CLINDIAG

Semi Automatic Biochemistry Analyzer

User's Manual

Digitally signed by Poiata Vitalie
Date: 2023.11.03 11:54:43 EET
Reason: MoldSign Signature
Location: Moldova

CLINDIAG SYSTEMS CO., LTD

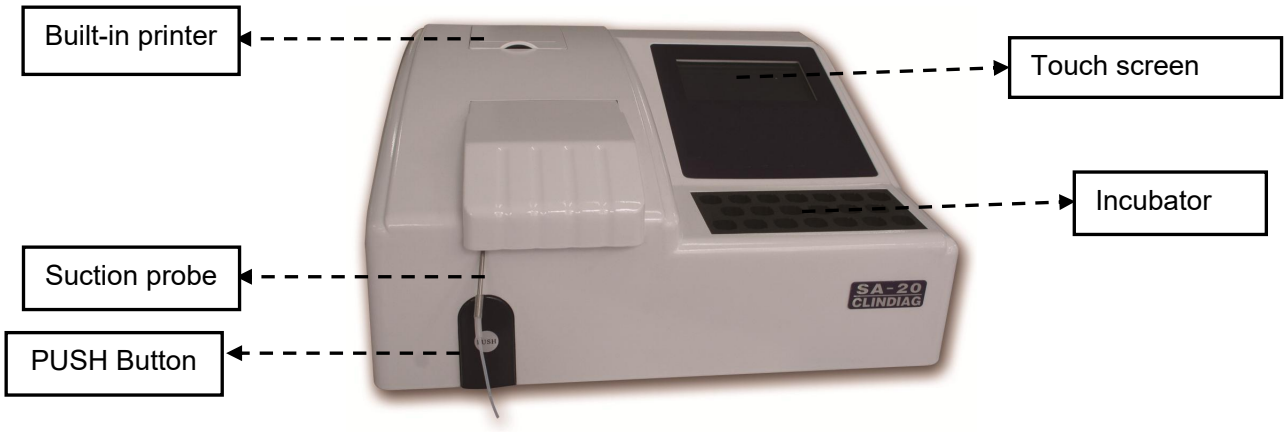
CONTENTS

1. GENERAL DESCRIPTION

Semi automatic biochemistry analyzer is a microcomputer-based in-vitro diagnostics device which unites optics, mechanics and automatic control in one. It is used together with the related reagents for quantitative determination of biochemical items,widely applied to hospitals, clinics and research institutes, with the characteristics of high precision,excellent repeatability and complete function.

1.1 Configuration

This device mainly consists of control system (single chip microcomputer,touch screen),samples and reagent incubation system,optical and measuring system,peristaltic pump aspiration system,built-in thermal printer etc.



1.2 Main Technical Parameters

The wavelength of transmitted light: 340nm,405nm,492nm,510nm,546nm,578nm,620nm;

Light source: 6V, 10W halogen lamp;

Absorbance: 0.000～3.500 OD;

Temperature for reaction cuvette: 37 ℃;

Test plate configuration: Flow cell;

Analytical Method: End point, two points, kinetic, multi-point, serum blank;

Interference light: ≤ 2.9A;

Linearity of absorbance: Shall meet the following requirements

a) Absorbance within 0.200～≤0.500, the bias should be in ±5%

b) Absorbance within 0.500～≤1.000, the bias should be in ±4%

c) Absorbance within 1.000～≤1.800, the bias should be in ±2%

Stability of absorbance: Less than 0.002A within 20mins at 340nm;

Repetition of absorbance: Coefficient variance(CV) ≤1.0%;

Rate of carry over: When reaction liquid volume is 1ml, the rate of carry over should be less than 1% by

flow cell test.

2. INSTALLATION

In order to ensure the normal operation of device, it must be installed and debugged by professional engineers. For any reason to reinstall and debug the device, only the authorized engineer can do the works.

Attention:

---No authorized installation may make wrong or damage to device, the problem or damage is not in term of free warranty.

