Kalstein®

Chemistry Analyzer

YR05115

Instruction Manual

Thank you very much for purchasing our Chemistry Analyzer YR05115.

Please read the “Operating Instructions” and “Warranty” before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the “Warranty” at a hand place for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

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Note: This instrument adopts a high-grade quartz flow cell. Every day before shutdown, click the 'Other Services' icon to enter into 'Other Services', and then click 'Wash' to aspirate the distilled water to clean the flow cell, so as to keep theliquid circuit system clean. For storing or operation environment prone to freeze,click the 'Wash' to aspirate air to evacuate the flow cell, so as to avoid the liquid in the flow cell freezing, which may lead to breakdown of the flow cell.

Statement

- *The Chemistry Analyzer User Manual* involves the agreements on the rights and obligationsof the product quality assurance responsibility and the after-sale service between of our company and the users.
- The user must read the manual carefully and operate in strict accordance with the guidance of this manual.
- If the user who is responsible for operation the instrument can't conduct a satisfying maintenance plan, it may result in instrument failure.
- We make no implied warranty of merchantability and fitness of the instrument for a particularpurpose.
- We will be paid to provide the circuit diagrams and relevant information upon user request, so that the user can find an appropriate and qualified technician to repair those parts of the instrument classified by us that can be repaired and maintained by the user.

Quality assurance and after-sale service commitment

Our company provides a one-year quality warranty and after-sale service for failures due to manufacturing process or material problem during normal operation from the day of the acceptance of the instrument. The company promises to make arrangement within 24 hours after receiving the maintenance request of the user.

We only undertake the obligation of free maintenance, including the man-hours and material expenses of the quality assurance maintenance but excluding the losses and additional costs causedby the instrument downtime. For example:

- Freight (including the customs fees and insurance premiums).
- Losses caused by out of commission of using the instrument.

We assume no responsibility for the direct, indirect or final damage and delay caused by the following conditions.

- Improper operation.
- Instrument maintenance is not achieved as required.
- Use of accessories which are not supplied or approved by us.
- Accessories are replaced without approval of our company, or personnel not authorized byour company have repaired or altered the instrument.

We have an experienced after-sale service department with rich working ability. If you have anyquestions, comments or suggestions, please contact us through the information on the back cover.

How to use this manual

Welcome to read the *Chemistry Analyzer User Manual*. This manual contains the contents aboutinstrument installation, routine test, quality control, maintenance, precautions, etc. In order to maintain the best performance of the instrument, the operation and maintenance must be carried out in accordance with the contents of this manual.

The data given in the manual are verified, effective and credible data for the Chemistry Analyzer. If the instrument is used for a particular purpose or operation step and method goes beyond the provisionof the manual, please consult us for validity and applicability, otherwise we cannot guarantee the accuracy and effectiveness of the test results and assumes no responsibility and obligation for thedirect or indirect results caused by this.

Avoidance of potential hazards

The users should carefully read the 'Safety notes' and 'Operation notes' in this manual.

This manual gives the following safety warning signs, guiding the instrument operator avoiding hurting himself or damaging the instrument and getting wrong test results. To remind the operator to avoid potential dangers and hazardous conditions, we give different warning signs depending on the hazard extent of the operation.

⚠**Warning:** If the instrument is not operated in accordance with the operation steps, great harm to the operator, environment or both may be caused.

⚠ **Attention:** Emphasis on the operation method that must be complied with, avoiding potential danger or damage to the instrument or generating incorrect test results.

Note: Emphasis on important information.

All personnel who may operate, maintain, move the instrument should read the manual carefully.

Chemistry Analyzer is hereafter referred to as the instrument.

Safety Notes

For the safe and effective operation of this instrument, be sure to firstly read the following notes carefully. If the instrument is not operated in the way specified by the manufacturer, the protection function of the system may be damaged, resulting in personal injury or damage to the instrument.

- **Prevention from electric shock**

Unauthorized maintenance personnel shall not open the instrument when the power is on.

If liquid enters inside the instrument or leakage occurs in the instrument, please turn off the instrument immediately and contact the after-sale service department of us in time. Improper use of liquid may cause a risk of electric shock and damage to the instrument.

- **Protection from biochemistry hazard**

Improper use of the sample will lead to the risk of infection.

Do not touch the sample, reagent or waste liquid with bare hands. Be sure to wear gloves during theoperation to protect against infection.

If the skin is exposed to the sample, remedial actions should be taken immediately in accordancewith the user's standard or by consulting the doctor.

Be careful when using the reagent, preventing bare hands or cloth contacting the reagent directly.

If hands or cloth is exposed to the reagent, rinse with soap and water immediately.

If the reagent gets into eyes, immediately rinse with plenty of water and consult a doctor to take further treatment.

- **Waste liquid disposal**

Some of the substances in the reagent, quality control serum and sample are subjected to the control of the pollution regulations and emission standards. Please abide by local emission regulations and consult the reagent manufacturer.

- **Fire and explosion prevention**

Do not use flammable dangerous goods around the instrument.

Operation notes

In order to operate the instrument safely and reliably, it is important to abide by the following notes.

- **Application range**

Pay attention to the declared application range of this instrument, and do not use it out of the application range.

- **Operation environment restrictions**

The instrument must be installed in the installation environment and conditions specified in this manual. Installing or operation the instrument exceeding the specified conditions may lead to unreliable results and may cause damage to the instrument.

If you need to change the instrument state, please contact the after-sale service department of us.

- **Requirements on operator**

This instrument is to be operated by persons who have been trained and authorized by the manufacturer only.

- **Operation and maintenance**

The components or parts shall only be supplied by the manufacturer and replaced by or under theguidance of the manufacturer engineers.

Operation and maintenance procedure shall be in strict accordance with the requirements of themanual.

Chapter I Overview

Section 1 Overview

1.1 Product Properties, Main Structure and Application Range

In order to meet the demands of purchasing and updating the clinical examination instruments of many medical institutions, and after years of research, development and clinical test, theChemistry Analyzer has been manufactured with stable performance and versatile functions. It possesses the following properties:

a) Analytical methods of the analyzer include dynamic method, end-point method, two-pointmethod, etc.

b) Calibration methods include one-point calibration and multi-point calibration, etc.

c) The wavelength range is 340nm ~ 630nm.

d) Data storage and output functions.

Main structure of the product

It is consisted of the microprocessor circuit control system, optical colorimetric system, printer, LCDtouch interface, etc.

Application range of the product

The analyzer adopts the measuring principle of Lambert - Beer Law to carry out quantitativeanalysis of Chemistry items including human serum, blood plasma, cerebrospinal fluid, etc.

1.2 Operation Environment and Working Conditions

a) Ambient temperature: 10 ℃~ 30 ℃.

b) Relative humidity: ≤ 70%.

c) Atmospheric pressure: 86 ~ 106Kpa

d) Power supply: 100 ~ 240VAC; 50/60Hz

e) Keep it away from strong electromagnetic interference sources.

f) Avoid direct exposure to bright light.

g) Good grounding environment.

1.3 Transport and Storage Conditions:

The analyzer should be transported in the packaging according to the requirements of the ordercontract.

The packaged instrument should be stored indoor where is free of corrosive gas and well-ventilated and the ambient temperature should be within -20 ℃~ 55 ℃with the relative humidity ≤ 70%.

1.4 Main Technical Indicators of the Instrument:

Test methods: dynamic method, end-point method, two-point method.Wavelength range: 340nm ~ 630nm.

Wavelength accuracy: ± 3 nm

Colorimetric pool: 32 μL flow cell, Light path: 10mmSample suction volume: 200 ~ 3000uL, adjustable Light source lamp: long service life halogen lamp

Absorbance range: 0 ~ 2.3 Abs; Absorbance accuracy: external 0.001Abs, internal 0.0001AbsTemperature control: 37 °C

Cross-contamination: ≤ 1%

Printing: thermal printer Display:

graphic LCD display

Operation mode: Touch interface Interface: RS-
232 standard interface Power supply: 100 ~
240VAC; 50/60HzPower: 60VA
Mean time between failures: 13,000 hours

1.5 Size and Weight

Contour dimension: 352mm (L) * 266mm (W) * 182mm (H)Weight:
about 6 Kg

Section 2 Instrument principles

2.1 Measuring Principle

The Chemistry Analyzer is mainly used for the quantitative analysis of clinical biochemistryitems. The measuring principle is the Lamber-Beer Law:

$$A=Kbc=lg(I_0/I)$$

where:

A: absorbance K: absorbance b: liquid layer thickness c: solution concentrationI_0: Incident light intensity I: transmitted light intensity

According to the above formula, under certain liquid layer thickness and incident light intensity, as long as the transmitted light intensity is measured, the concentration C of the solution can be calculated.

2.2 Optical System of the Instrument

Based on the above measuring principle, the Chemistry Analyzer adopts an optical filter developedand produced with special technology, possessing the features of high humidity resistance, high temperature resistance, long life, small central wavelength drifting and high translucent signal-to-noise ratio. As the wavelengths are identical in the entire filter area, the selection of the monochromatic light wavelength is more accurate. A small mechanical error will not lead to wavelength selection error, ensuring reliable operation. The schematic drawing of the optical colorimetric system of the Chemistry Analyzer is as follows:

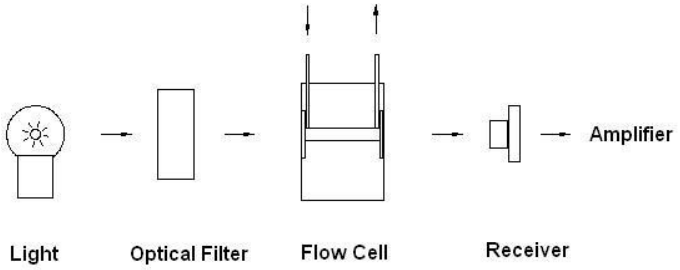


Figure 1 The optical system of the Chemistry Analyzer

2.3 Circuit System

The circuit system of the Chemistry Analyzer is mainly composed by signal acquisition, signal amplification, A/D conversion circuit, microcomputer control system,etc.

Section 3 Instrument Introduction

3.1 Schematic drawing of the main components of the instrument

Figure 2 Main structural schematic drawing

3.2 Main Interface

The main interface as follows:

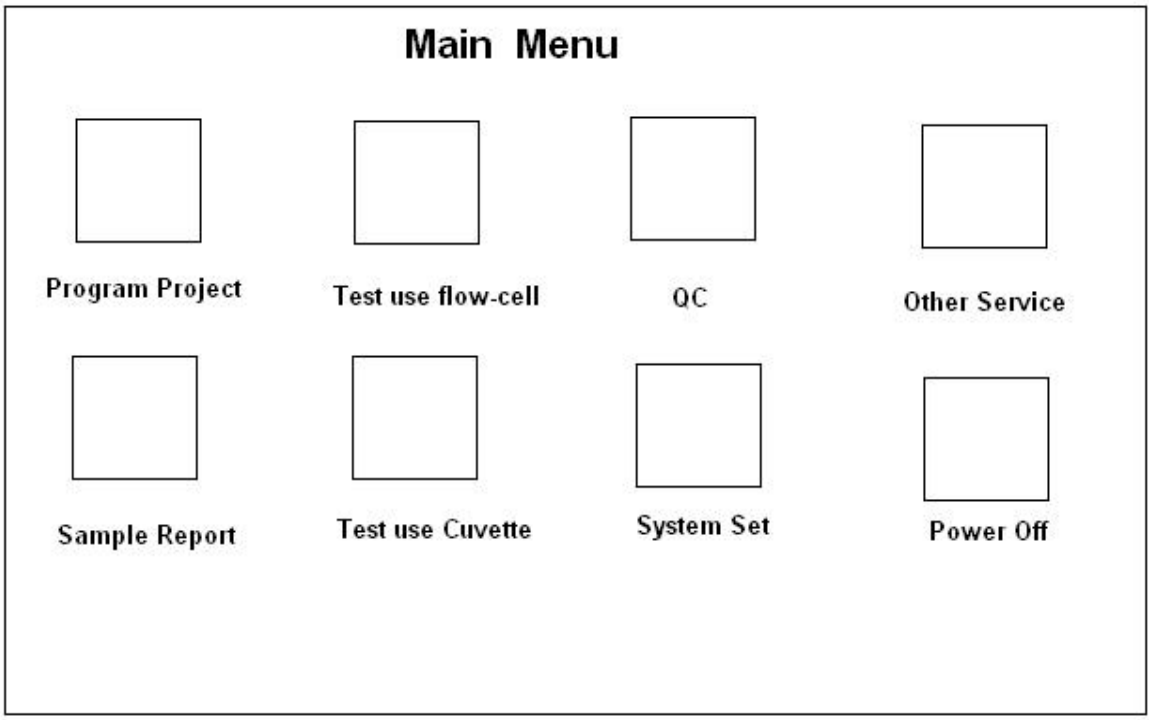


Figure 3 The main interface of the Semi-auto Chemistry analyzer1, Touch the function button to enter different function interfaces

2, According to the function tips, touch different function buttons with the fingertip or stylus to complete the operation of the corresponding function.

3, The display boxes in white can be modified or input. This kind of boxes have two categories: one isthe choice box, and the other is the input box. For the choice box, touch with fingertip or stylus for once, and it will change for once. For the purpose of inputting numbers or characters, firstly click the input box and the cursor starts flashing, and then click the corresponding button on the keyboard to input.

3.3 Instrument Rear Panel

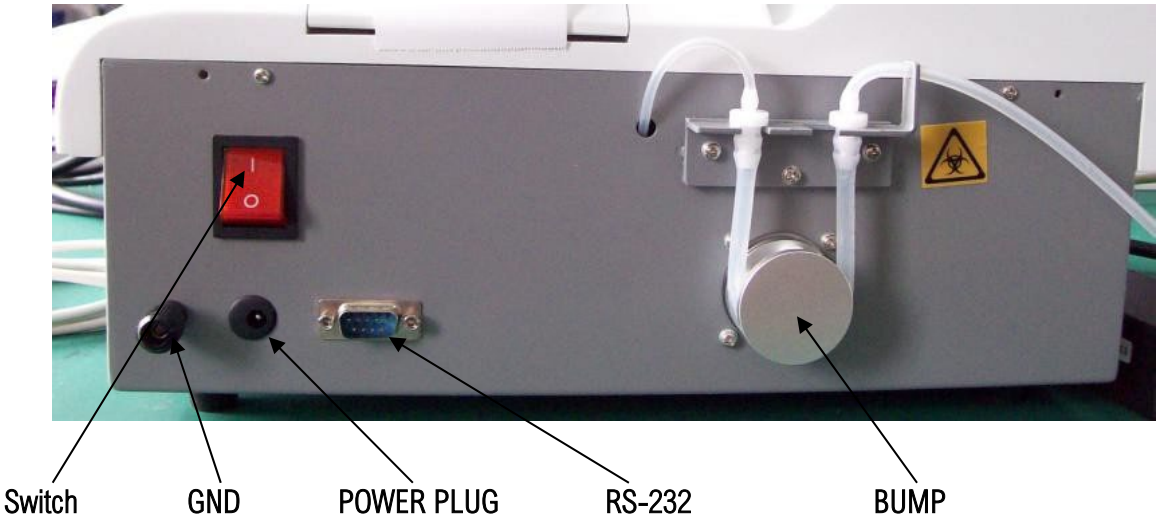


Figure 4 Rear panel of the Semi-auto Chemistry analyzer

Section 4 Instrument Installation

4.1 Preparation before installation

1，Earthed the machine

The Semi-auto Chemistry analyzer is a precision electronic instrument. Inspect the laboratory to check if there is dedicated ground wire for medical instrument and the required ground resistance is less than 0.1 Ω; or appoint a professional electrician to install the indoor power ground wire.

2，Voltage Stabilizer

Unstable power supply voltage has a negative effect on the instrument. Please purchase a high-quality stabilizer whose power is greater than 500W before the installation and connect its voltage ground terminal to the ground.

3. Working Conditions

⚠**Warning:** This instrument cannot be placed in the same room or use the same electric outlet with high power and big disturbance equipment like centrifuge, refrigerator and incubator, etc.

⚠**Attention:** Keep the instrument away from fan, air condition, etc., so as not to affect the accuracy of temperature control. Avoid vibration during the test process. Avoid direct sunlight and dusty working conditions.

4.2 Instrument Installation

1. Open the dedicated packaging box and check carefully whether the instrument and accessories in the packing box comply with the 'Semi-auto Chemistry Analyzer Packing List' and whether the appearance is intact. If any component is missing or damaged, please contact the supplier.
2. If the inventory is correct, take out the instrument carefully and place it on a stable and smooth working table, avoiding fierce shaking.
3. Connect the medical instrument ground wire to the dedicated ground column on the rear panel.
4. Place the outlet of the waste liquid pipe in a waste liquid bottle.
5. Prepare a cup of distilled water in a beaker or other container.
6. Take out the power supply device of the instrument, connect the small round end to the power hub on the lower right side of the rear panel, and connect the other end to a grounded three-pin socket.

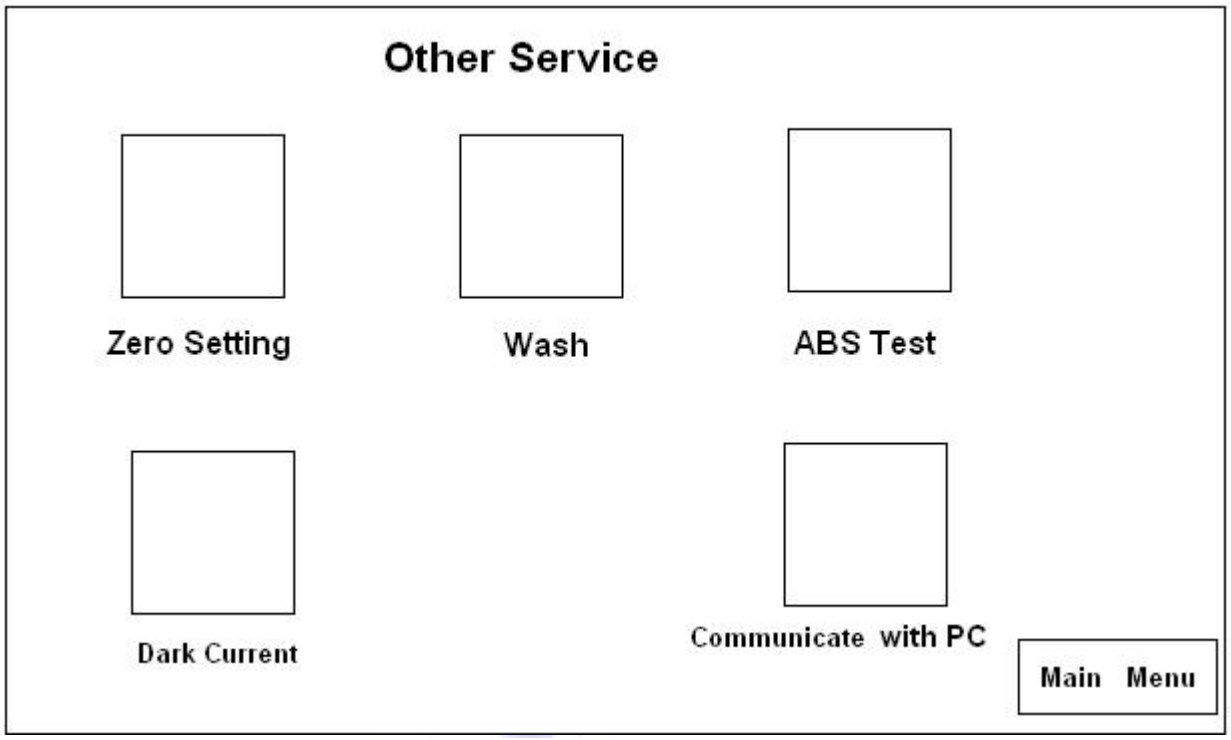
Turn on the power switch on the right side of the rear panel. Then it will enter into the 'System is preheating' interface automatically. At the moment the user can click the 'Cancel' button to enter the main interface, otherwise it will enter the main interface automatically after the preheating is completed. Then the user can start the daily operation.

The system will firstly show first Interface as follows:

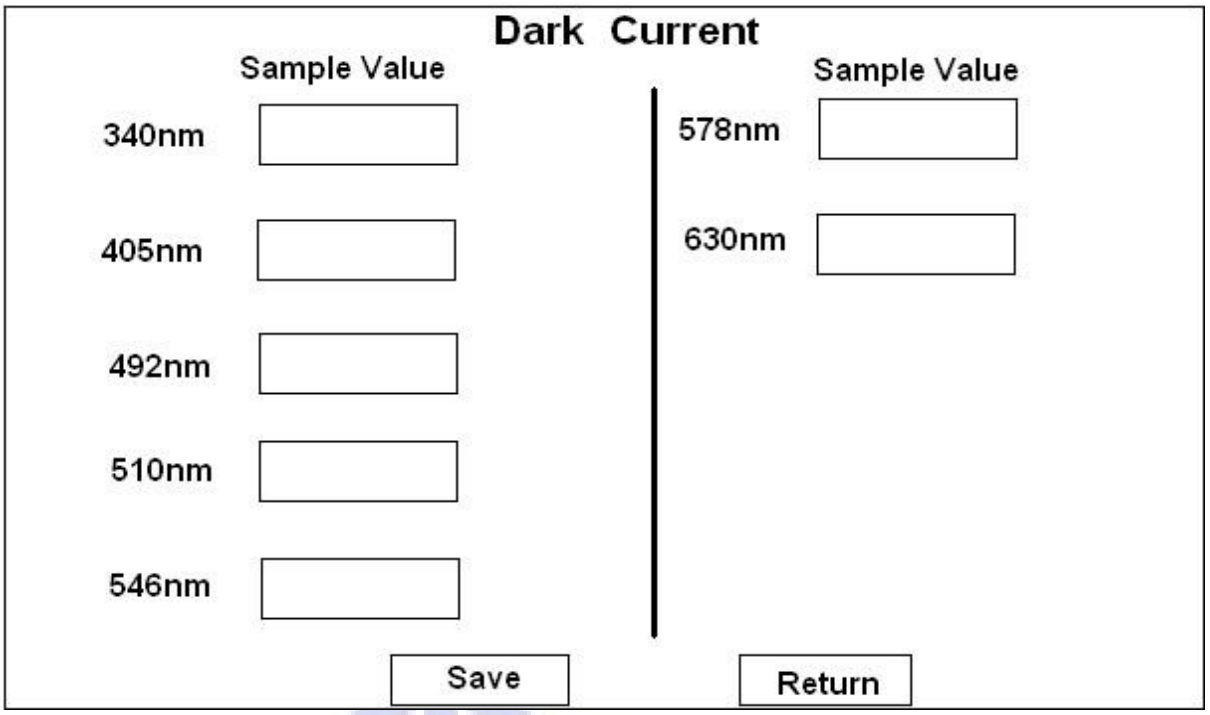
Then it will enter into the 'System is preheating' interface automatically. At the moment the user can click the 'Cancel' button to enter the main interface, otherwise it will enter the main interface automatically after the preheating is completed. Then the user can start the daily operation.

