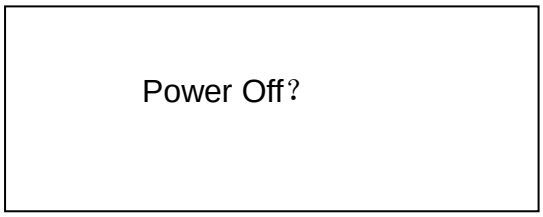


Figure 4-1 Confirmation of power off

When system displays as Figure 4-2, it indicates aspiration of distilled water, and cleaning flow flow-cell.

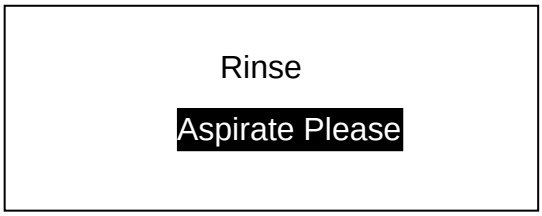


Figure 4-2 Clean flow flow-cell

At the moment, prepare enough distilled water, press **Aspiration** key or **RINSE** key, clean flow-cell. As the display of Figure 4-3.

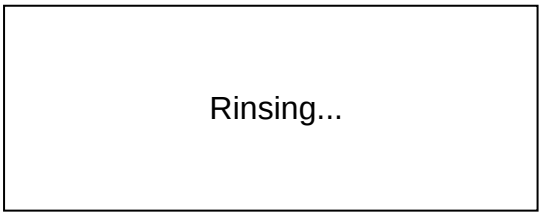


Figure 4-3 Indication of cleaning procedure

After cleaning flow-cell, the system displays "Power off please!". As the display of Figure 4-4.

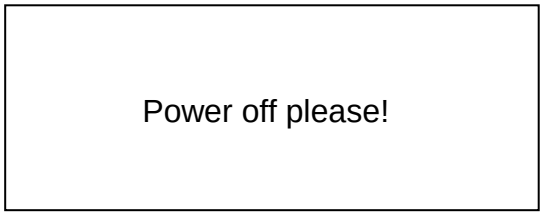


Figure 4-4 Power off

Turn off power switch.

5. Maintenance

5.1. Overview

LabLife ChemMaster Chemistry Analyzer is a clinical precise analyzer, and daily maintenance work must be well done to keep the instrument in a good condition. The maintenance of **LabLife ChemMaster Chemistry Analyzer** is very simple, but it must be serious and careful.

5.2. Clean instrument

5.2.1. Clean the surface of instrument

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

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

5.2.2. Clean Flow-cell

Flow-cell must be kept clean, so as to ensure the accuracy and reliability of the test results.

1、Clean the outside of flow-cell

a） Flow-cell must be placed according to the requirements. (refer to 1.5.5)

b） If the outside of flow-cell is polluted, soft cloth moistened with dehydrated alcohol can be used to slightly clean.

2、Clean the inside of flow-cell

c） Put the container with distilled water under the aspiration tube, press **RINSE** key, and start the continuous washing function. Press **RINSE** key again, and washing is finished. It is usually continuously washed for half a minute.

d） Glassware cleaner, or dilute hydrochloric acid (0.1N), Tween 20 diluents (2-3 drops/L) is used to clean flow flow-cell. Press **RINSE** key, aspirate cleaner, press **RINSE** key again to stop the rotation of peristaltic pump, make cleaner stay in flow-cell for 5 minutes, and finally use distilled water to continuously wash for 1 min. If it is not cleaned after washing once, cleaner can be used to wash again.

Flow-cell must be cleaned under the following conditions:

- At the moment of power on, the different value of water blank is too big.
- Change test items.
- Before power off.

Warning: Don't leave the reaction fluid or other pollutants in the flow-cell for a long time.

5.3. Instrument maintenance

5.3.1. Change fuse

Fuse is installed in the fuse box beside the power switch of the back of the instrument, open the box cap, and it's very convenient to change the fuse.

Fuse specification: 3.15AL250V.

Users are suggested to use voltage regulated power supply.

Warning: Must use the fuse of the specifications above.
While the consumer is changing fuses, he must ensure the power cable is pulled out. Forbid to operate with electricity!