2.1 Requirements of Installation

Before the installation, user must check and confirm that the lab should meet the requirements of space, power supply and working environment etc.

2.1.1 Space Requirements

In order to ensure enough space for releasing heat, repairing, maintenance, keeping the pipeline not squeezed and ensure the liquid can flow freely, the space must meet the requirements as follows:

1. keep the device not less than 100mm distance from wall and other objects for each side(left, right and back).
2. Ensure enough space for the device to place distilled water container and waste liquid container.

2.1.2 Power Supply

1. Power supply: 220V/110V～ ±10%, 50Hz/60Hz±1 Hz.
2. A good grounding socket within 1m from the device.

Attention:

---The power supply socket should be within 1m from the device in order to pull out the plug timely when accident happens.

---Check if working voltage is the same with device voltage.

2.1.3 Working Environment

1. Working temperature: 10 ℃ ~ 30℃
2. Working humidity: 30% ~ 70%
3. Working atmospheric pressure: 860hPa ~ 1060hPa
4. Power supply: 220V/110V～ ±10%, 50Hz/60Hz±1 Hz
5. Fuse: T2AL250V
6. Input power: 200VA

7. Environment should be in quiet and clean room and keep away from dust, noise, big equipment (X-ray machine, CT, centrifuge, etc) and radio interference.

8. Avoid direct sunlight and ultraviolet rays and keep away from hot and cool source and outlet of air condition.

2.2 Open the Package

Before opening the package, please carefully check the package. If the package is broken or wet or polluted, please do not open it and contact carrier or local dealer immediately. If no outer damage, please open it by following steps:

--- Unpack the package and check whether the packing contents are complete or not referring as packing list.

--- Check whether the outer appearance is damage.

--- Check whether the serial number is in accord with packing list and outer package.

2.3 Installation Steps

1. Place the device on stable worktable.

2. Connect power supply line to the appointed power supply.

3. Put the waste pipe at the back ofthe device into waste liquid container.

4. Install peristaltic pump tube properly.

5. Turn on the device before testing.

6. Install the printer paper.

---Open printer cover ofthe device.

---Load the new printer paper into the paper slot with correct direction.

---Put the printer paper to the Feed form and click “FEED”.

---Cover printer cover.

Attention:

---Please pay attention to the direction of the printer paper when installing thermal printer paper.

---Don’t print before installing thermal printer paper, otherwise it will cause system crash.

---Aspiration probe and waste liquid joint may carry some serum, control, calibrator and reagent, which are of potential biological risk. Therefore, it is very dangerous to touch them directly.

3. Functions and Operation

3.1 Working Principle

The principle of semi automatic biochemistry analyzer is based on Lambert-Beer Law.

3.2 Functions

Turn on the device, it will show as Figure 3- 1

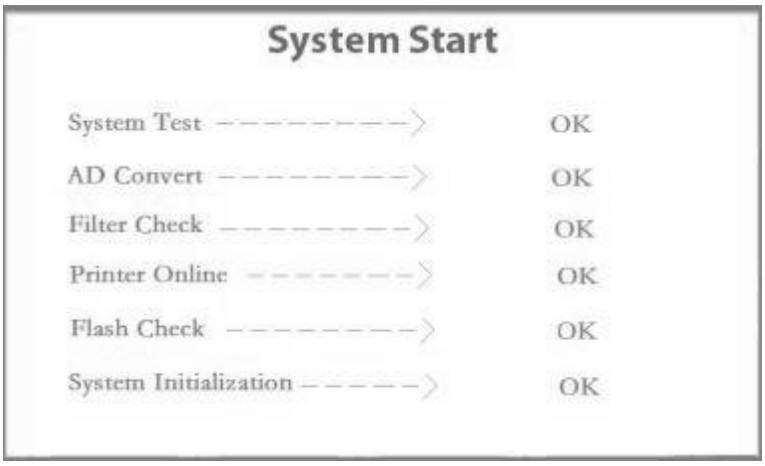


Figure 3-1

Click the touch screen, device will enter main menu as shown Figure 3-2.