For the first operation of the instrument, further test is necessary before the operation.

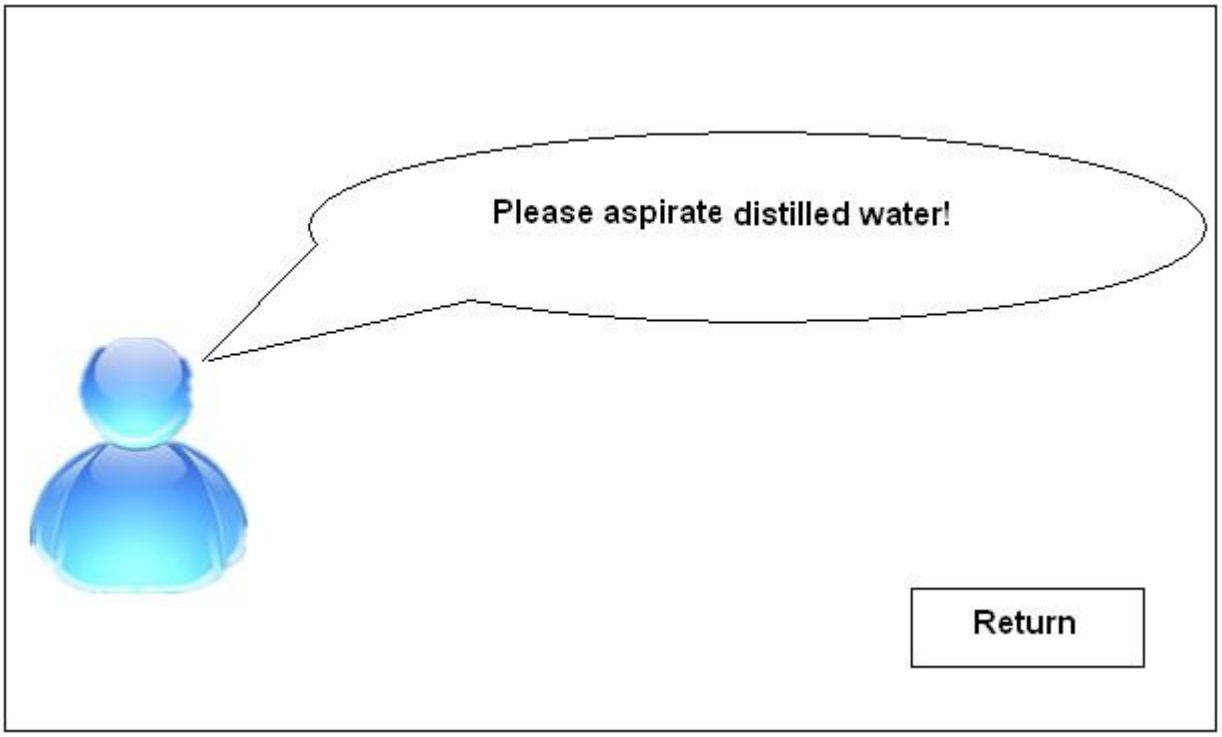
After entering the 'Main Menu' interface, click 'Other Service' to enter the 'Other Service' interface.

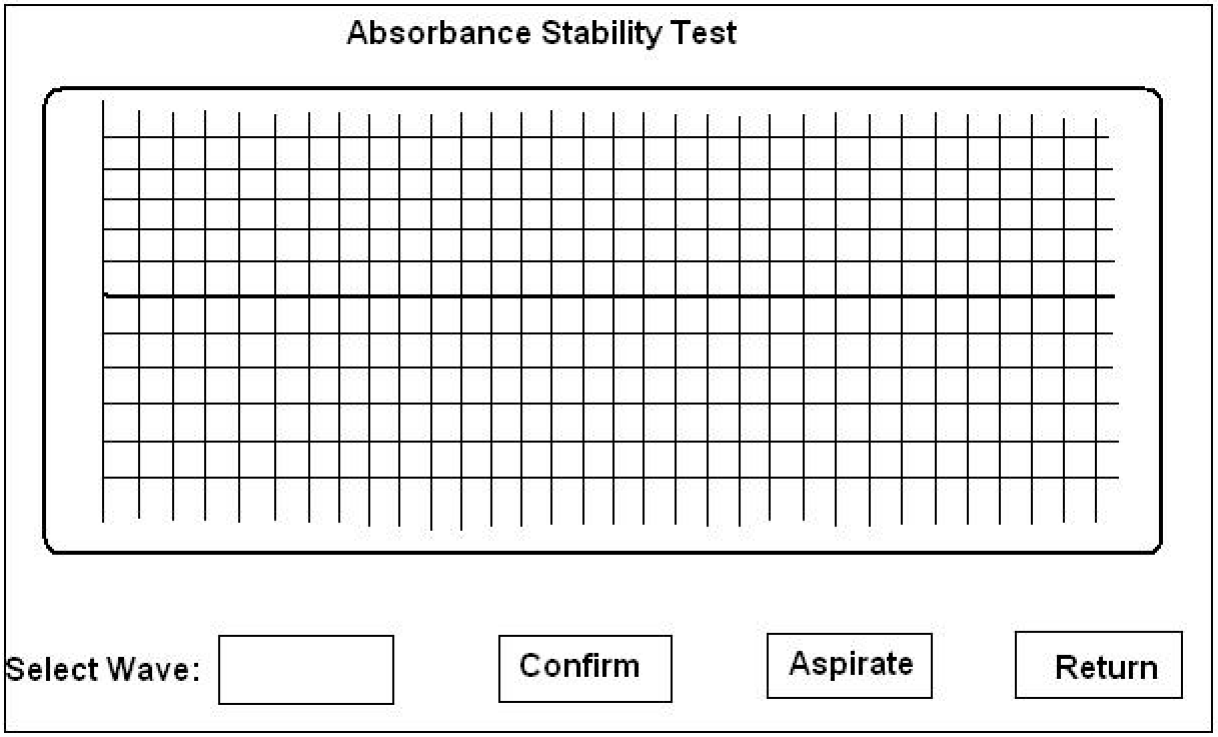


Click the 'Dark Current' button, the system will automatically turn off the light and start testing the darkcurrent. The normal dark currents of all the wavelengths should be between I0 to 50; as shown below:



Then click the 'Absorbance Test' button; the system will prompt on absorbing the distilled water. Afterthat, the system will start testing and show the absorbance, the AD values and the absorbance curve of a particular wavelength. Observe for 5 minutes to see if the curve becomes flat. If the curve is still not flat after five minutes, click the 'Select Wave' input box. Select the desired wavelength and click the 'Confirm' key, the system will test the absorbance stability for five minutes again. As shown below:





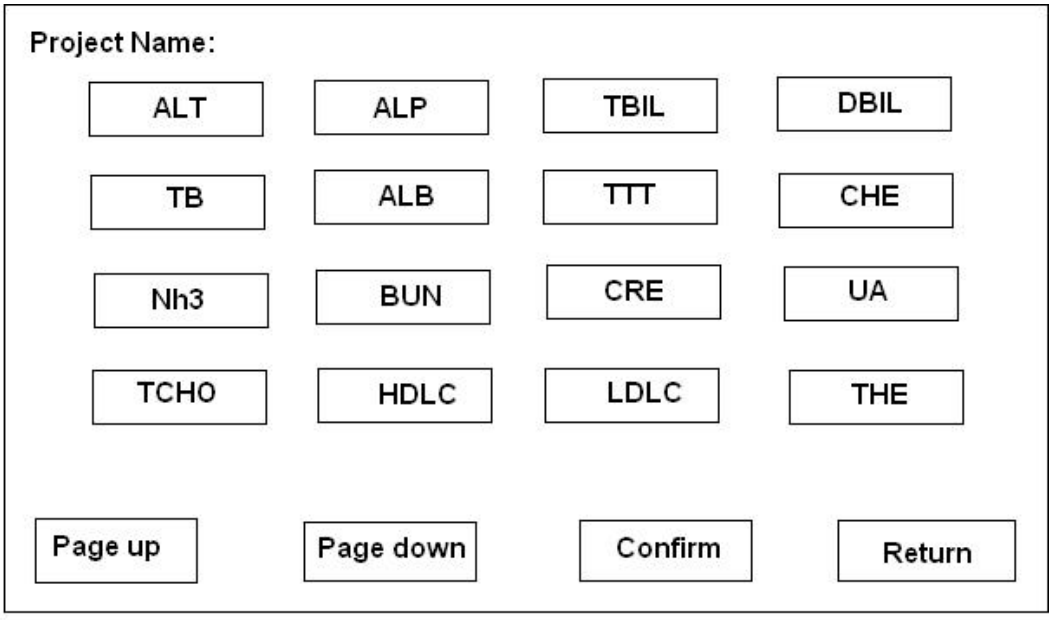
When each wavelength absorbance is in a stable state, the machine can work normally.

Chapter II Test Sample

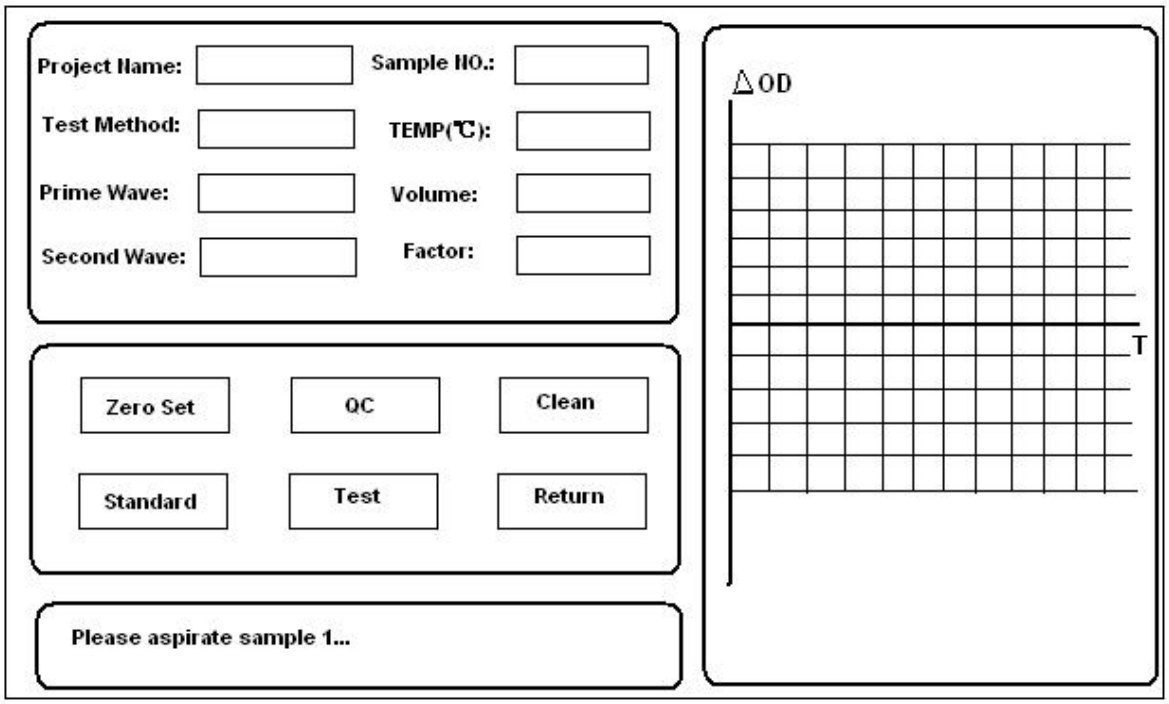
Before testing the sample, the test project must be set according to different reagent manuals. After completing the settings, enter the test project to test the corresponding project. See Section 3, Chapter III in this manual for specific setting methods.

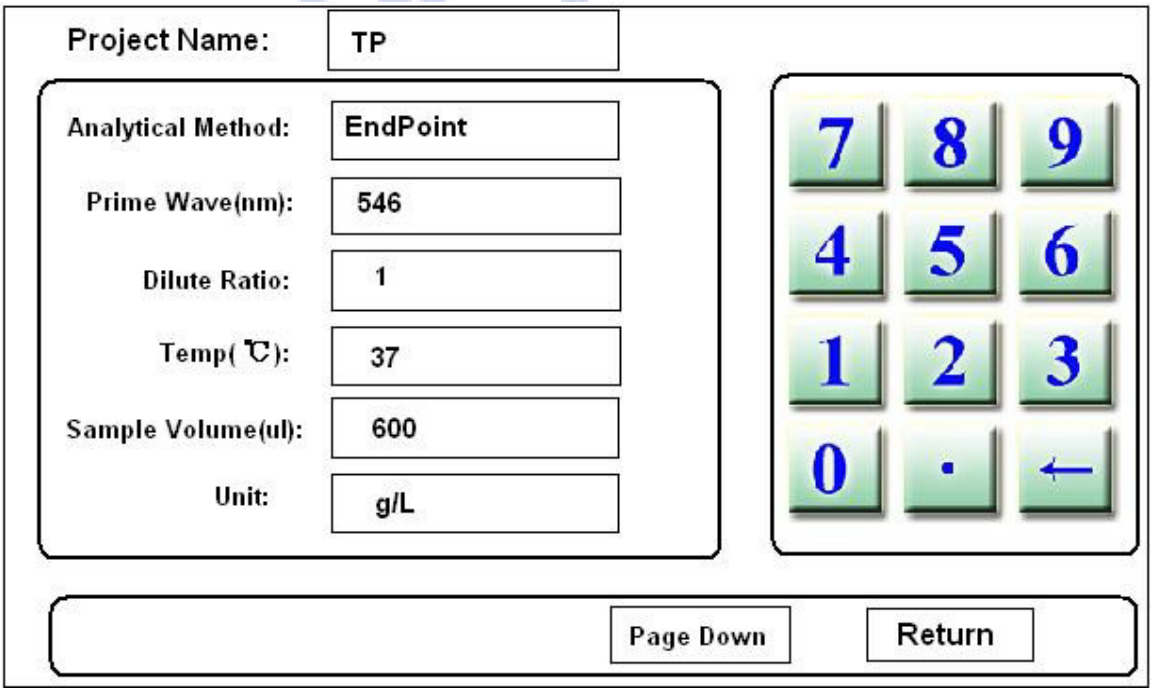
2.1 Test Use flow cell

2.1.1. Under the 'Main Menu' interface, touch the 'Test Use flow cell' menu, the system enters the project selection interface. Select the project to test and click 'Confirm' to enter the specific project test.



2.1.2. The project parameter information is displayed on the top-left of the test interface, where the 'Sample No.' is a white input box, the user can modify the Sample No. If not modified, the Sample No.will automatically increase by one in order, as shown below: ℃





2.1.3. For the first test sample, zero setting is required. Touch the 'Zero Set' button, the system will prompt 'Please aspirate distilled water' for the zero setting. After the zero setting is completed, if the project needs to test the blank value, the system will prompt 'please aspirate reagent blank' or 'pleaseaspirate sample blank' for the test.

2.1.4. QC test, please click the 'QC' button, will prompt 'Please aspirate QC1' for the QC test.

2.1.5. Standard test, please click the 'Standard' button. The system will prompt 'Please aspirate standard' for the calibration test.

2.1.6. Sample test, please click the 'Test' button. The system will prompt 'Please aspirate sample 1'

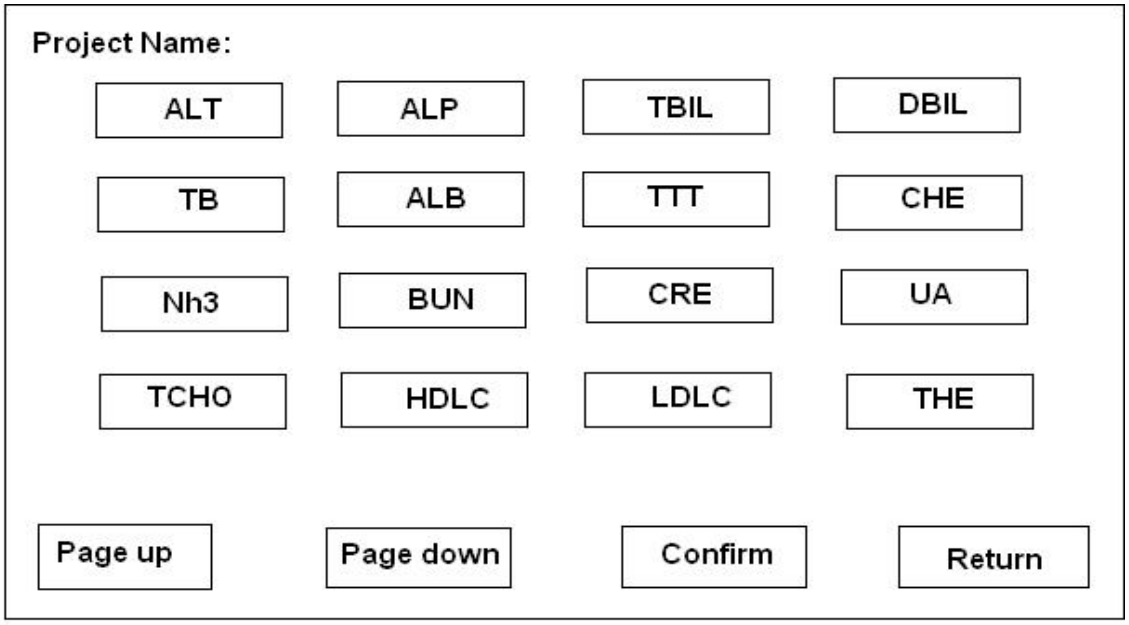
for the sample test.

2.1.7 To clean the system before or after the test, please click the 'Clean' button. The system willprompt 'Please aspirate cleaning' to clean the liquid circuit.

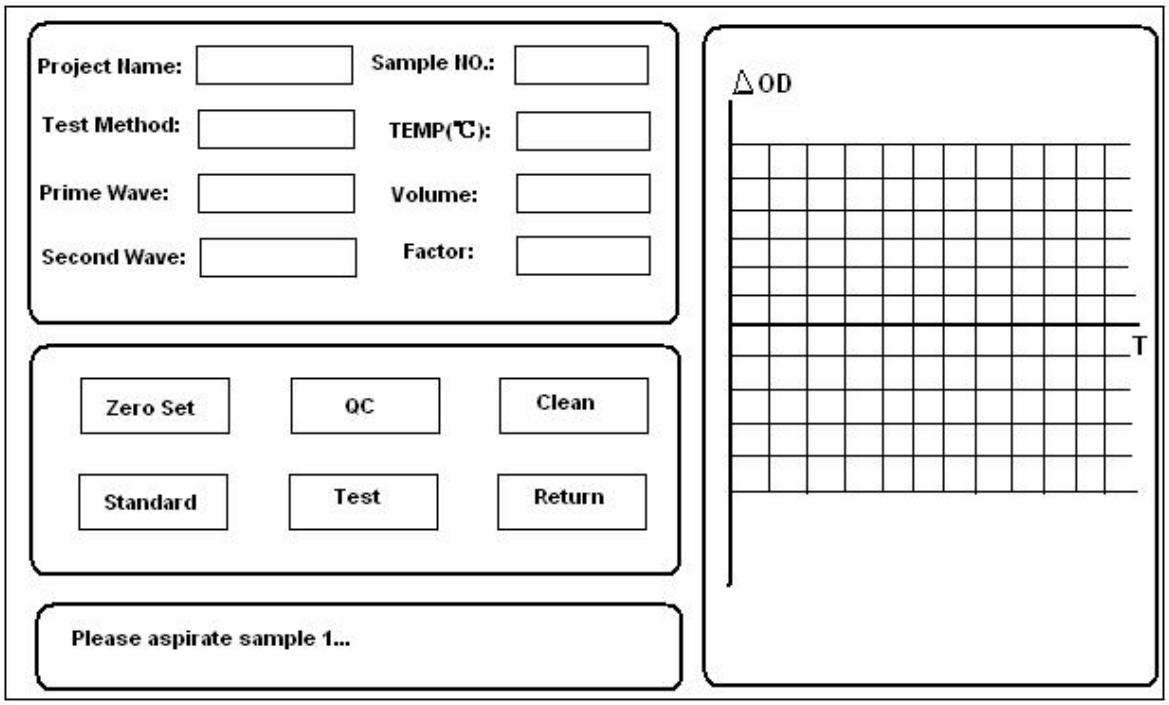
2.1.8 To exit the test, please click the 'Return' button. The system exits to the 'Program Project'interface.

2.2 Test Use Cuvette

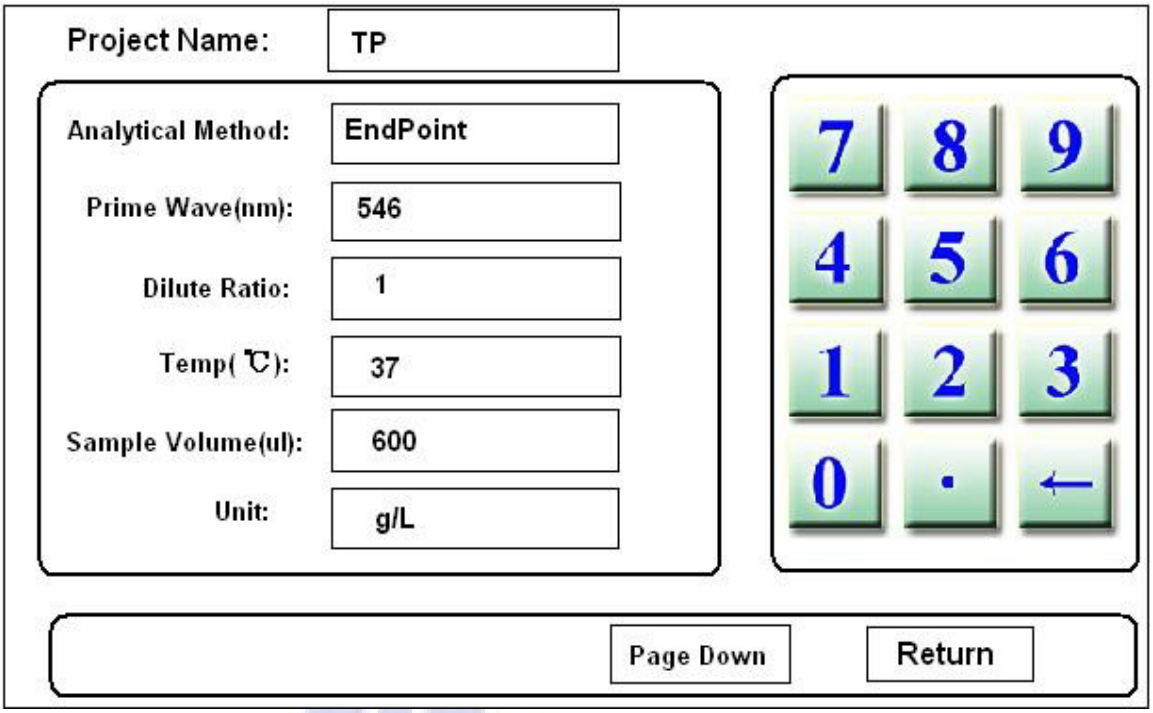
2.2.1. Under the 'Main Menu' interface, touch the 'Test Use Cuvette' menu, the system enters the project selection interface. Select the project to test and click 'Confirm' to enter the specific project test.