5.3.2. Adjustment of peristaltic pump tube

After the instrument is used for half a year, the position of peristaltic pump can be adjusted. The methods are:

- Rotate the lock catch of peristaltic pump tube clockwise, and open the backplate of pump tube.
- Take off the peristaltic pump tube.
- Loose the fixing steel wire on the connecter of pump tube, rotate the pump tube for 180°, and then refix the steel wires.
- Install the pump tube well, and lock (rotate the lock catch of peristaltic pump counterclockwise).

Note: If the pump tube is not installed well, the instrument will not aspirate.

5.3.3. Change of aspiration tube

If aspiration tube (or flow flow-cell) is blocked by miscellaneous objects, syringe can be used to clean and dredge. If the damage or block of aspiration tube is serious, you can change an aspiration tube. The methods are:

- Pull flow flow-cell out.
- Remove the aspiration tube at the entrance, and change a new aspiration tube. At one end of the new aspiration tube, compass tube (the middle) is sheathed first, and then fixing tube (the thickest) is sheathed. Pay attention to leave 1cm outside the compass tube. (as the display of figure 5-1)
- Fix the fixing tube to the entrance of flow flow-cell.

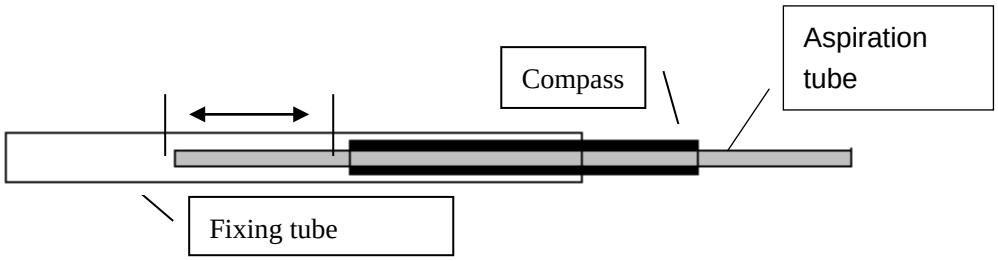


Figure 5-1 Aspiration tube connecter at the entrance of Flow Flow-cell

5.4. Simple trouble shooting

Trouble	Shooting
1）Analyzer can not be started.	——Check whether the instrument is on switch. ——Check whether the power plug is loose. ——Check the fuse. ——Check the voltage.
2) The lamp of photometer is not lighted.	——Check power supply before changing lamps. ——If lamp is damaged, change lamp.
3) Internal printer can not print.	——Check whether the plug is normally connected.
4) There is no fluid in the low flow-cell.	——Check whether peristaltic pump is normally running. ——Check the connection of the interfaces of aspiration tube and flow flow-cell, etc. ——Aspiration tube is too long or too short. ——Aspiration tube may be blocked, and it should be cleared and dredged. ——Flow Flow-cell is very dirty.
5) There is no reading on the photometer.	——Check whether the bulb of photometer is lighted. ——Try another wavelengh to read. ——Flow Flow-cell is not inserted to the bottom.
6) The difference value of water blank is too big.	——Clean flow-cell. ——Change new distilled water. ——Check the bulb of photometer.

7) The result reproducibility is low.
——There are bubbles inside the flow-cell, and it should be washed.
——Check the aspiration condition of flow-cell.
——The usage amount of reagent is too little, and the dosage should be increased.
——Change the bulb of photometer.
——Reaction fluid is polluted.
——The insertion of aspiration tube in the flow-cell is relatively deep, and pulls it out slightly.

8) The aspirate volume of flow Flow-cell is not constant.
——Check whether aspiration tube is blocked.
——Peristaltic pump tube may be changed.

9) Quality control is not within the target value range.
——Check the valid date of reagent.
——Check whether the settings are correct, and whether it need revise parameters.
——Make sure quality control is not polluted.
——Measure again with other methods.
——Check flow flow-cell, and use the other reagent and quality control to measure again.

Note: Instruments of different versions may have slight changes. All these changes are performed on the premise of not affecting the functions and operation of instrument, consumers can take it easy to use it.