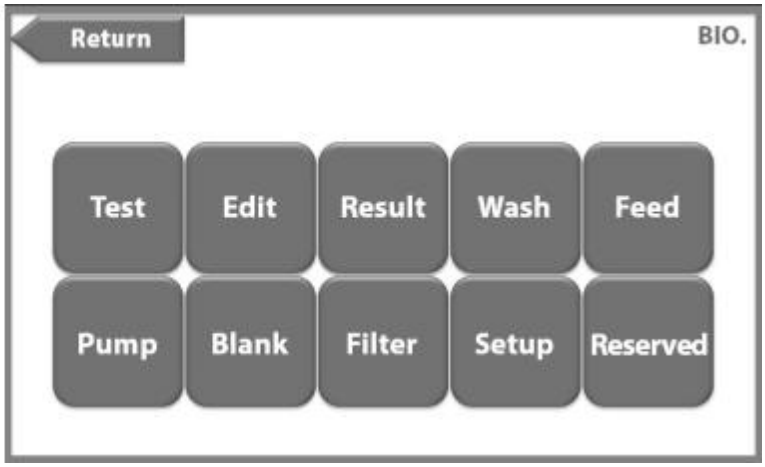


Figure 3-2

Select function as the requirement

Test: Select biochemical item to run sample test. After test, it will show test result and print it automatically.

Edit: Add, modify, delete and print biochemical item.

Result: Enter the result database to query, print, delete and QC management, QC statistics and print general report etc.

Wash: Clean flow cell. Aspiration volume of peristaltic pump is 1.5ml every time.

Feed: Use for built-in printer to load printer paper, pass paper and cut paper.

Pump: Peristaltic pump calibrate for aspiration volume.

Blank: AD Auto Zero to confirm if the device is in good condition.

Filter: Measure and adjust each filter's AD value, blank value and absorbance.

Setup: Show cuvette's temperature; set filter number, cuvette diameter, language, aspiration format, standby format; hospital and device model settings; time format and date/time settings; screen brightness settings etc.

3.3 Program Settings

Click "Edit" on main menu (Figure 3-2) to add, modify, delete and print biochemical item.

Figure 3-3

3.3.1 Program Add

Click "Program Add" to add new biochemical item. Set up parameters according to related reagent manual and select correct test method.

Regular test methods include Kinetic, end point and two points.

Attention:

In experience, Kinetic method is used for enzymes; two points method is used for Creatinine, Urea; end point is used for other biochemical items. Please refer related reagent manual to select the test method.

Following is process of set up and operation, take ALB (End point) as an example.

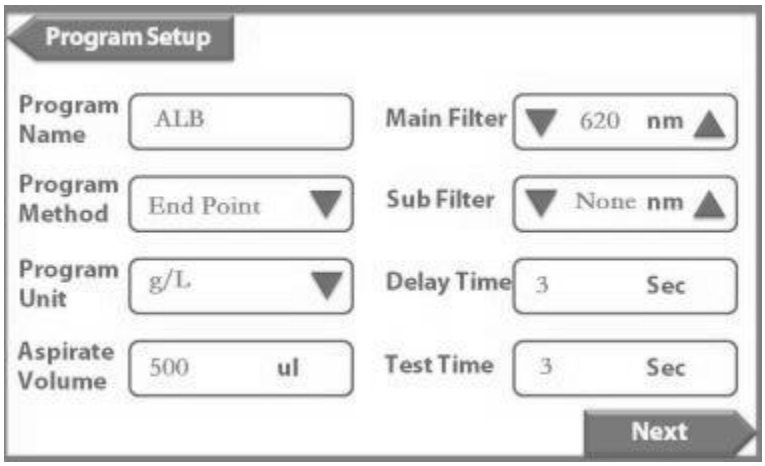


Figure 3-4

Program Name: Input item via keyboard as Figure 3-5, such as ALB etc., then click "OK".