2.2.2. The project parameter information is displayed on the top-left of the test interface, where the 'Sample No.' is a white input box, the user can modify the Sample No. If not modified, the Sample No.will automatically increase by one in order, as shown below:



Interface of modifying the Sample No. is as follows:



2.2.3. For the first test sample, zero setting is required. Touch the 'Zero Set' button, the system will prompt 'Please input distilled water', after input distilled water tube in the test position, press the sample key to confirm, the screen display "testing distilled water" to zero setting. After the zero setting, if need to test the blank, the system will prompt 'please input reagent blank' or 'please aspirate sample blank' for the test.

2.2.4. QC test, please click the 'QC' button. The system will prompt 'Please input QC1' for the QC test.

2.2.5. Standard test, please click the 'Standard' button. The system will prompt 'Please input standard' for the calibration test.

2.2.6. Sample test, please click the 'Test' button. The system will prompt 'Please input sample 1' for the sample test.

2.2.7 To clean the system before or after the test, please click the 'Clean' button. The system will prompt 'There is no need to wash'.

2.2.8 To exit the test, please click the 'Return' button. The system exits to the 'Program Project' interface.

2.3 Result Report:

The instrument uses two modes to print the result report, as described below:

2.3.1 Automatic Print

If the 'Real-time Print: On' is set in the 'System Setting', the test result will be printed automaticallyafter each sample test.

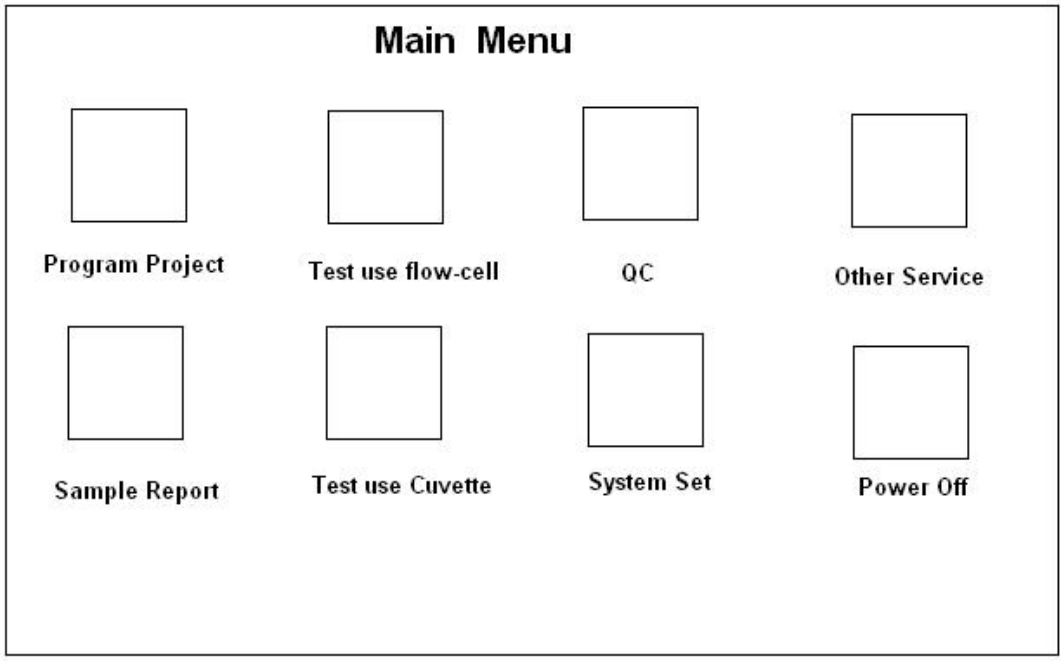
2.3.2 Manual Print

Enter the 'Sample Report' in the main interface to print the patient report according to Section 2, Chapter III.

Note: Due to the limited storage space of the instrument system, the instrument can only store 10,000 test results. To review greater storage capacity, can connecting to the computer. The instrument will automatically transmit the test results to the computer software. The storage, calling and searching of the database are done by the computer.

Chapter III Main Menu Functions

The menu structure is that the submenus are embedded in the main menu. The contents of the mainmenu are as follows:



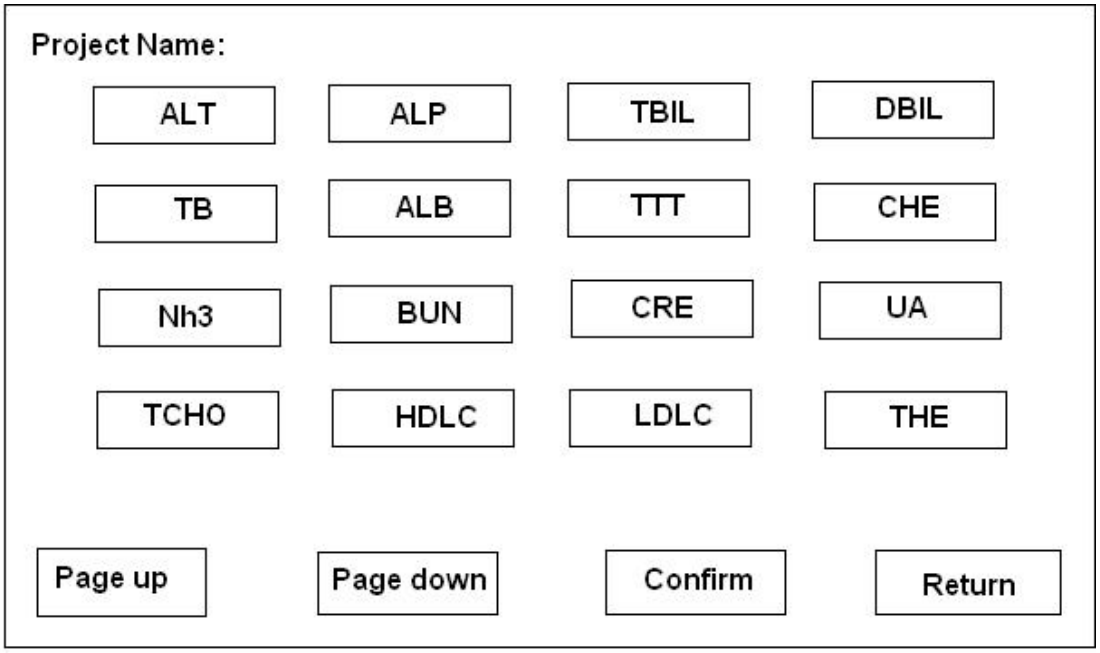
The operator can use the stylus to click the icons in the main interface to complete the corresponding operations.

1-Project Programming 2-Sample Report 3-Test Use Flow-cell 4-Test Use Cuvette
5- QC 6-System set 7 - Other Service 8- Power off

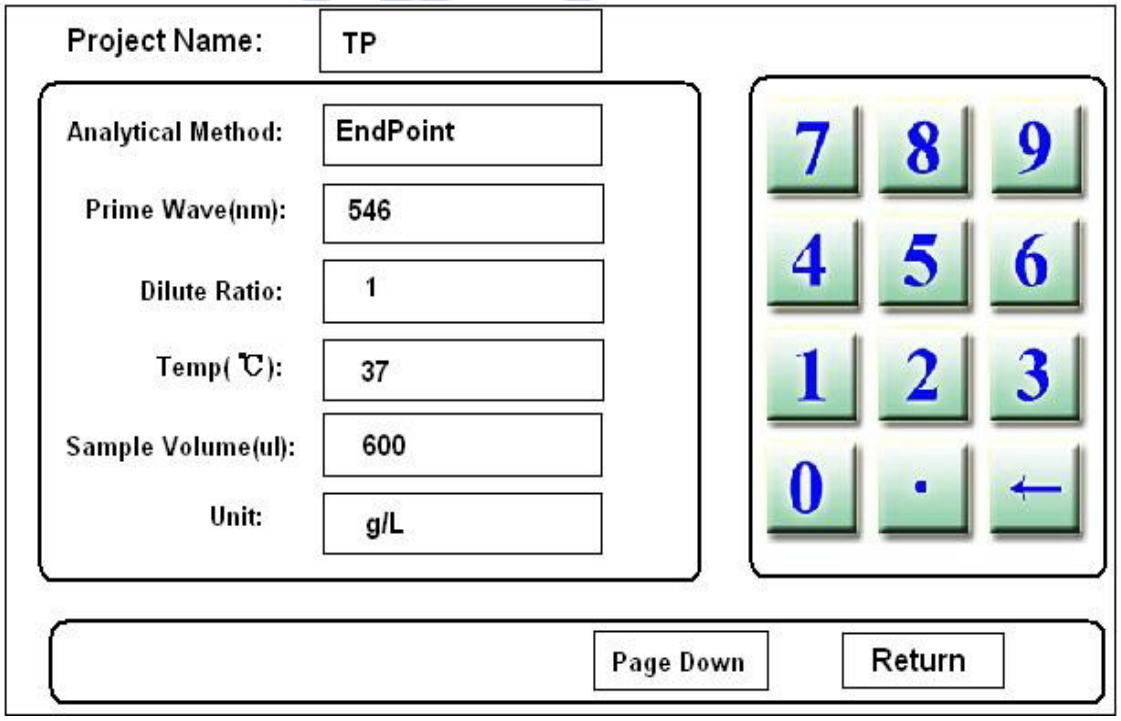
During daily operation, the operator mainly operates the items of 1, 2 and 3 or 4. Details are asfollows:

Section 1 Project Programming

Projects have been preset in the instrument, with a total of 80 preset test projects available. The preset 71 projects have English names and English abbreviations. Users can specify English abbreviations for the added project. Select the 'Project Program' in the main interface to enter the project selection interface. As shown below:



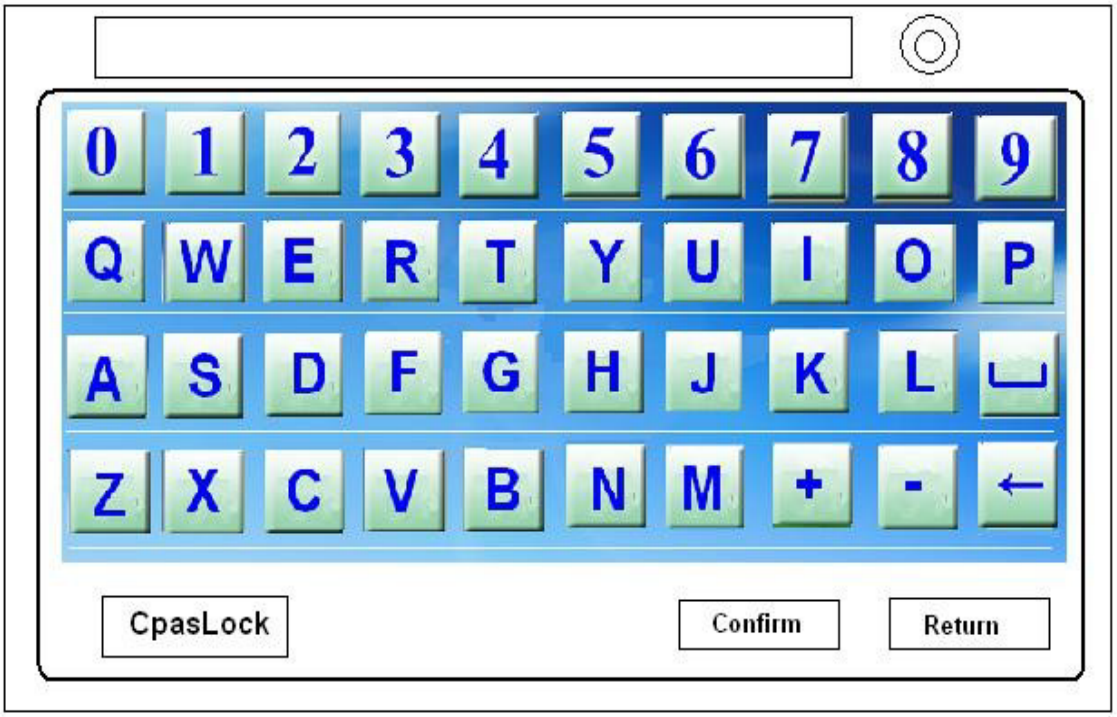
In the project selection interface, each button displays the English abbreviation of the project. When you click a project, the top of the interface will display the corresponding English name. Click 'Confirm', the system will enter the programming mode of a project, as shown below:



The specific programming method is as follows:

1.1 Project Name

When entering this interface, the 'Project Name' input box will display the initial English abbreviation of the project. If the user wants to modify the initial English abbreviation, please click the 'Project Name' input box, and the keyboard interface will pop up. In the keyboard interface, the user can inputall of the numbers and characters in the keyboard and can shift case of the input letters by clicking the 'Caps Lock' button. In case of input error, click the '←' button to delete it. As shown below:



1.2 Analytical Method

Optional methods include 'end-point method', 'two-point method" and 'rate method'. Repeatedly touch the white box behind the 'Analytical Method:' to select the corresponding analytical method. Each touch will change the analytical method once.

1.3 Dominant wavelength

There are 7 optional wavelengths including 340nm, 405nm, 492nm, 510nm, 546nm, 578nm and 630nm. Touch the white box behind the 'Prime Wave:' to select the corresponding wavelength. Eachtouch will change it once.

1.4 Dilute ratio

The default value for dilute ratio is 1, it is not needed to dilute the sample. If the absorbance of patientsample is very high, it is over test range. For example, if we want to dilute the sample by two times, test over, the patient result will two times as the test result automatically.

1.5 Temperature

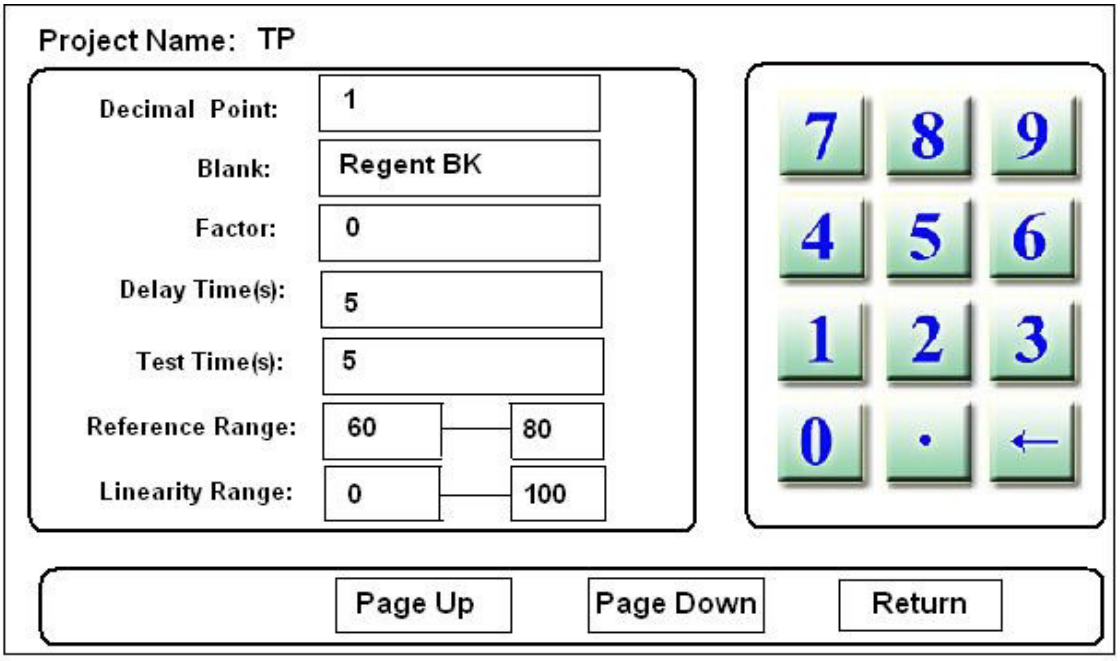
Set the project test temperature by inputting the corresponding temperature through the softkeyboard on the right of the interface. The temperature is generally 37 °C.

1.6 Pump Volume

Set the sample absorption volume of the test project. The unit is 'μL'. The pump volume has been calibrated when leaving the factory, and the users only need to input the corresponding sample absorption volume. Independent pump volume can be set for each project. The system will absorb samples according to the corresponding pump volumes during the test.

1.7 Units

Set the units for the test results. According to different units, the system will convert to the set units before display. Each touch will change it once. After these settings are completed, click the 'Page Down' to set other project parameters. As shown below:



1.8 Decimal Point

Set the decimal places of the test results by touching the choice box, it can change from 0 to 3.

1.9 Blank

There are three options including 'Reagent BLK', 'Sample BLK' and 'Without'. Specify and set the typeof blank used in the test. The default type is 'Reagent BLk'. Each touch will change it once.

1.10 Factor

The test factors of the rate method are generally known. Input the factor by the soft keyboard on theright of the interface. For the project with unknown factors, the instrument can automatically calculate the factor by testblank and standard, with no need for manually inputting.

1.11 Test Time

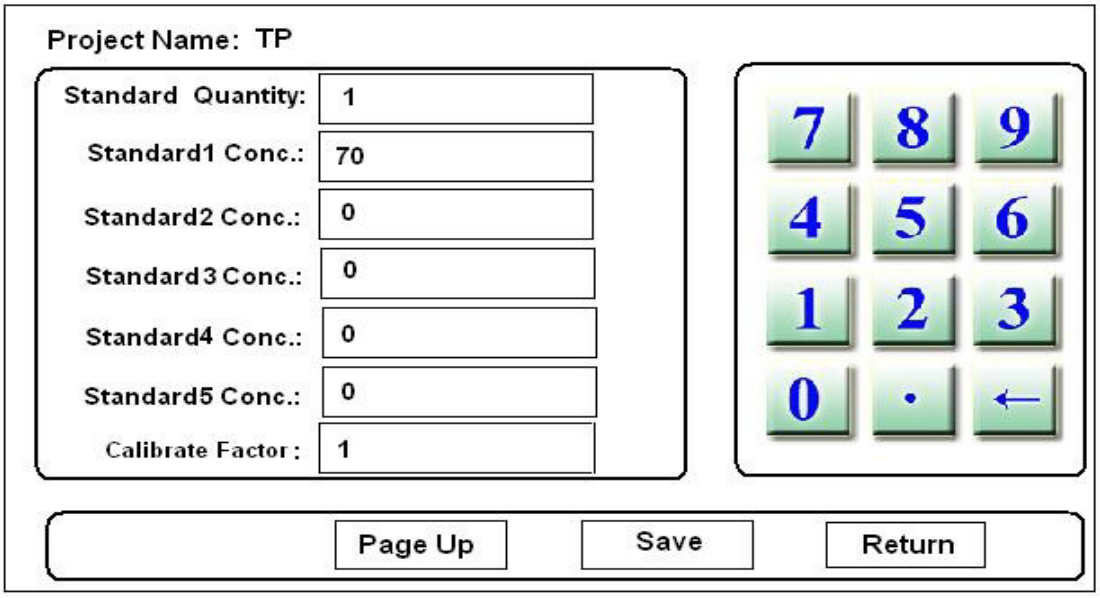
Different test projects require different test times. The test time of the Kinetic method and the two-point method have been given in the reagent manual, and the test time of the end-point methodis generally 5 seconds.

1.12 Delay Time

Different test projects require different delay times. The delay time of the Kinetic method and the two-point method have been given in the reagent manual, and the delay time of the end-point methodis generally 5 seconds.

1.13 Reference Range

Set the reference range of the test results. The latter value must be greater than the former value.After these settings, click 'Page Down' to set other project parameters.



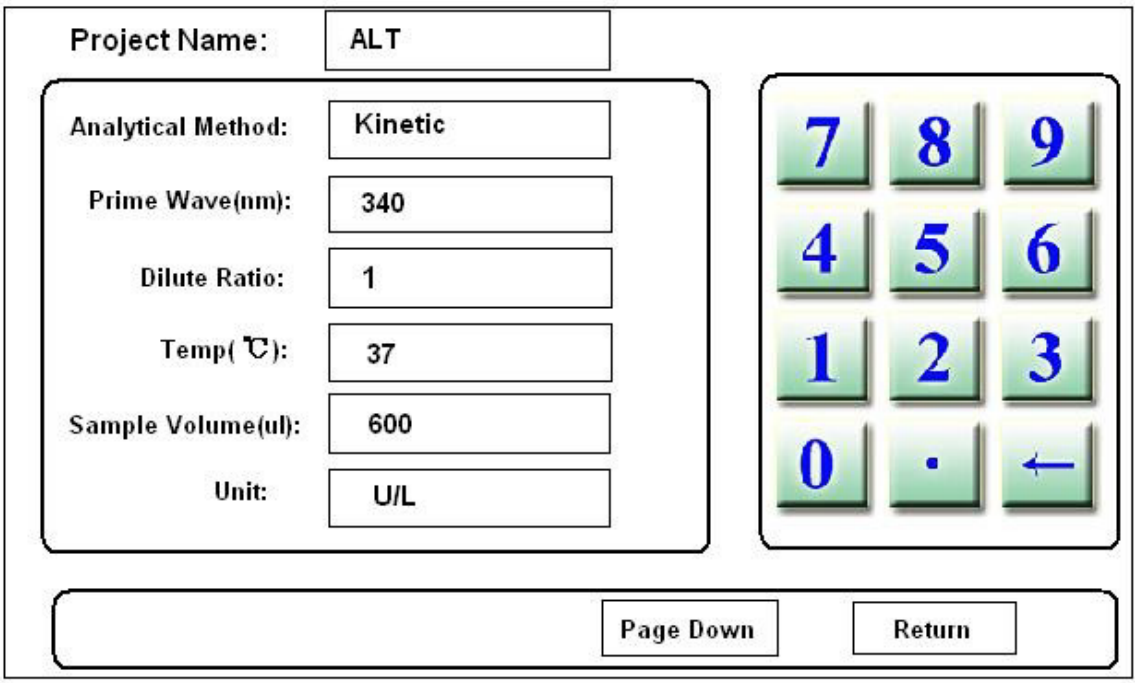
If the test project requires calibration, specify the quantity of standard concentration and input the values of the standard concentration in this interface. Touch the white box behind the 'Standard Quantity' to change the standard quantity from 0 to 6. Once the standard quantity is specified, the corresponding quantity of standard concentration can be inputted in the following standard concentration box. For example: The standard quantity is specified to '1', the operator can input the standard concentration value in the 'Standard 1 Conc.:', and the 'Standard 2 Conc.:' ~ 'Standard 5 Conc.:' will become gray to disable input. Note: During Project Programming, use the 'Page Up' and 'Page Down' buttons to turn the page, anduse the 'Cancel' button to exit setting. But these operations will not save any previous setting operations. The previous settings can only be saved by click the 'Save' button on the third page.

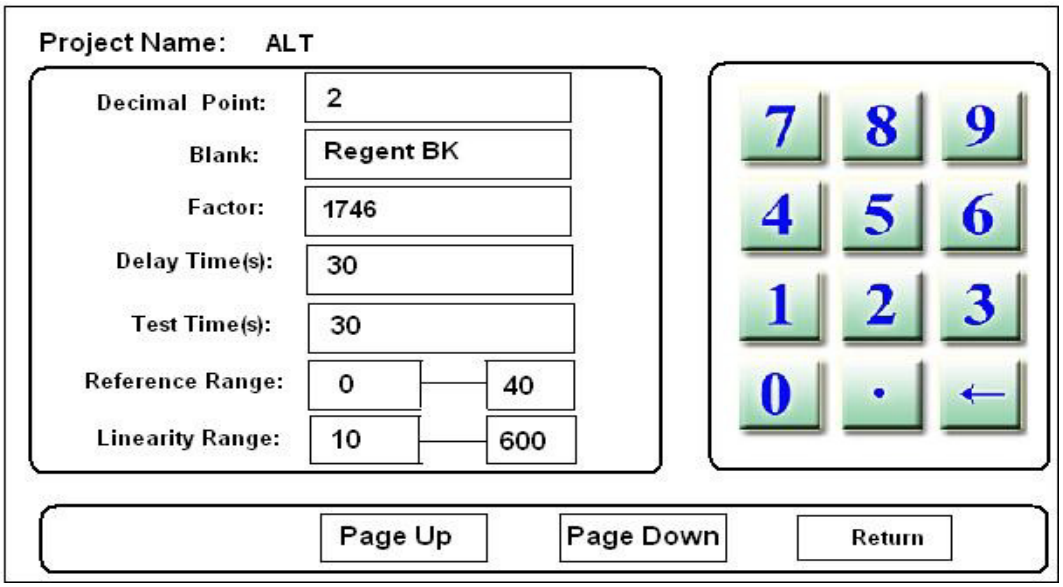
The default value of calibrate factor is 1. If the result of measure is low, modify this value greater than

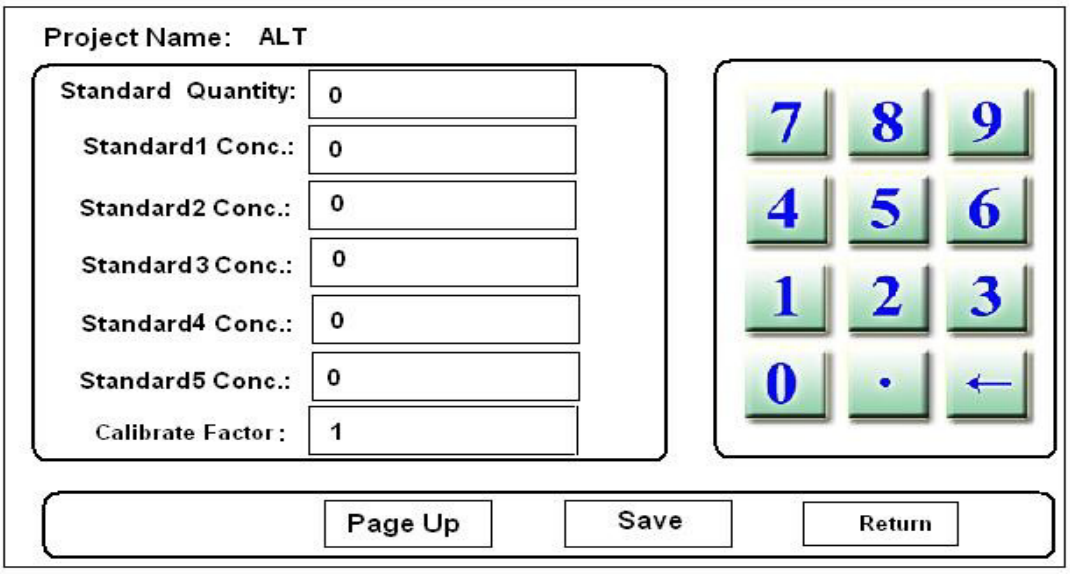
1. If the result of measure is high, modify this value less than 1.Typical project

parameter settings are as follows:

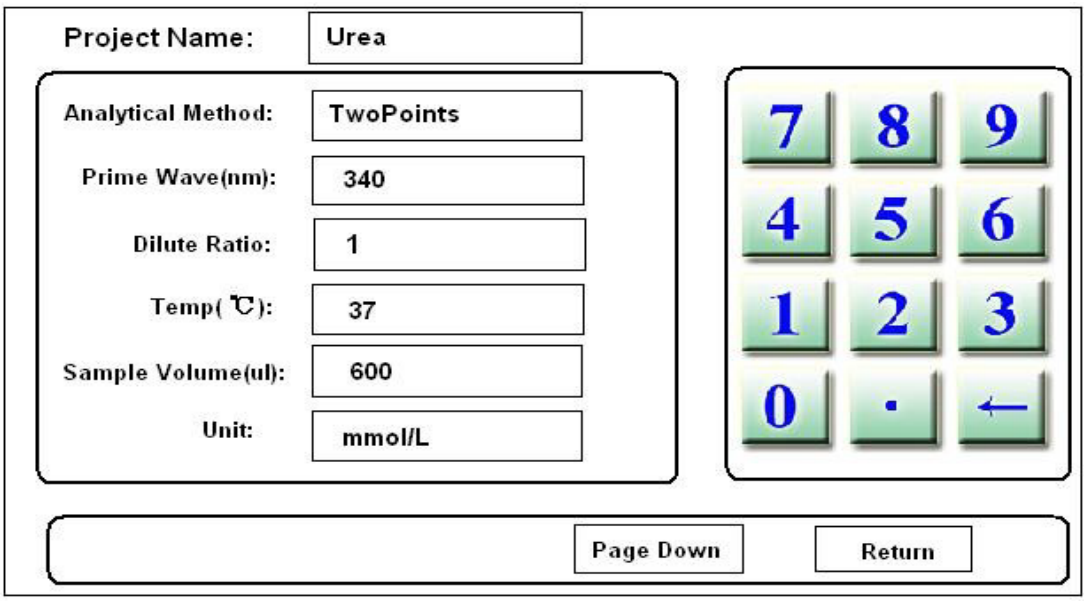
1、 Kinetic method (ALT reagent)

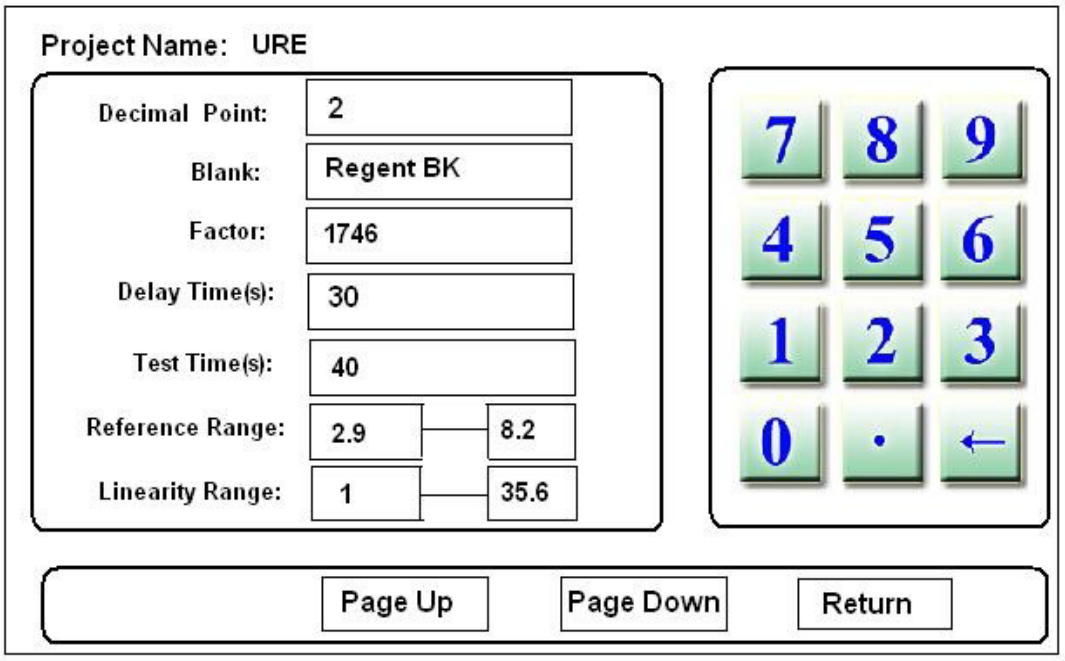


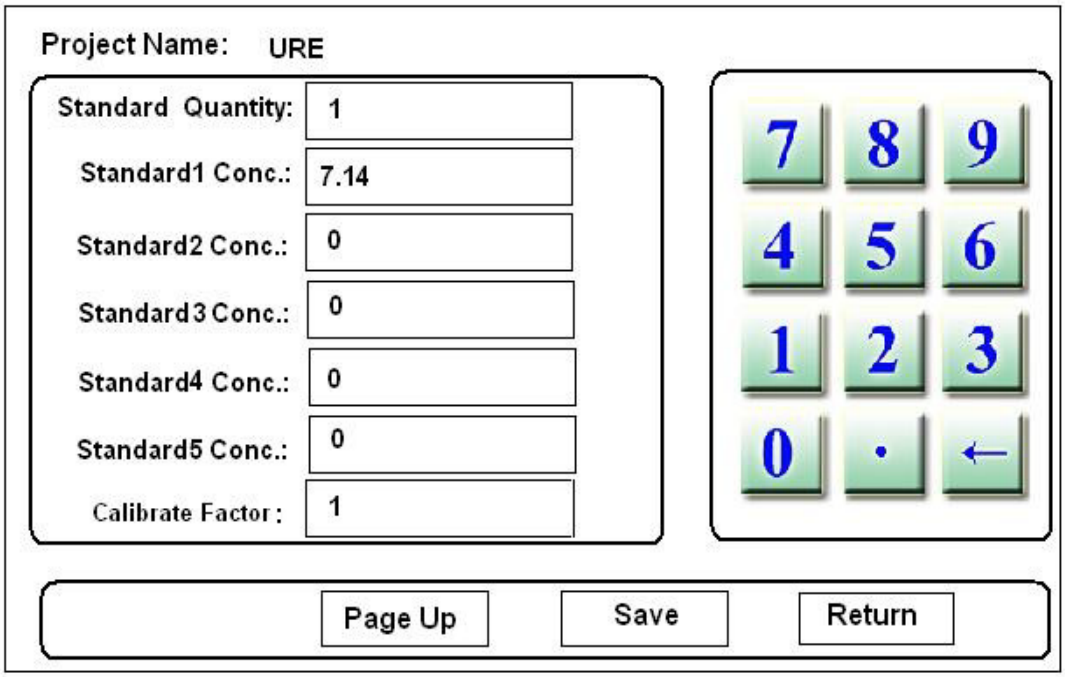




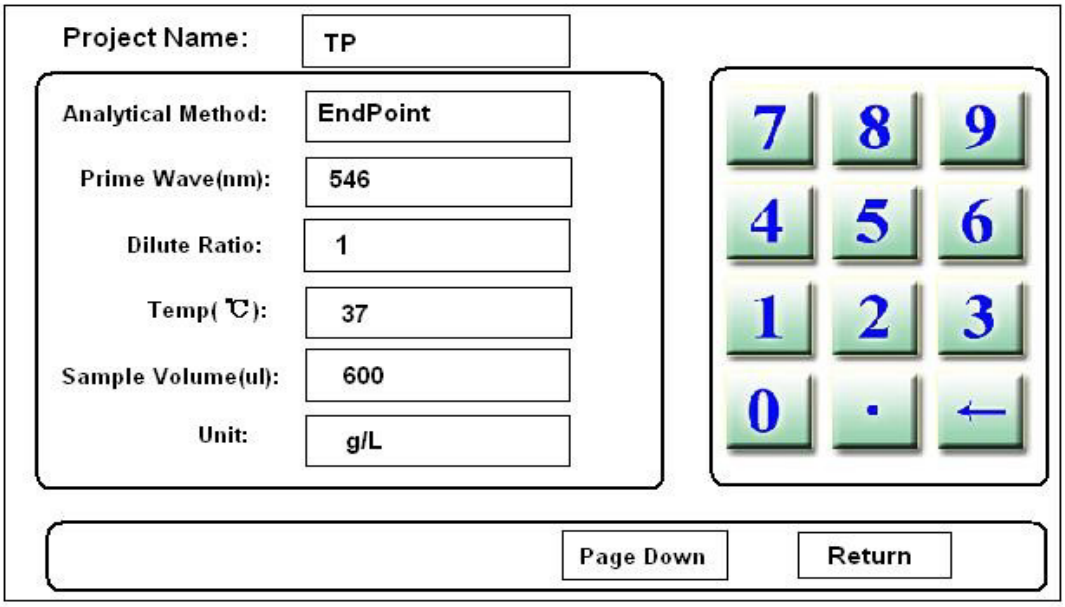
2、 Two-point method (UREA reagent)

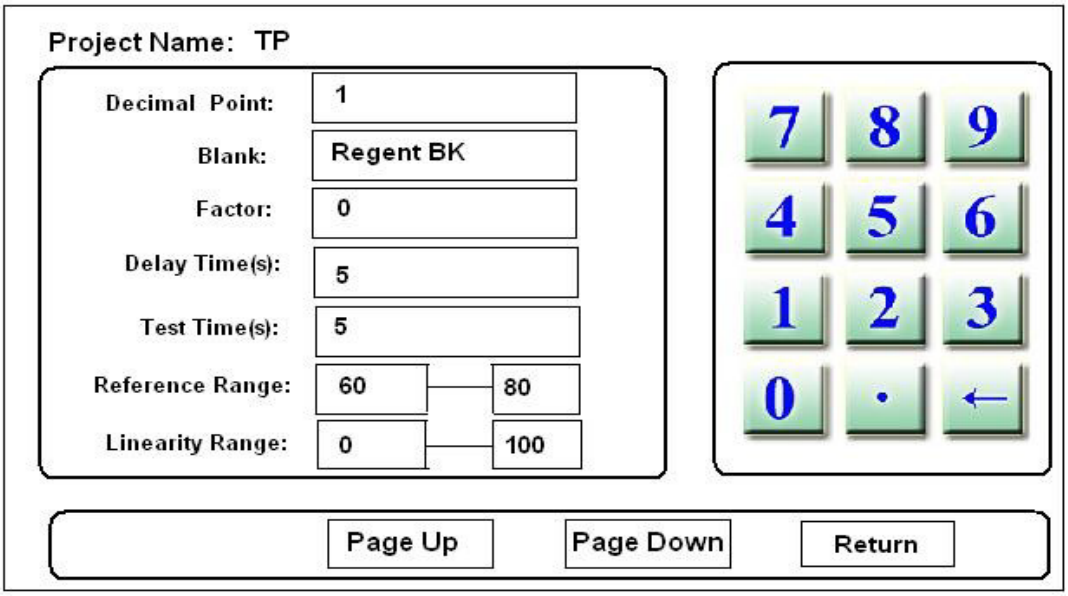


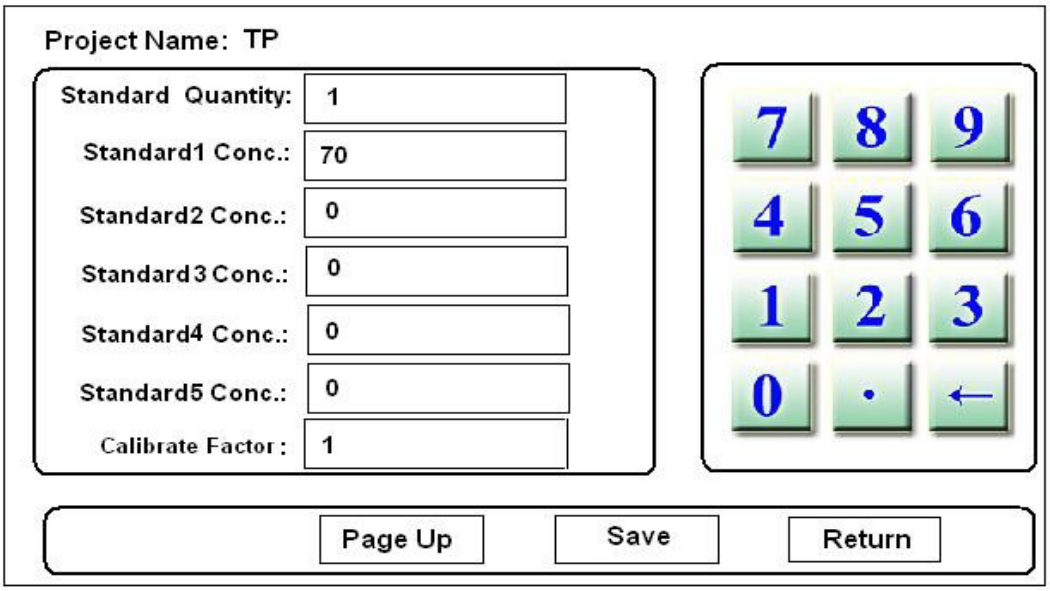




3、 End-point method (total protein TP reagent)


Project Name:
TP
Analytical Method:
EndPoint
Prime Wave(nm):
546
Dilute Ratio:
1
Temp(℃):
37
Sample Volume(ul):
600
Unit:
g/L
7 8 9
4 5 6
1 2 3
0 · ←
Page Down
Return


Project Name: TP
Decimal Point:
1
Blank:
Regent BK
Factor:
0
Delay Time(s):
5
Test Time(s):
5
Reference Range:
60
80
Linearity Range:
0
100
7 8 9
4 5 6
1 2 3
0 · ←
Page Up
Page Down
Return

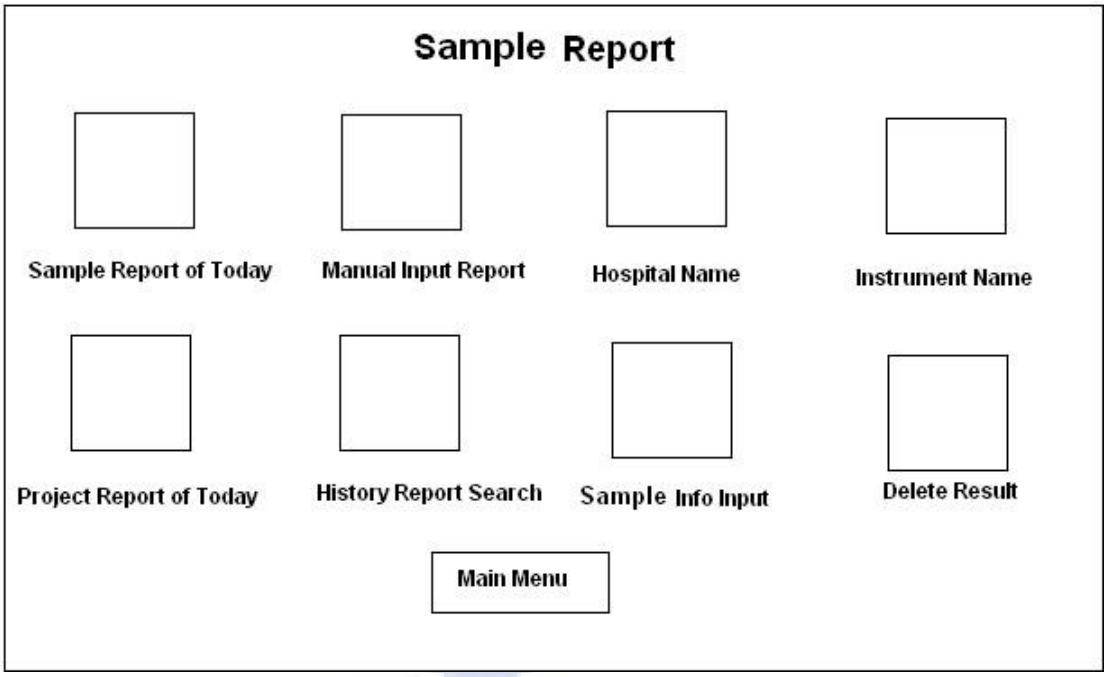

Project Name: TP
Standard Quantity:
1
Standard1 Conc.:
70
Standard2 Conc.:
0
Standard3 Conc.:
0
Standard4 Conc.:
0
Standard5 Conc.:
0
Calibrate Factor:
1
7 8 9
4 5 6
1 2 3
0 · ←
Page Up
Save
Return

Section 2 Sample Report

In the 'Main Menu' interface, click the 'Sample Report' button to switch to the 'Sample Report'interface. In this interface:

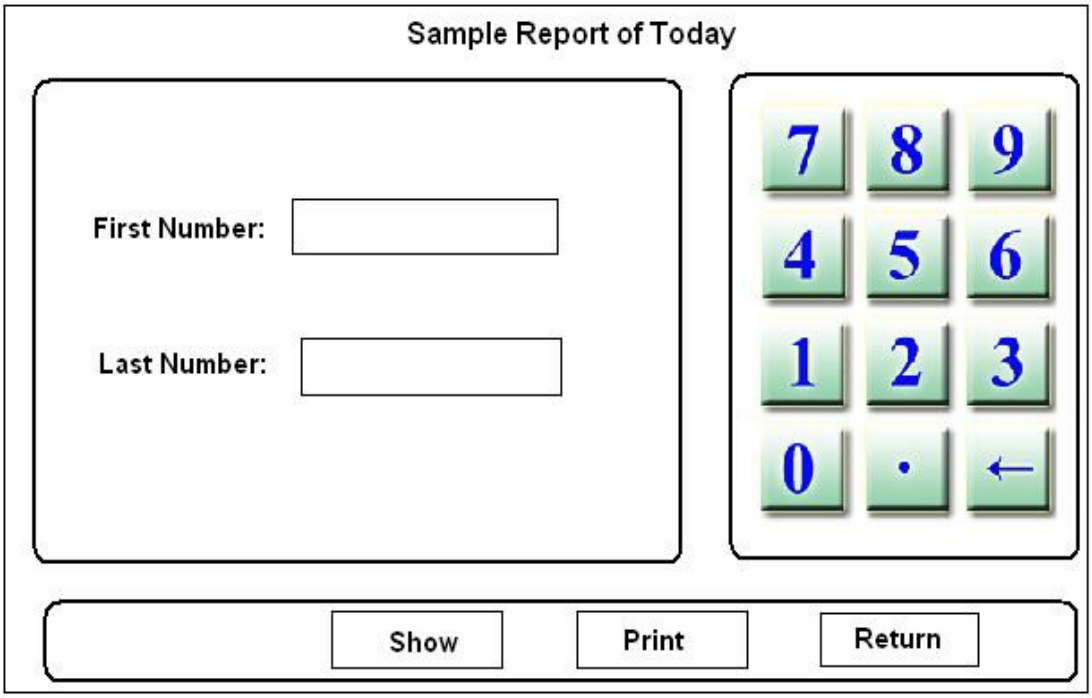
1. Sample Report of today
2. Project Report of today
3. History Report Search
4. Manual input Report
5. Hospital Name
6. Sample info Input
7. Instrument Name
8. Delete test results

As shown below:

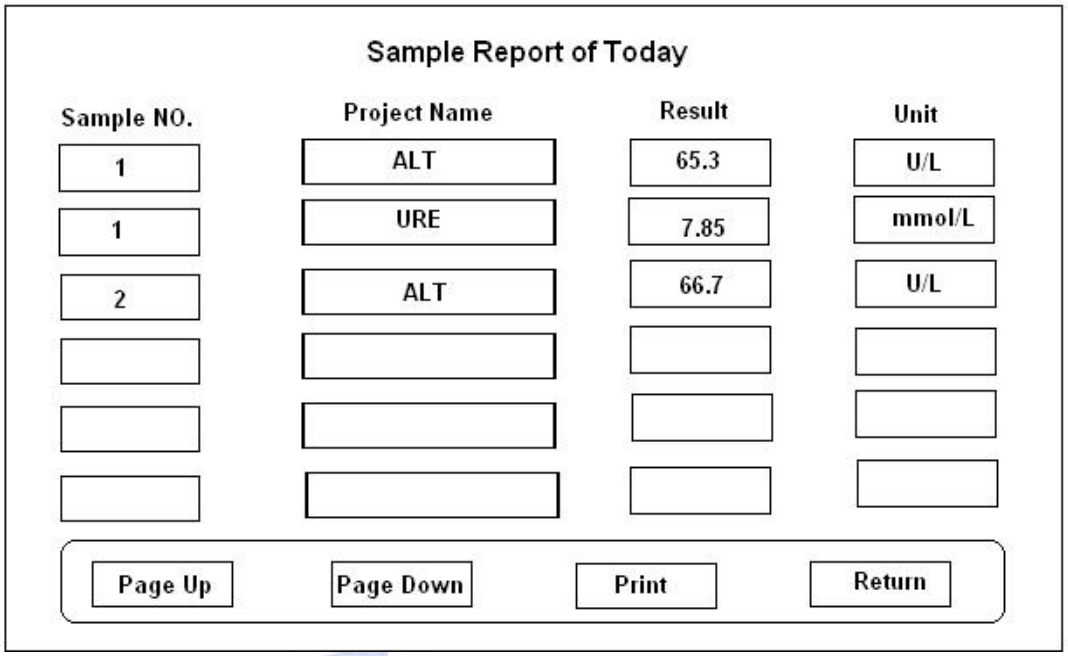


2.1 Sample Report of Today

In the 'Sample Report' interface, select the 'Sample Report of Today', as shown below:



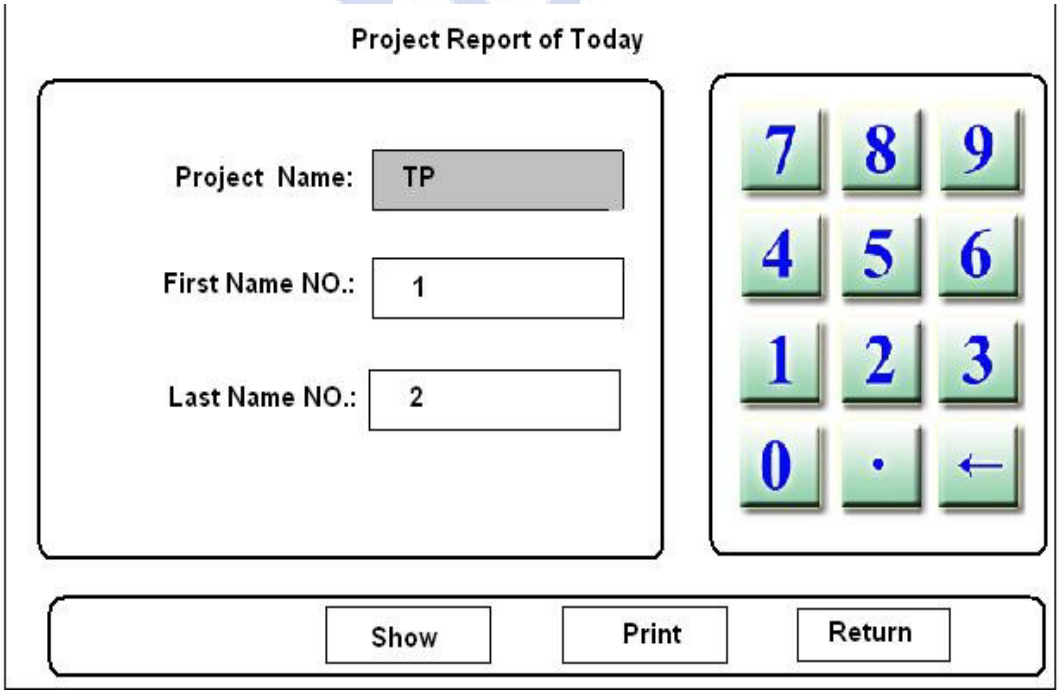
Input the first and last sample number, click the 'Show' to show all the sample test results oftoday in the following format:



This function can achieve the search of a particular sample number of today. If needing to print, click the 'Print' button after outputting the search results to print all the currently displayed samples in the order of sample number.

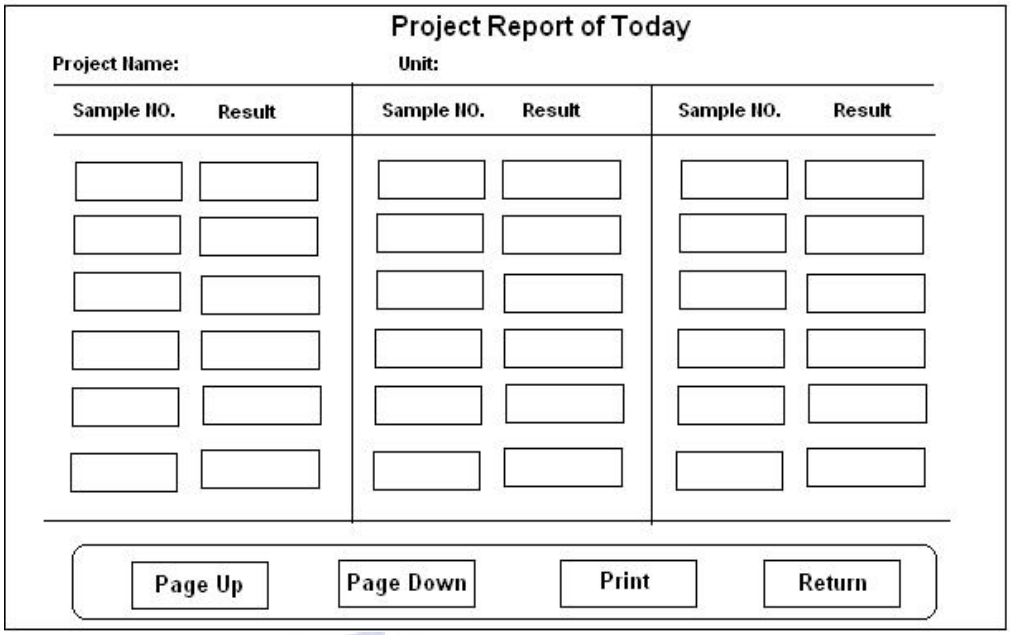
2.2 Project Report of Today

In the 'Sample Report' interface, select the 'Project Report of Today'. Then select a project in the project selection interface and click 'Confirm' to enter the 'Project Report of Today' interface, as shown below:



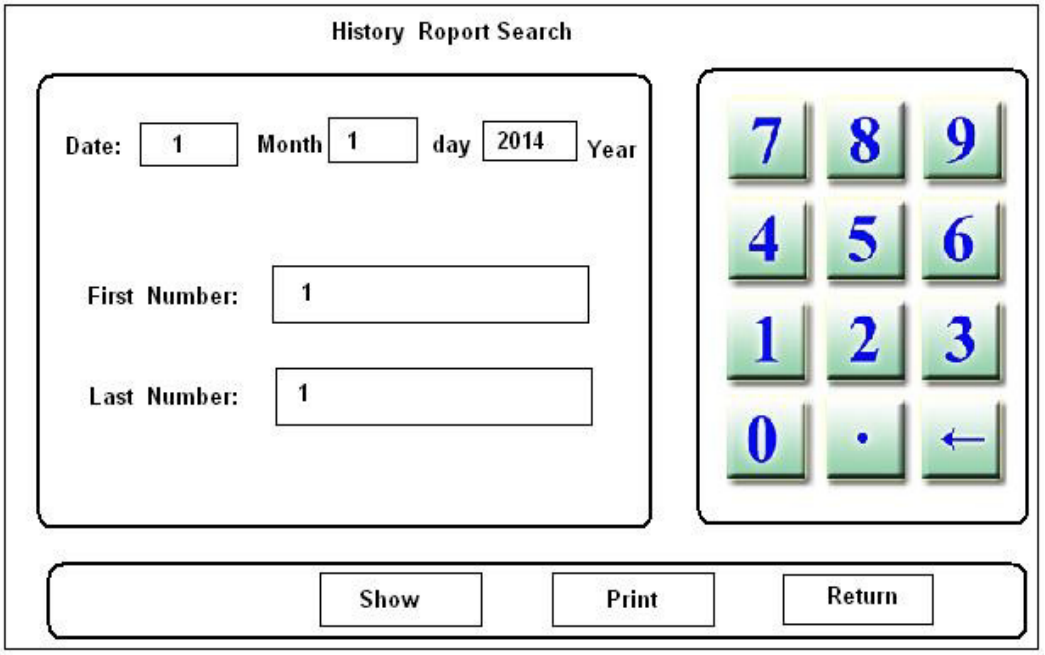
Input the first and last sample number, click the 'Show' to show all the sample test results of today. This function can achieve the search of a particular sample of a particular project of today. If needing to print, click the 'Print' button after outputting the search results to print all the test results of the project of today.

As shown below:

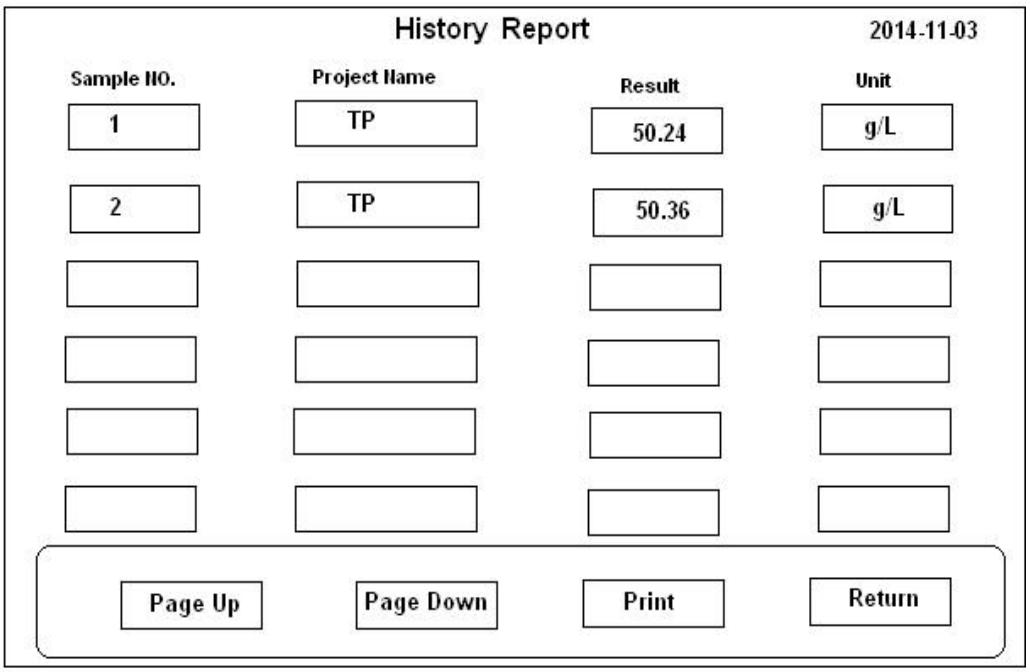


2.3 History Report Search

In 'Sample Report' interface, select the 'History Report Search' to search the test results of aspecific day in the history. Input the date, the first and last sample number, and then click 'Show'.



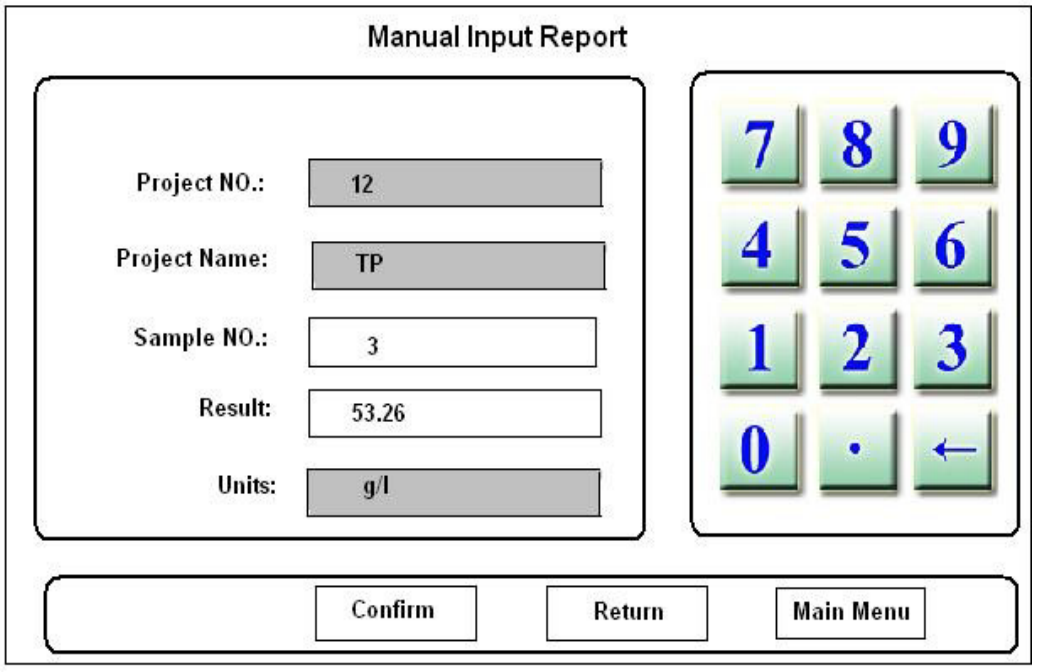
If needing to print, click the 'Print' button after outputting the search results to print. As shownbelow:



Due to the limited storage space of the instrument, it can only store 10000 history records. Only when the number of records from the searched history date till the searching day is less than 10000, can the report be searched.

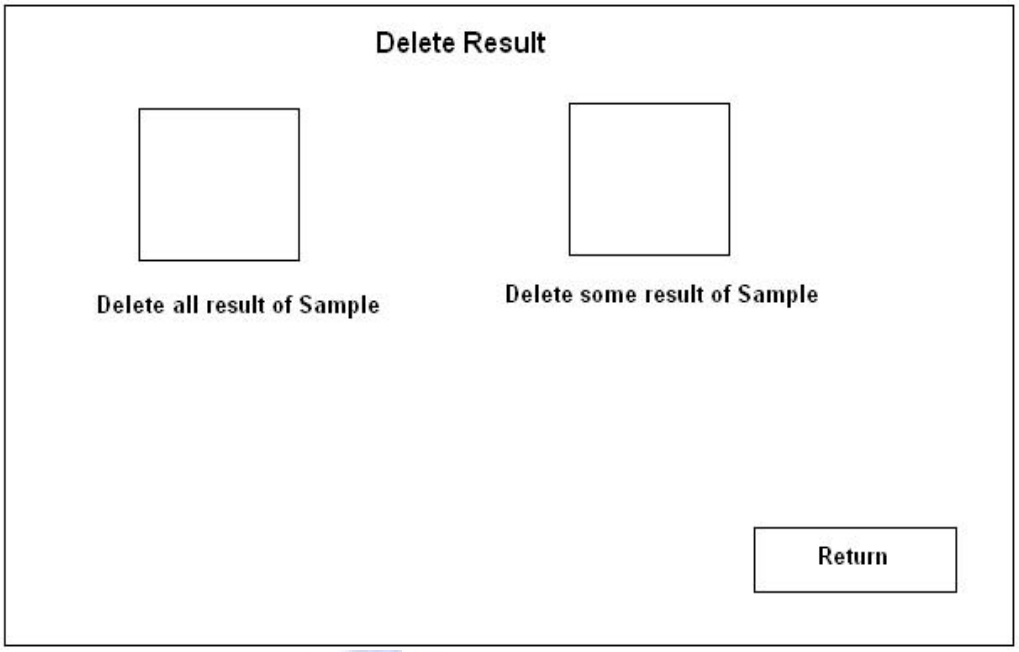
2.4 Manual Input Result

In the 'Sample Report' interface, select the 'Manual Input Report' to manually input test report.

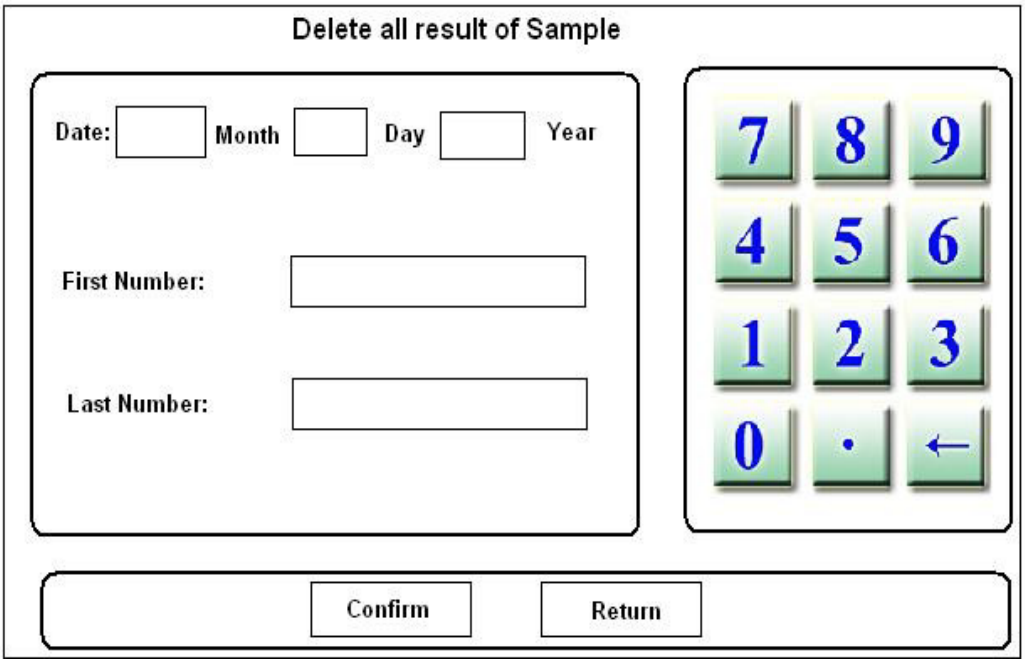


2.5 Delete Result

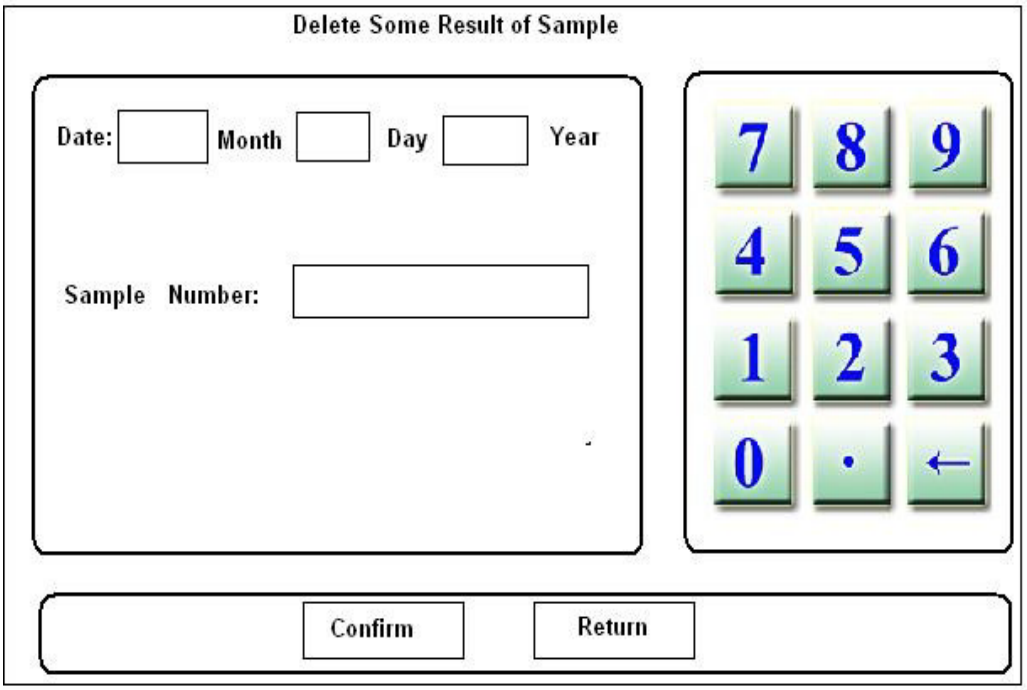
In the 'Sample Report' interface, select the 'Delete Result' to delete a particular test result.



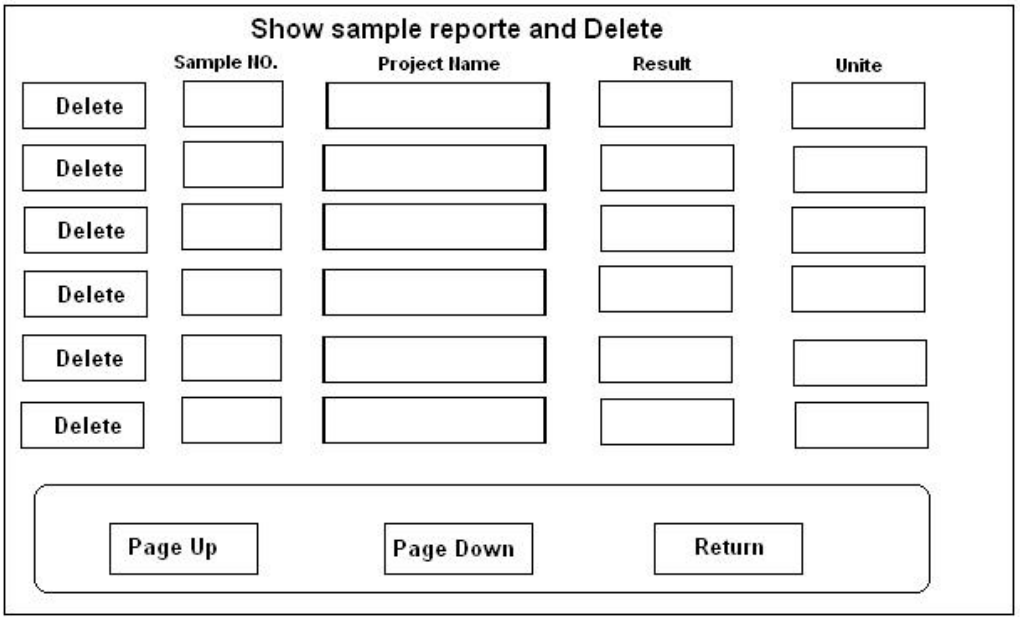
If you choose" Delete all result of Sample", can delete all the result of some samples, as following:



If you choose" Delete some result of Sample", can delete some of the sample results, as following:



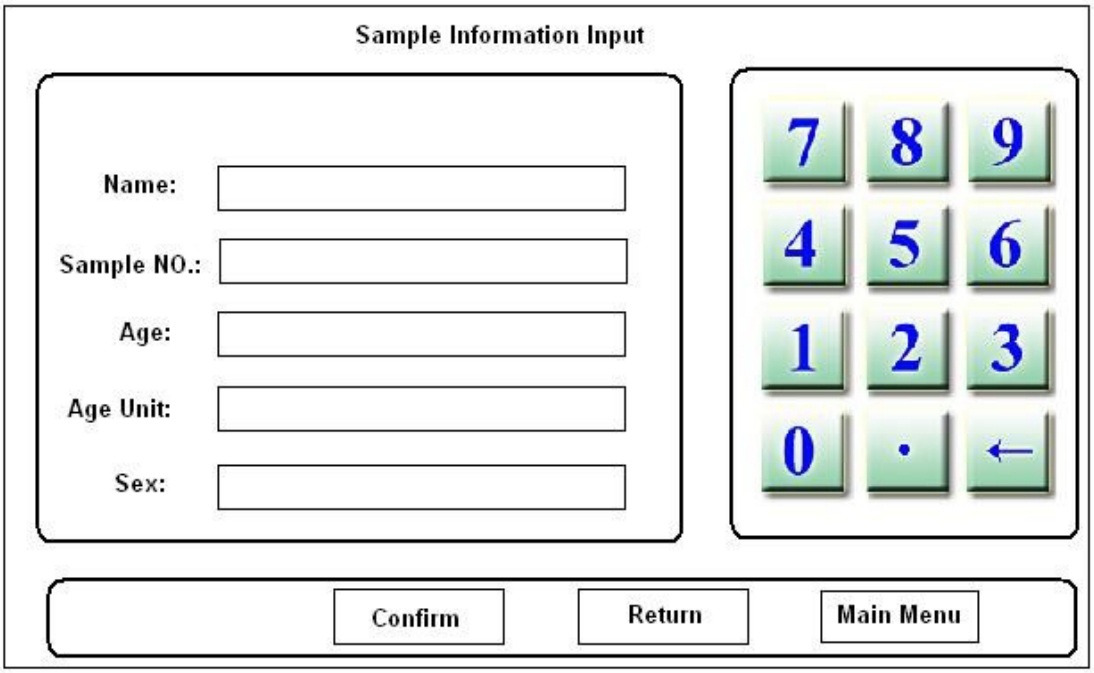
Press “Confirm”, the result will display as following:



Press the “Delete” button before the result, the result would be deleted.

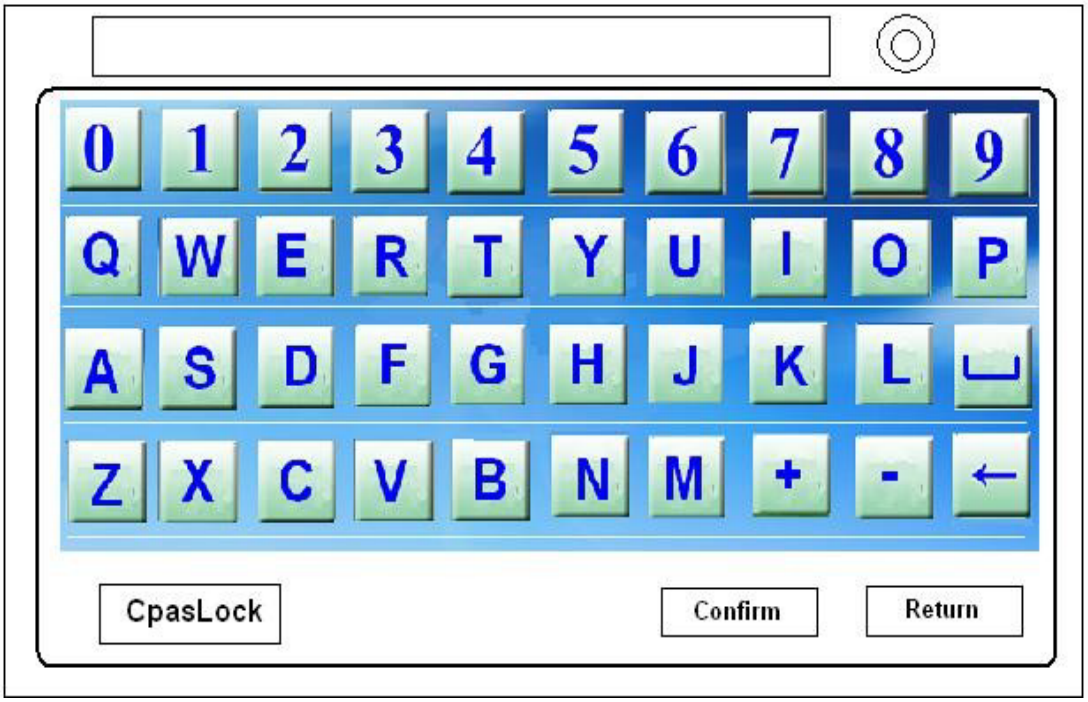
2.6 Sample Information Input

In the ‘Sample Report’ interface, select the ‘Patient Info Input’ to input the patient information ifthe information is needed to be printed on the report after the test is completed.



2.7 Hospital name Input

In the 'Sample Report' interface, select the 'Hospital Name' to input the name of hospital or clinicor others. If the information is needed to be printed on the report after the test is completed.



2.8 Instrument name Input

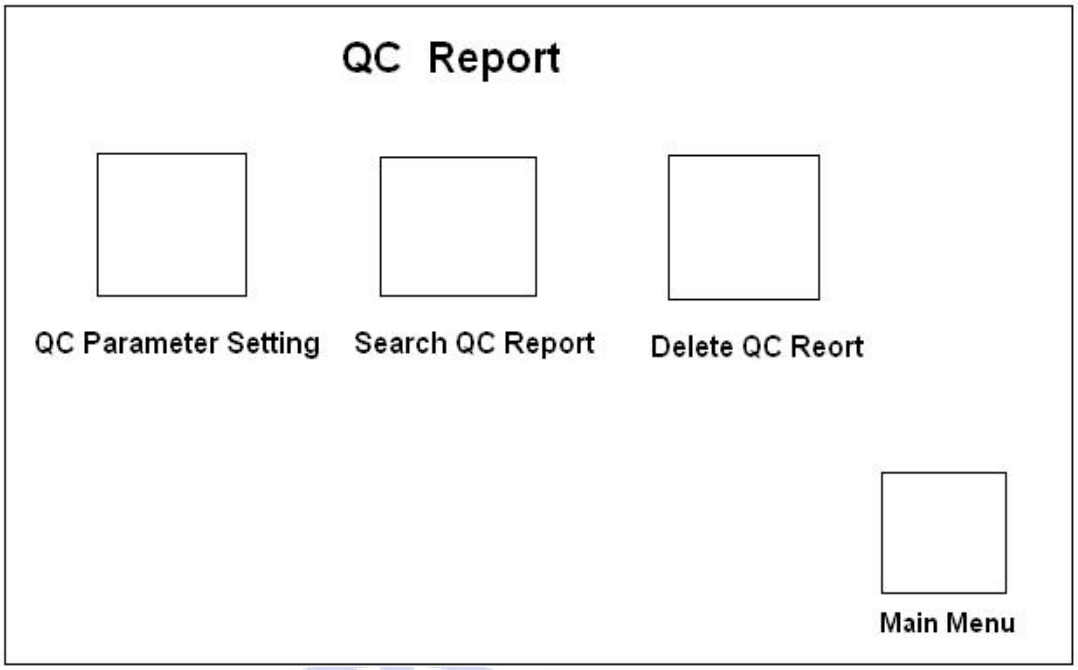
In the 'Sample Report' interface, select the 'Instrument Name' to input the name of instrument, itwill print on the report

Section 3 QC Report

Click the 'QC Report' button in the 'Main Menu' interface to enter the 'QC Report' menu. The QCreport contains the following 3 functions:

1、 QC Parameter Setting 2. Search QC Report 3. Delete QC Report

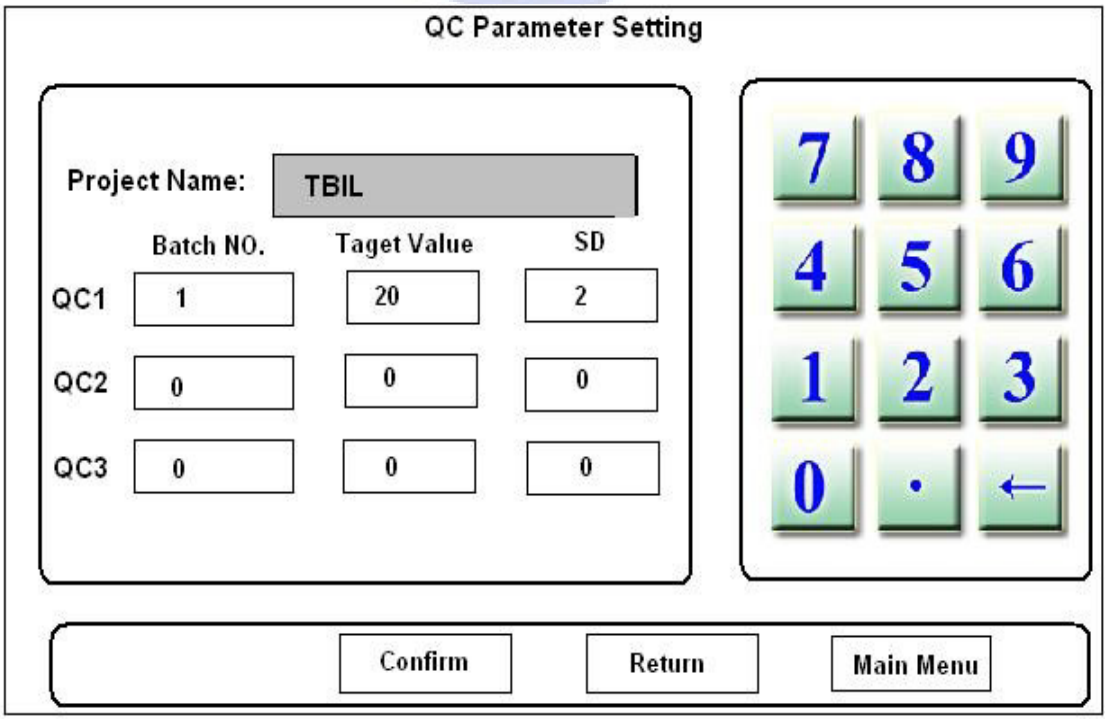
As shown below:



3.1 QC Parameter Setting

To carry out the QC measurement correctly, you must set QC parameters firstly.

Click the 'QC Parameter Setting' button. The system will enter the 'Item Selection' interface. Select the items that you want to modify in this interface, and then press the 'Confirm' button. The system will switch to the 'QC Parameter Setting' interface.

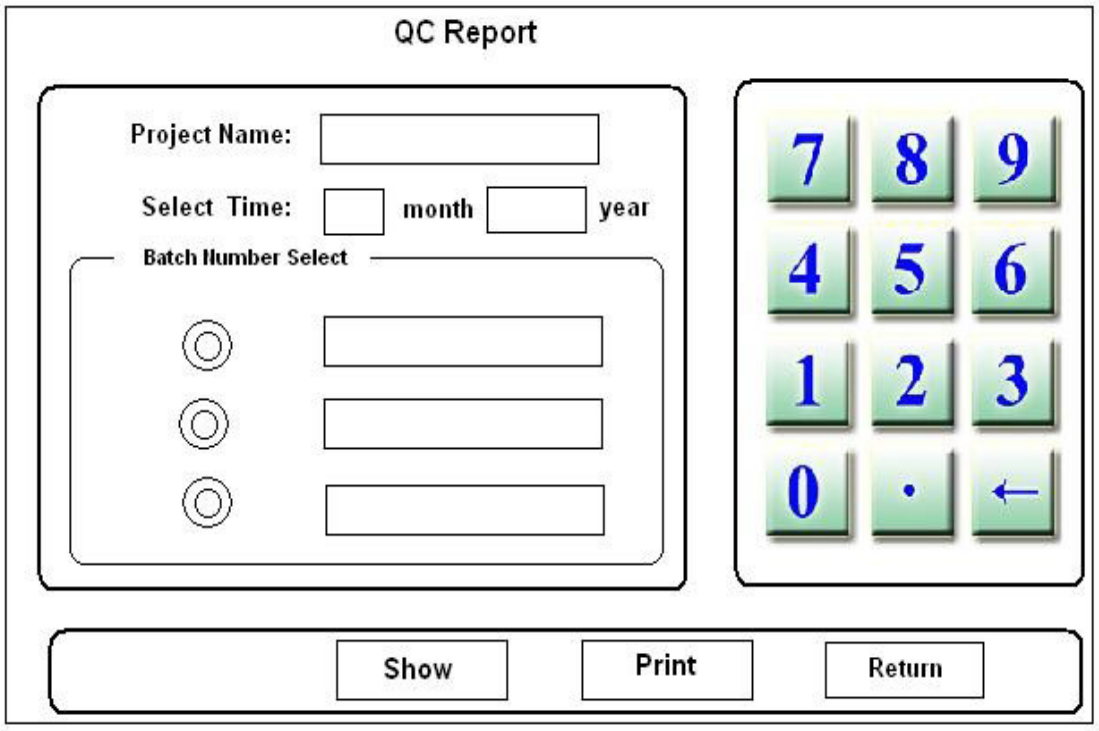


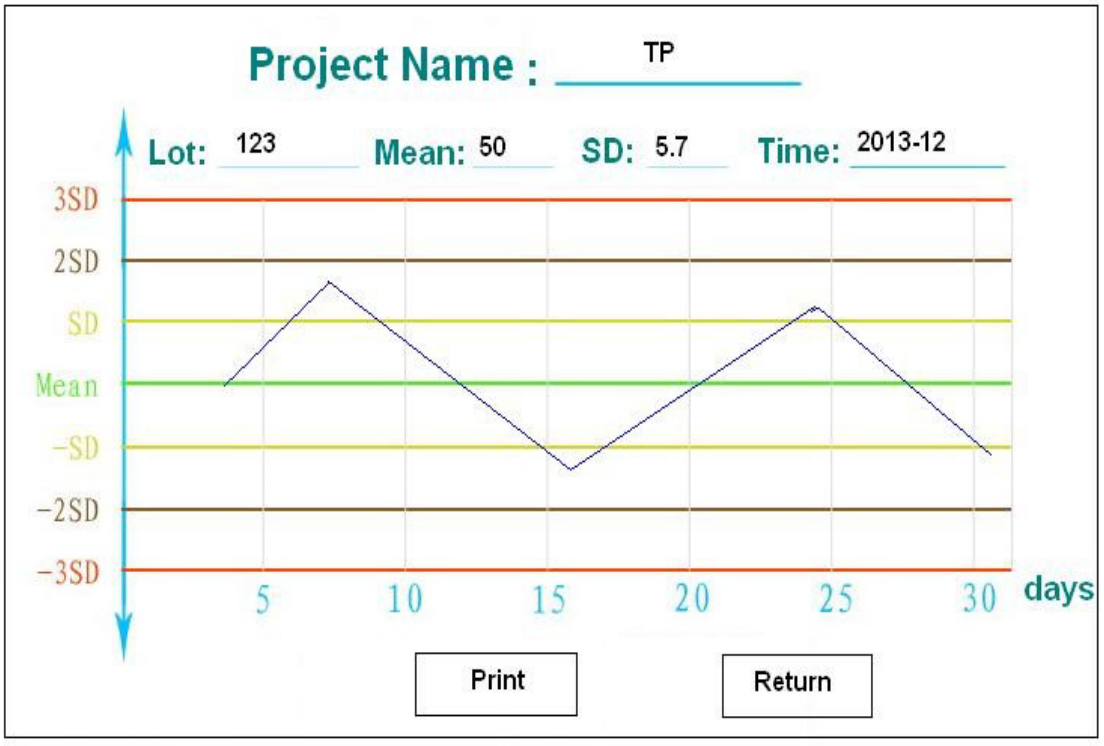
In this interface, 'Batch No.' represents the batch number of the QC solution. 'Target Value' is the nominal value on the QC solution instructions. 'SD' is the reference range of the QC solution measurement.

After the completion of setting the parameters, the results of these settings will be used in associationwith the QC test introduced in Chapter II.

3.2 Search QC Report

As shown in Figure 14, input the time and QC batch number you want to search in the interface, andthen you can get the QC report results.

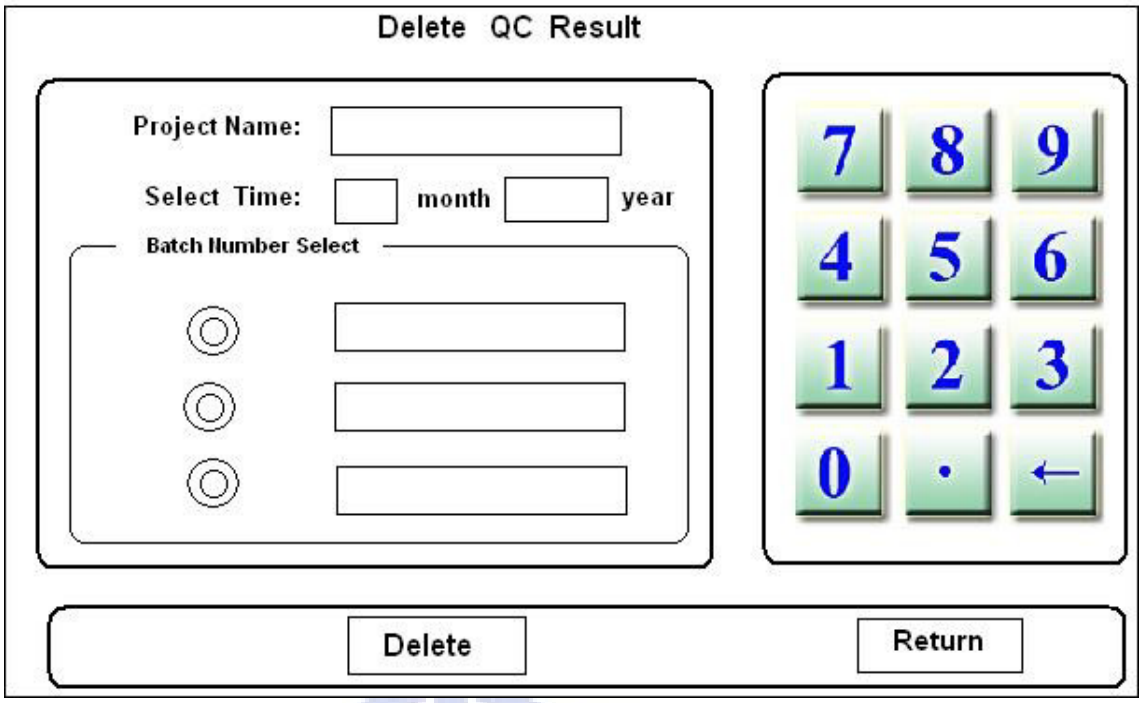




If you need to print the QC report, click the 'Print' button.

3.3 Delete QC Result

Input time and QC batch number you want to search in the interface, and then click the 'Delete'button to delete it.

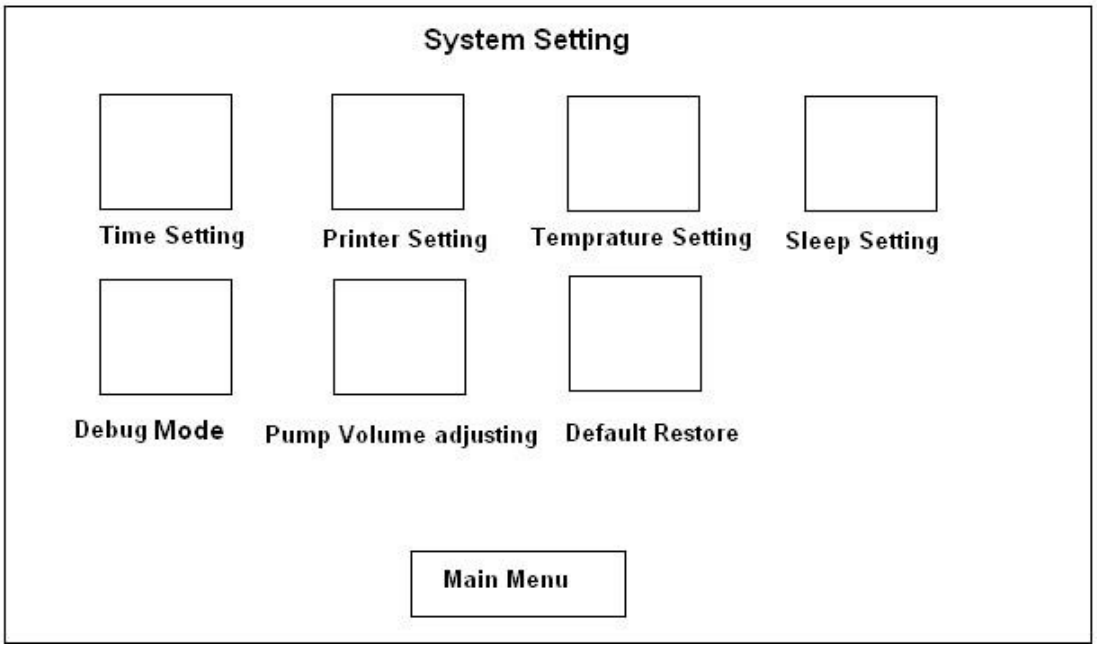


Section 4 System Set

Click the 'system setting' button in the 'Main Menu' interface to access the 'system set' menu.'System set' contains the following 7 functions:(Figure 14)

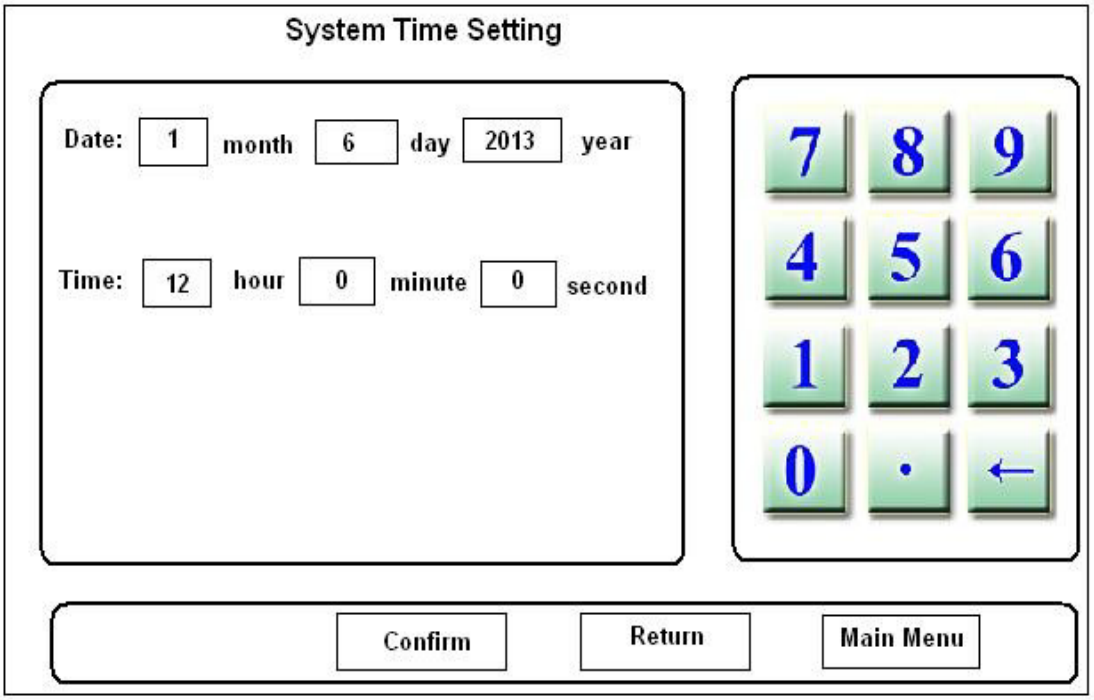
1、 Time Setting 2. Printer Setting 3. Temperature Setting 4. Sleep Setting5、 Debug Mode 6. Pump Volume Adjusting 7. Default Restore

As shown below:



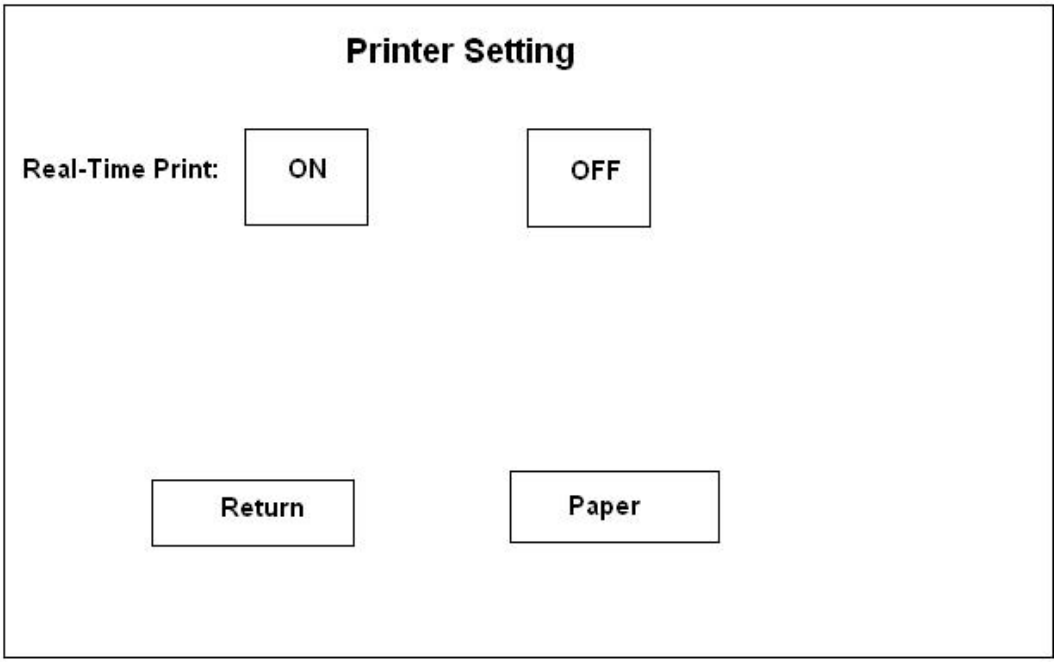
4.1. Time setting

This function is used to set the system time. Refer to the system prompt for the specific operations.



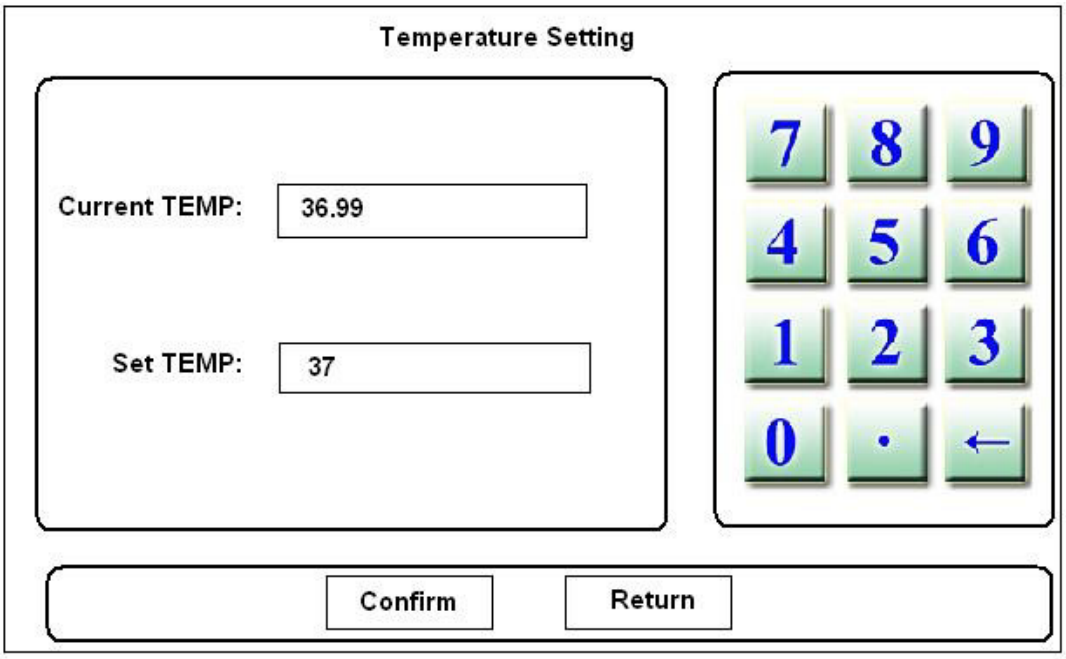
4.2 Printer Setting

After entering the printer setting interface, enable/disable the 'Auto Print' function by selectingwhether the printer is turned on. After clicking on the 'Paper' button, you can conduct the printer test.



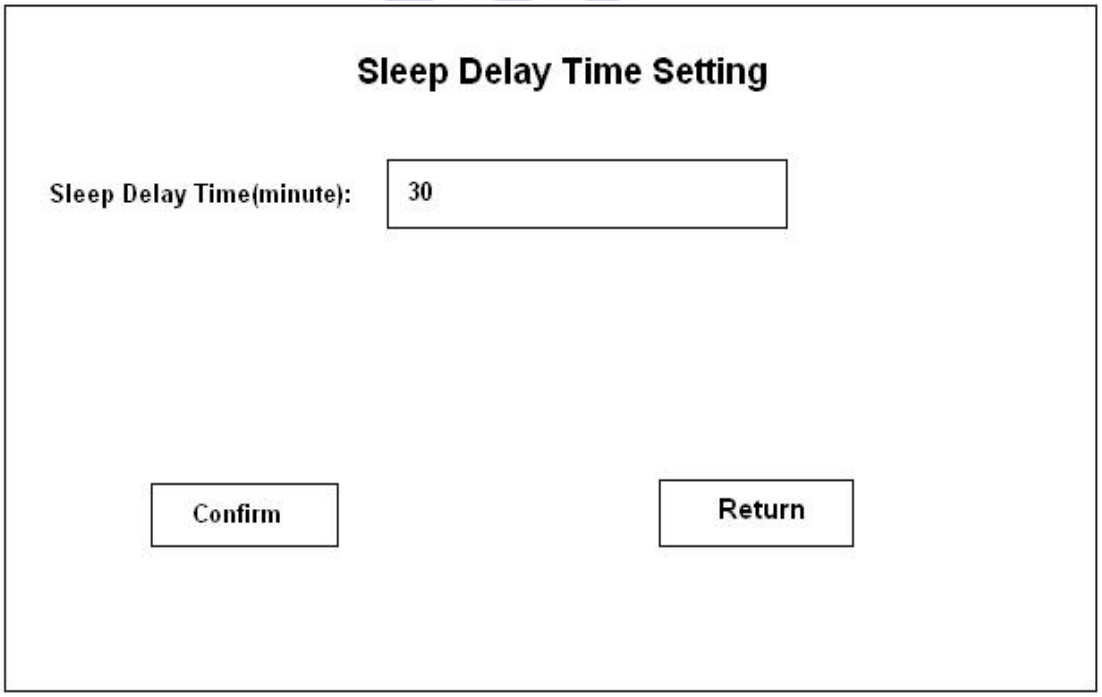
4.3 Temperature Setting

This function is used to observe the current system temperature and reset the target temperature.



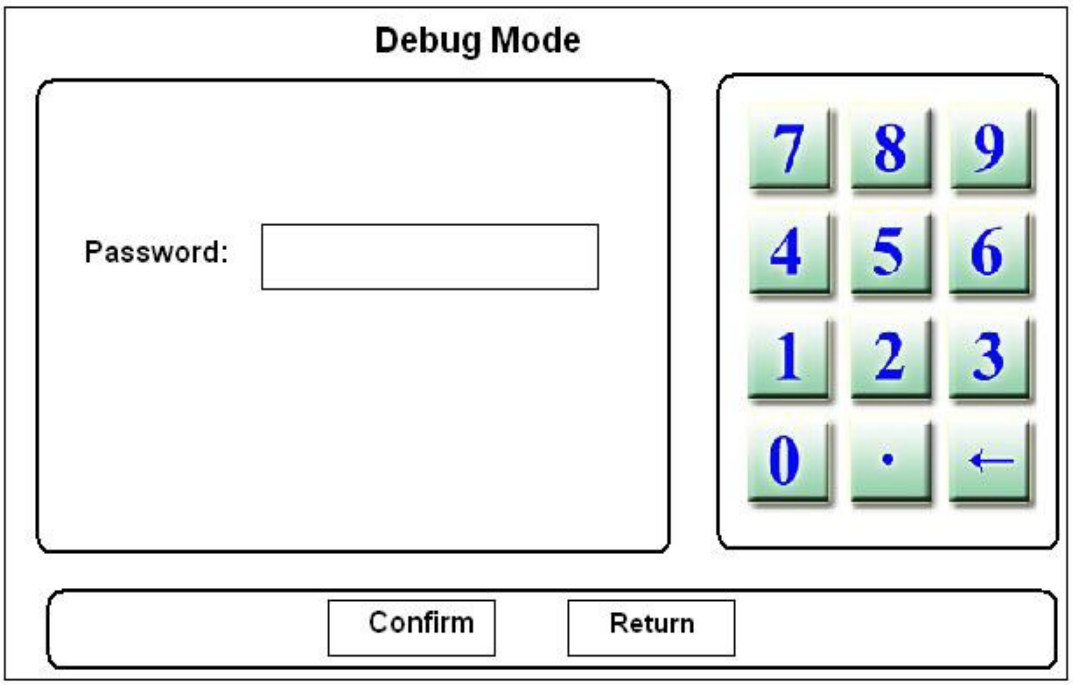
4.4 Sleep Time Setting

Enabling this function can extend the working life of light source lamp inside the instrument. After entering the setting interface, the user can select from five options, namely, 'Without', '30 minutes','60 minutes', '90 minutes' and '120 minutes'. When you choose 'Without', this function is disabled. When you choose '30 minutes', the instrument will turn off the inside light source automatically and turn into sleep state after no operation for 30 minutes. Other options are similar. When the system is in sleep state, the user can touch any part of the interface to wake it up.

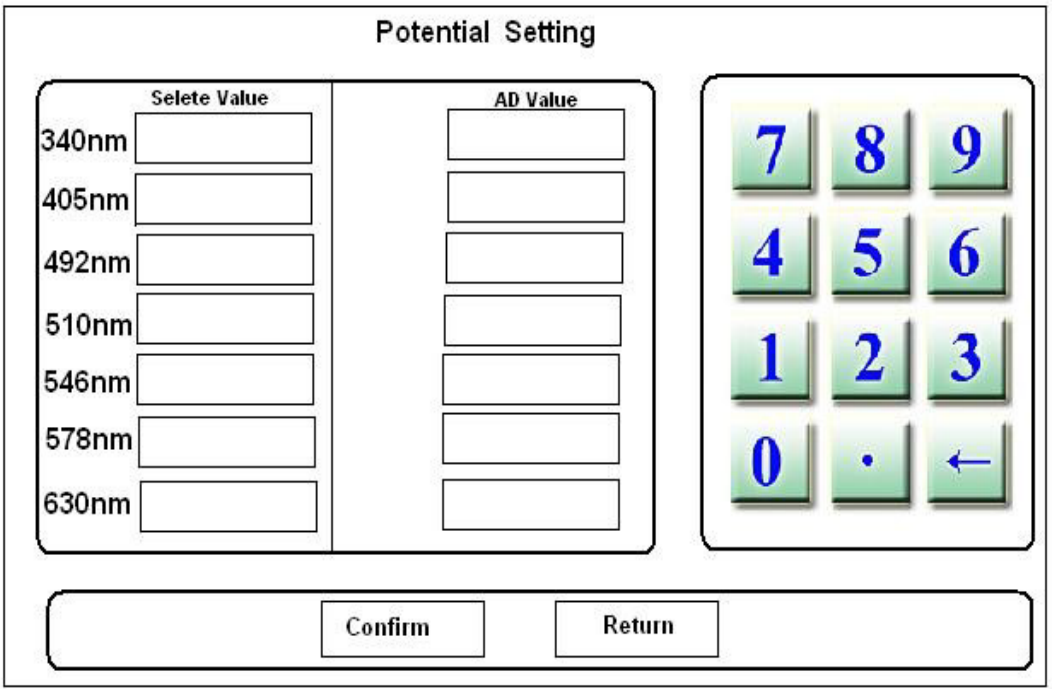


4.5 Debug Mode

This function is only available to the factory or the maintenance engineer. You can enter this function only after inputting the correct password, the default password is 666688.

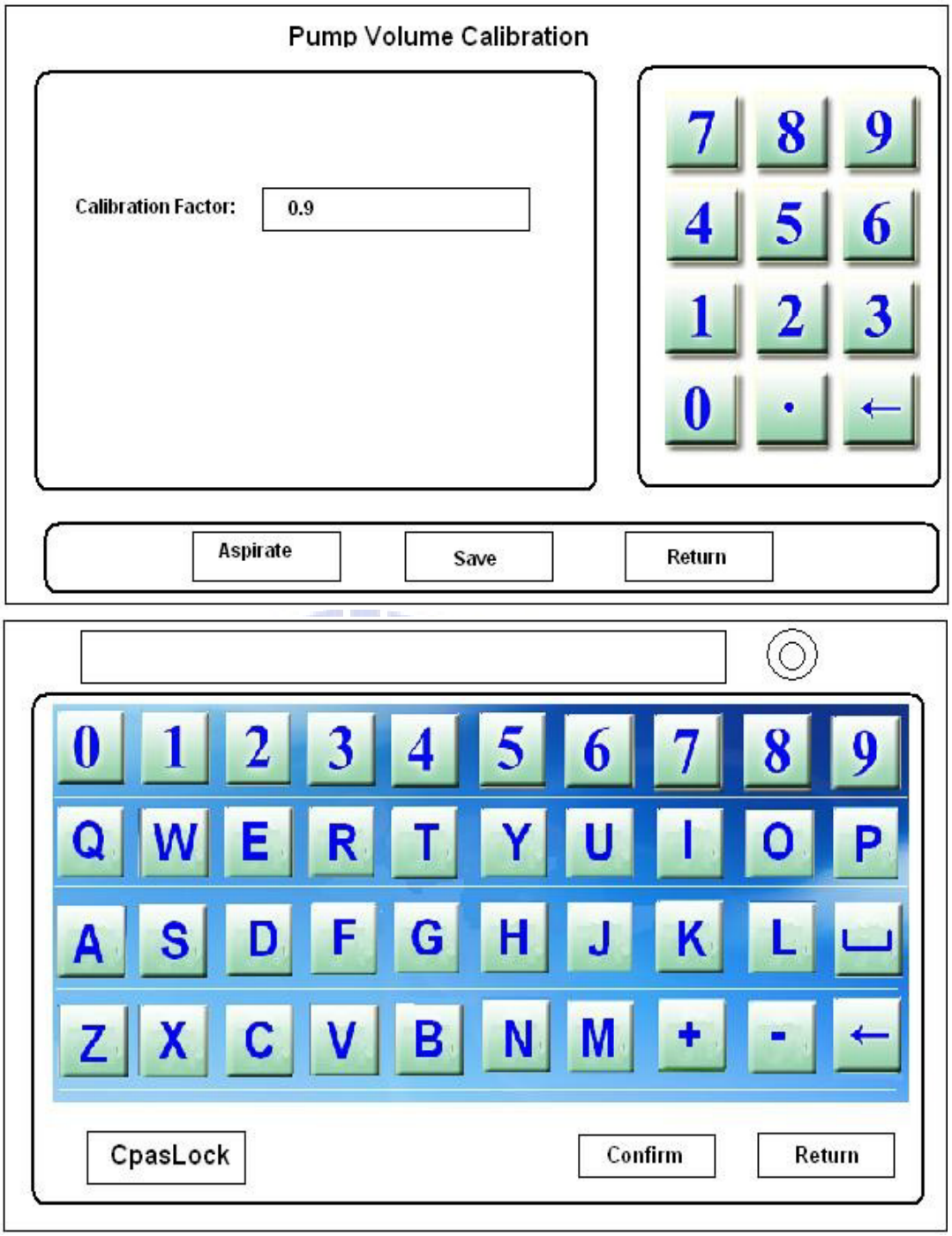


If the distilled water AD value is less than 10000, the gain of the wavelength must be adjusted. After changing the select value from 1~7, press "Confirm" the AD value of the wavelength will display, it must be within 15000~25000.



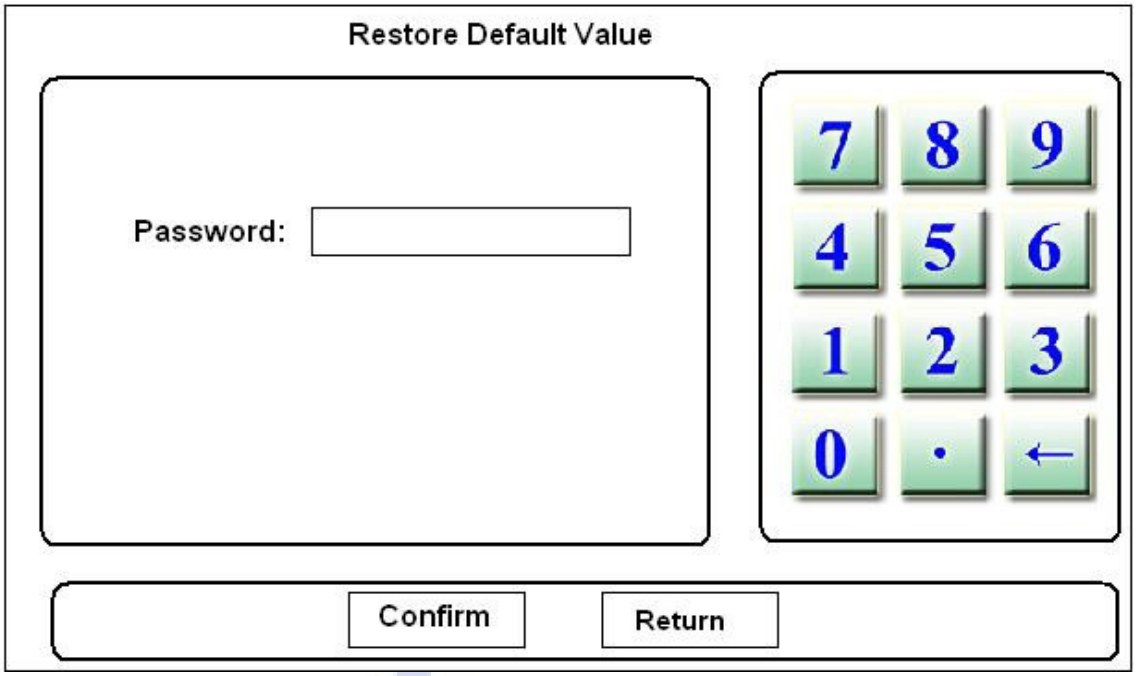
4.6 Pump Volume Calibration

Instruments have all been strictly calibrated before leaving factory, but during the long-term use, the aging of some parts of the instrument liquid circuit will result in the inexact lotion amount. The user can adopt this function to calibrate the lotion amount. After entering the pump volume calibration interface, you can input different calibration factors from 0.5 to 1.5. When you want a comparatively smaller pump volume, the input value is less than 1; otherwise, the input value is greater than 1.



4.7 Restore Default Value

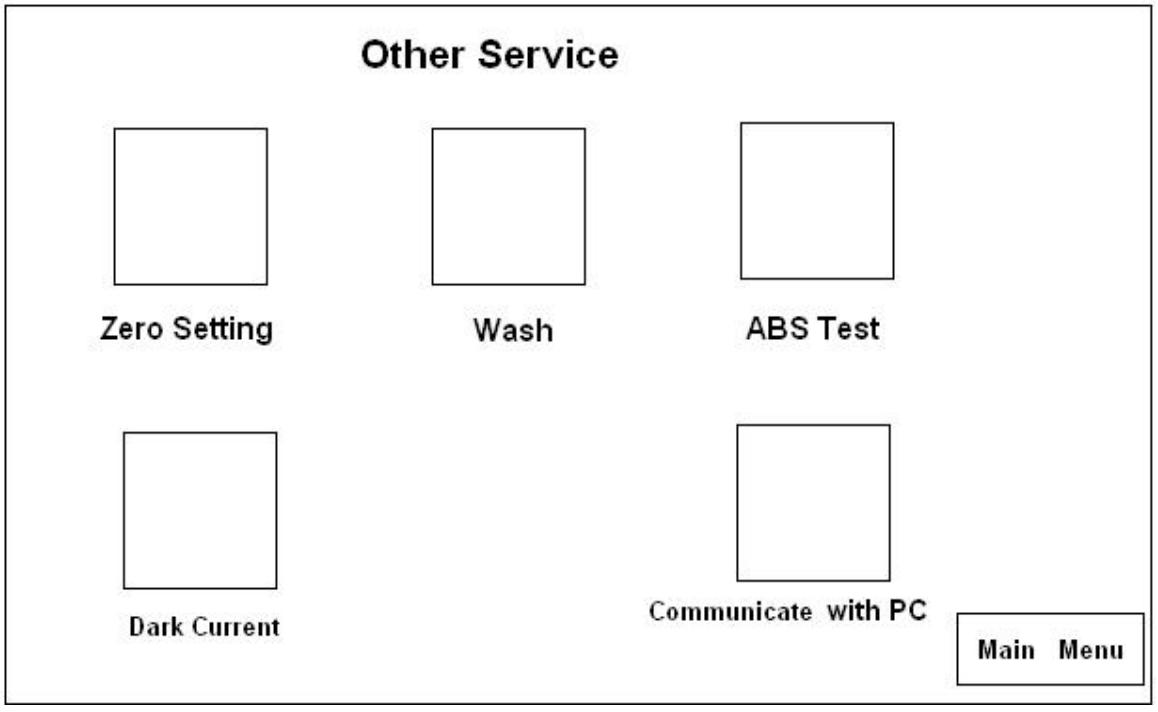
This function is used to restore any parameter of the system to the factory defaults. When executing this function, the system will prompt the user to wait. After completing restoration, the system prompts'Restart'. Then you must restart the instrument to complete the restoration successfully. the default password is 666688.



Section 5 Other Service

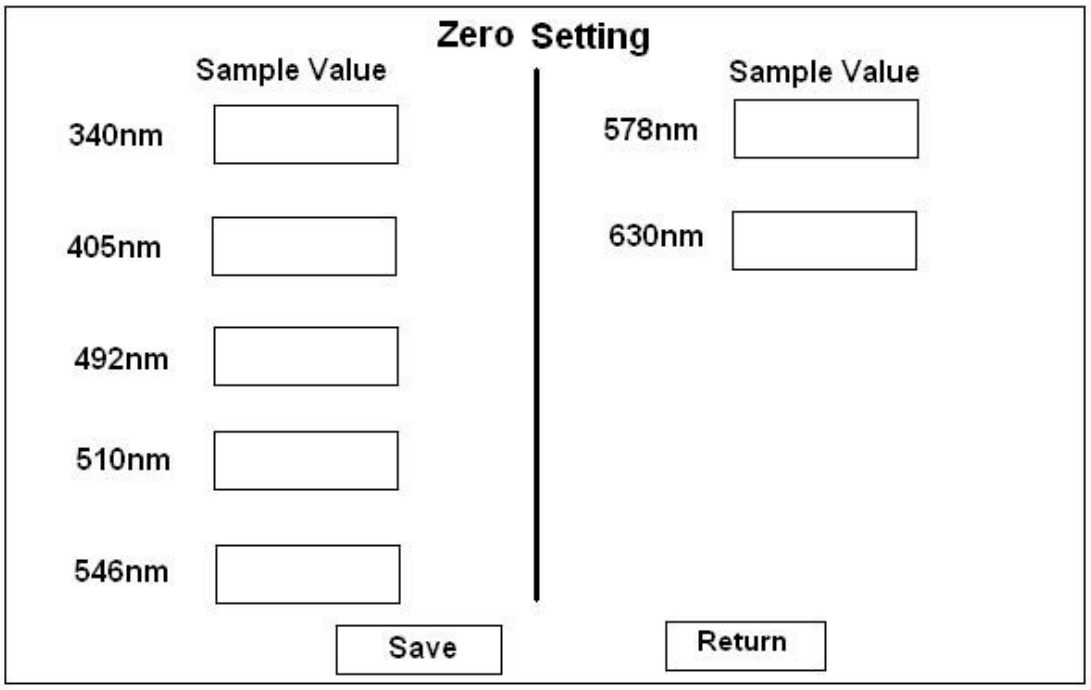
Click the 'Other Service' button in the 'Main Menu' interface to enter the 'Other Service' menu. 'Other Service' menu contains the following five functions:

1. Zero Setting 2. Wash 3. Absorbance Test 4. Dark Current Test 5. Communicate with PC



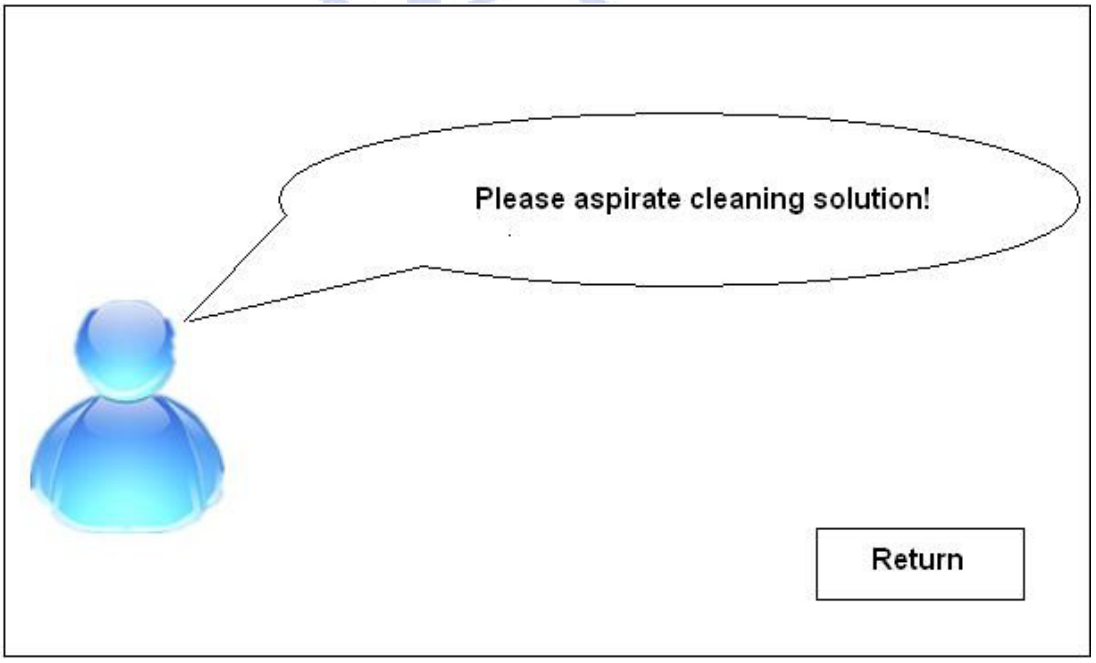
5.1 Zero Setting

This function is mainly used for zero setting operation for all 7 options of wavelength supported by thesystem one-off. Before zero setting, absorb distilled water in accordance with the system prompts to set to zero. When zero setting is finished, it will show zero values of 7 options of wavelength in the 'Zero Setting' interface. The user can choose to save or cancel this operation.



5.2 Wash

Click the 'Wash' button, and the system will complete the cleaning of liquid circuit.



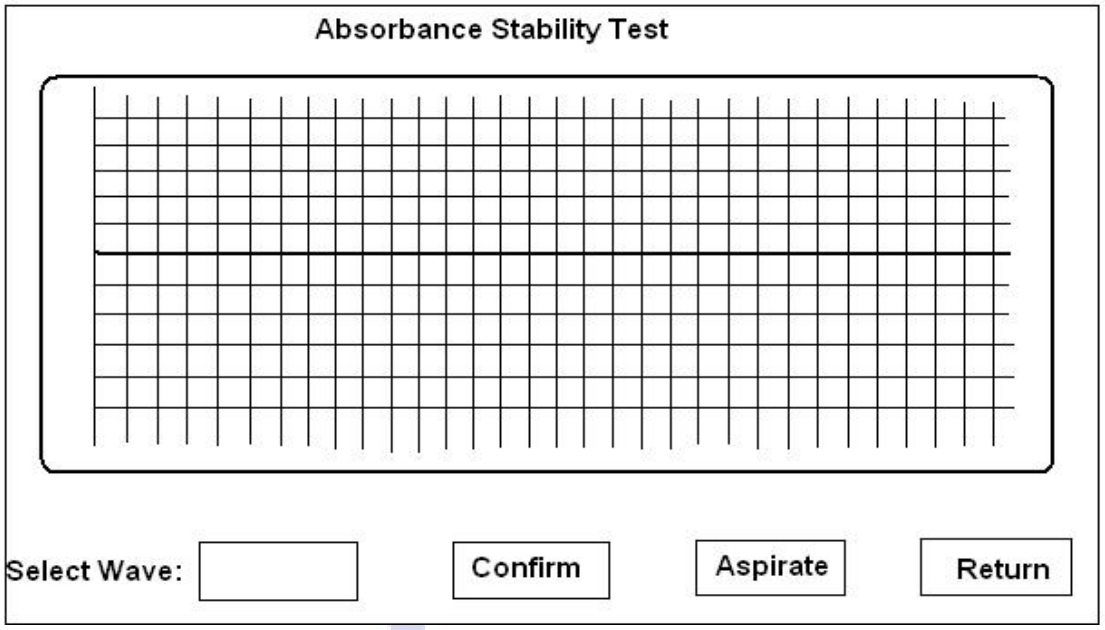
5.3 Absorbance Test

Click the button 'Absorbance Test'. After absorbing the reagent to be measured, the system enters the absorbance measurement interface to test. When measuring in this interface, the system will display the measured values of absorbance, absorbance difference and AD value at the bottom in real-time.It will show the curve of measured absorbance change in this interface in real-time to observe the absorbance stability.

While entering the 'absorbance test', the initial wavelength is 340nm. The user can click the wavelength selection dialog box. When the required wavelength is shown in the dialog box, click the 'Confirm' button to choose different wavelengths.

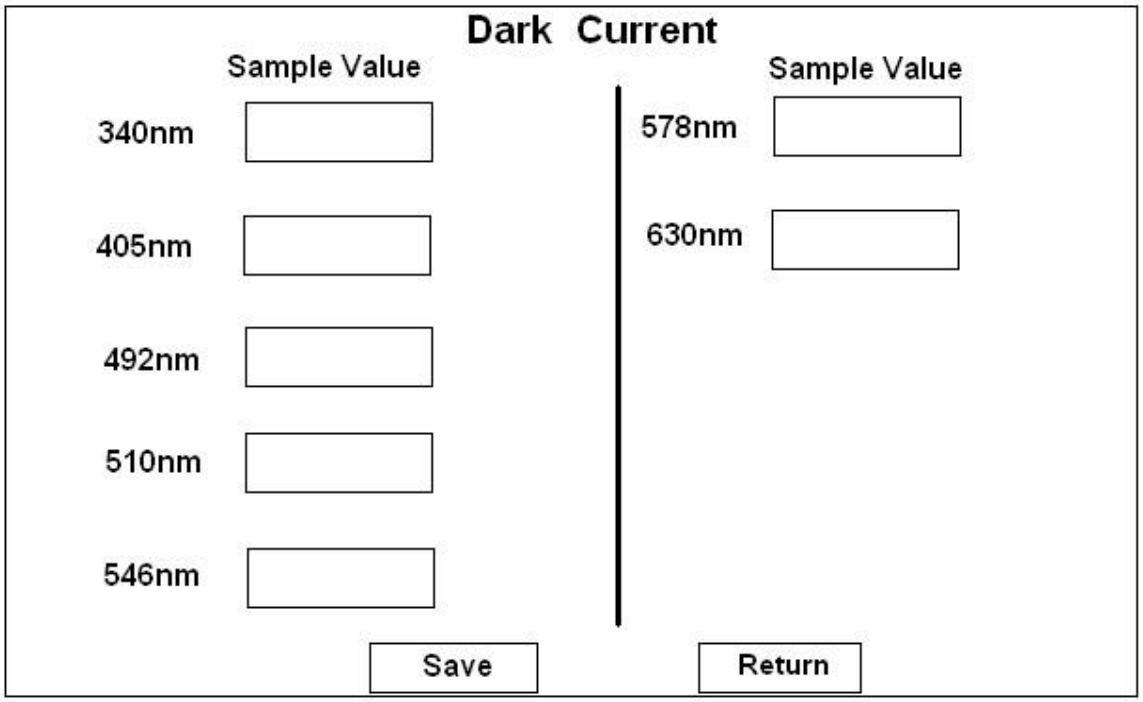
If you want to replace the test reagent, Click the 'Sample suction' key and follow the prompts of the

system to complete the replacement of different reagents.



5.4 Dark Current Test

Complete the dark current measuring function of the system. When the measurement is completed, the user can choose whether to save and replace the dark current value of the system's internal storage

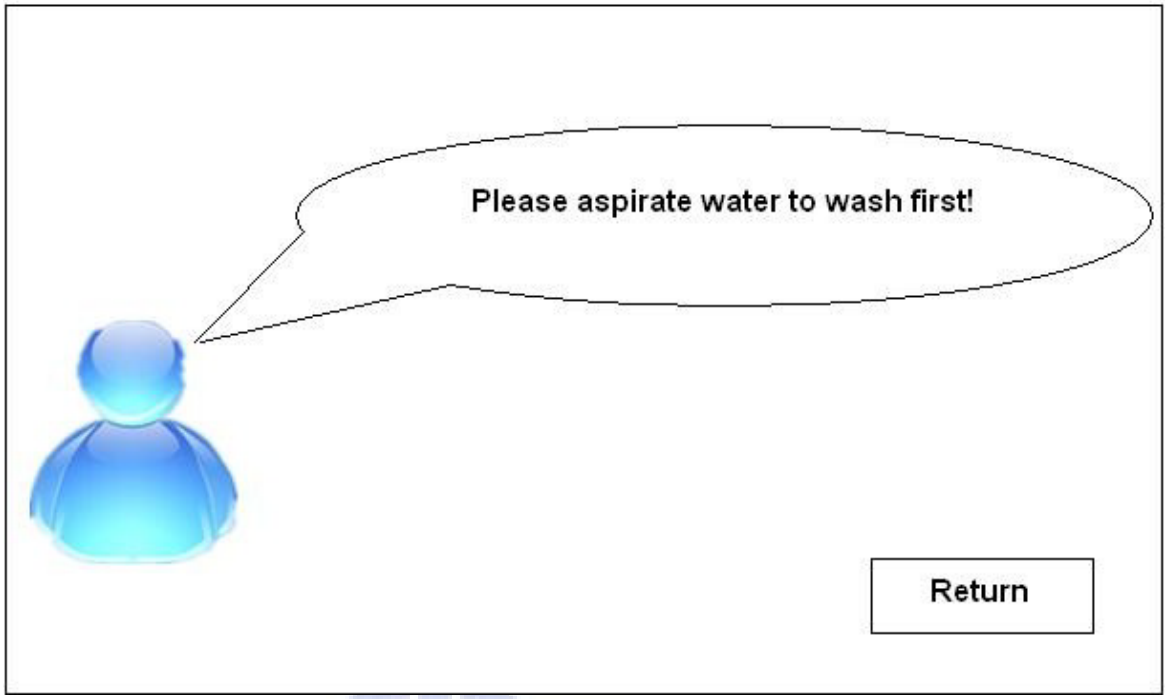


5.5 Communicate with PC

When clicking the 'Communicate with PC' icon, the system serial port gives a handshake command toconduct handshake operation with host PC computer software.

Section 6 Power off

Click the 'Power off ' button in the 'Main Menu' interface to enter the following interface as following:



After washing for 3 minutes, the system will prompt “Please turn off the power switch”, you can shut offthe power or press “Return” to return to the main interface.

Chapter IV Daily use and maintenance Section 1 Brief operation instructions of daily use

1.1. Preparation and inspection before use

1. Before starting up the instrument, you should inspect whether the power plug and outlet is connected firmly, whether the instrument is placed levelly, whether surface of the instrument is clean and undamaged and whether sample tube is folded. After the inspection, turn on the power switch at the back of the instrument.
2. After the preheating of the system for 10 minutes, it automatically goes to the ‘Main Menu’ interface. (Note: The preheating time should be extended when the room temperature is very low).
3. After each startup, flush the system liquid circuit.
4. Enter the absorbance stability interface to observe whether the absorbance is stable.

1.2. Computer Practice

1. Program Project

Program the item to be measured according to the method in Section 1, Chapter III in this Manual. You should check whether reagent parameters are correct when replacing the reagents. Only with the completely correct reagent parameters can you get the correct measure results.

2、 Measurement of the sample

Measure the sample according to the method in 2.1, Chapter II in this Manual.

3、 Print the Patient Results

According to the method in 2.2, Chapter II in this Manual, choose one of the four measuringmethods to print the sample measurement results.

1.3. Shutdown

After the completion of the operation, clean the pipelines with distilled water. Turn off the power switchafter entering the main menu and shutting down.

Note: Do not turn off the power switch suddenly in the measurement process.

1.4. For precautions and maintenance, to make sure the instrument has reliableoperation and accurate results, please conform to the following precautions.

1、 The cleaning solution used is distilled water. Maintenance solution is 5% sodium hypochloritesolution.

2、 Maintenance steps:

A Enter the 'Other Service' interface.

B Click the 'Wash' button to absorb the prepared maintenance solution. Wait for ten minutesafter the completion of the maintenance solution suction.

C.Absorb the distilled water twice.

D. Repeat the above steps for three times.

E. Carry out the maintenance once a week.

3、 Daily maintenance: every day after work, immerse the sample suction tube in distilled water andclean the system repeatedly by pressing the 'Wash' button until the pipelines are completely cleaned up.

4、 The reason is that the colorimetric pool is intermixed with bubbles troubleshooting:

Enter the 'Other Service' interface, immerse the sample suction tube in 75% alcohol, and then press the 'Flush' button to flush the system. Repeated suction of distilled water can remove the airbubbles.

Section 2 Maintenance and Calibration

1.1 Use of the touch interface

When you are operation this instrument's touch interface, you need to use the stylus. The styluscannot be replaced by other sharp objects in case touch interface is damaged. When touchingthe touch interface, use moderate force. Do not use excessive force. During the touching process, sometimes due to improper operation, it appears single touch is not good. Please try torepeat the operation.

1.2 Daily maintenance

Every day, after sample measurement, please clean the pipes with distilled water several times immediately, so that you can minimize the number of residual reagents or serum proteins insidethe pipelines, and particularly, on the inner wall of flow colorimetric pool. Pipelines should be filled with distilled water. Colorimetric pool should be drained before shutdown.

1.3 Weekly maintenance

The weekly maintenance: after specimen measurement, firstly clean the pipelines twice with distilled water, then let the instrument absorb cleaning solution (main ingredients: sodium hypochlorite, i.e., 84 disinfectant or disinfectant diluent, etc.) for one time. After suction, keep thecleaning solution in the pipeline for 10-20 minutes, and finally clean the pipelines with distilled water for 3 times. Pipelines should be filled with distilled water. The colorimetric pool should be drained before shutdown.

1.4 Instrument housing cleaning

Wipe with a damp cloth when cleaning the instrument case. Detergent can also be used, other

than organic solvents such as alcohol.

1.5 Common failures and troubleshooting are shown in the following table:

Table II Common failures and troubleshooting table

Failure phenomenon	Cause Analysis	Troubleshooting
Sample suction failure	1. Sample suction pump doesn't work. 2. Pump pipe is loose. 3. Sample suction time is 0. 4. Pump pipe is damaged 5. Pump pipe adhesion	1. Fastening screws of pump head isloose. Tighten the fastening screws. 2. Cut off a small portion of the pump pipejoints. 3. Reset the correct sample suction time. 4. Replace the pump pipe. 5. Remove the pump tube and open upthe adhesion positions.
No interface display	1. The power switch is not turned on. 2. Power failure 3. Display signal line is loose	1. Turn on the power switch 2. Reinsert the power plug 3. Reinsert the display cable
The printer doesn't work	1. Either the printer power lineor communication line is loose. 2. Out of paper 3. Paper is jammed. 4. Thermo sensitive paper is reversed.	1. Reconnect the power line or communication line. 2. Replace the paper. 3. Clean up the paper jam site. 4. Reinstall the print paper.
Absorbance test long-time unstable	1. Certain wavelength is overthe range, while the rest arenormal: distilled water is notused. 2. All wavelengths are detectedover the range. A: There're bubbles in the colorimetric pool. B: Colorimetric pool is dirty.	1. Redetect with distilled water. 2. Exhaust bubbles in the colorimetricpool. 3. Clean the colorimetric pool withcleaning solution.
Unstable measurement results	1. No absorbance test at startup; 2. Reagent failure. 3. Sample suction amount insufficient. 4. Without standard solution. 5. The wavelength indicated onthe reagent manual is not applicable.	1. Retest absorbance during system maintenance. 2. Replace with effective reagent. 3. Adjust sample suction amount ≥ 600 μL. 4. Retest with blank standard solution. 5. Test with another wavelength.

1.6 Calibration and maintenance cycle:

The instrument has already been calibrated by relevant national standards and the enterprise productstandards before shipment. In operation process, instrument should be sent to a local technical supervision agency for calibration once a year or as required, or you can contact the manufacturer forcalibration or repair.

1.7 Normal maintenance procedures

If you find imprecision or other failures when using the instrument, you can directly contact our service department for repair or overhaul. Our company offers free home repair service for instruments within warranty period. As to instruments beyond the warranty period, both parties can negotiate on the maintenance issues. Please refer to the back cover of this Manual for contact information of the company.

1.8 Repairs and maintenance in long-term storage

The instrument, if unused for more than six months, should be stored in the packing case. Before

storage, the surface of the instrument should be cleaned, and the colorimetric pool be emptied afterthe pipelines are cleaned up with distilled water. The instrument should be stored under environmental conditions in line with transport storage conditions in the Section I of Chapter I.

Chapter V Packing list

Semi-auto Chemistry Analyzer configuration list is as follows:

No.	Item	Unit	QTY.
1	Chemistry Analyzer	Unit	1
2	Power Cable	PC	1
3	12V DC Power Adapter	PC	1
4	Grounding Line	PC	1
5	Screen-touch Pen	PC	1
6	Thermal Printing Paper	PC	1
7	Spare Pump Tube	PC	1
8	Operation Manual	PC	1
9	QC Certificate	PC	1
10	Packing List	PC	1
11	Lamp component	PC	1

Chapter VI

Graphics, Symbols and Abbreviations on the Product and Packaging


: Protective conductor terminals; marked at the proper grounding position of the instrument.


: Attention. Refer to the enclosed documents.


: Hazardous voltage, marked on the power supply section inside the instrument


: 'Fragile' logo, marked on the outer packing case of the instrument. Handle with care whencarrying this package.


: 'Upward' logo, marked on the outer packing case of the instrument, means the correctposition to transport this package is upright direction as shown by the logo.


: 'NO Rain' logo, marked on the outer packing case of the instrument, means this package isvulnerable to rain.

: Stacking layer limit, marked on the outer packing case of the instrument; the maximumstacking layer limit of the same package is 4 layers.

IVD: means that the equipment is for in vitro diagnosis.


: Biohazard