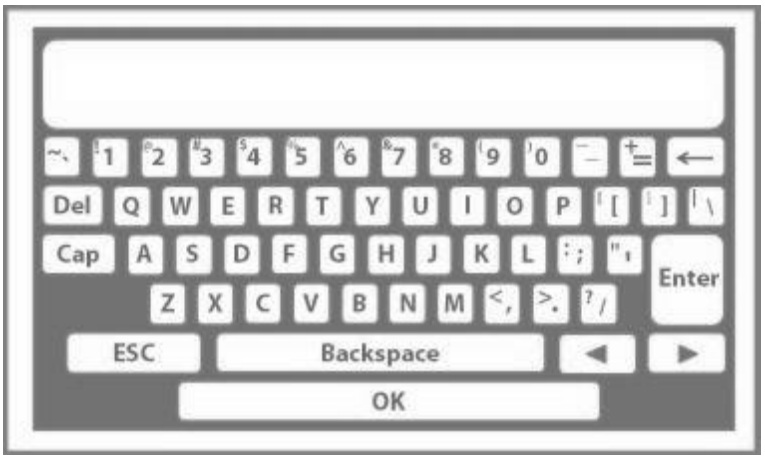


Figure 3-5

Program Method: Select Kinetic, end point,two points and bichromatic.

Program Unit: Select g/dl, g/l, mg/dl, mg/l, mmol/l, U/L, umol/l, U/ml, ug/ml, ng/ml, and ug/dl etc.

Aspiration Volume: 100 to 1000ul(Default value is 500ul)

Main Filter (nm): Select 340, 405, 492, 510, 546, 578, 620, etc.

Sub Filter (nm): Select "Yes" for Bichromatic method only, select "None" for other test methods.

Delay Time (sec):001 to 999 seconds.Kinetic (60S recommended), End point(3S recommended), Two points(30S recommended).

Test Time(sec):001 to 999 seconds.Kinetic (30S recommended), End point(3S recommended), Two points(30S recommended).

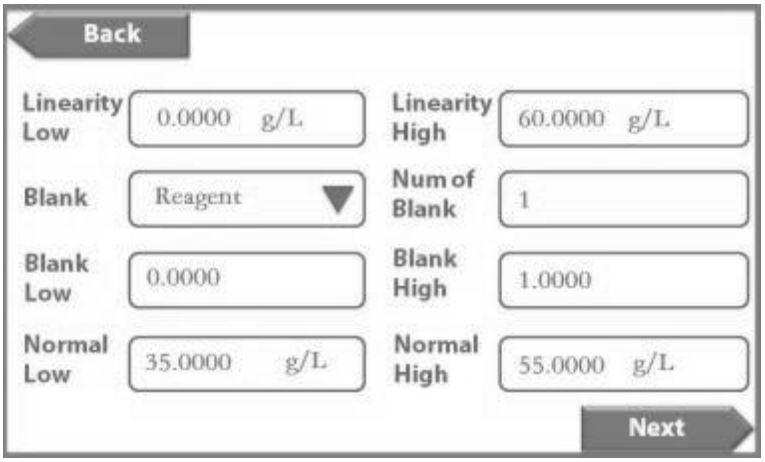


Figure 3-6

Linearity Low: Input value according to related reagent manual.

Linearity High: Input value according to related reagent manual.

Blank: Select water, reagent or serum.

Num ofBlank: Input value from 1 to 3(Default value is 1).

Blank Low: Input value according to related reagent manual. Recommend "0".

Blank High: Input value according to related reagent manual. Recommend "2".

Normal Low: Input value according to related reagent manual.

Normal High: Input value according to related reagent manual.

If select serum blank method, test procedure is to test reagent blank firstly, then Aspirate solution (Sample+Regent 1), then aspirate Sample+Reagent 1+Reagent 2 and get the test result finally.

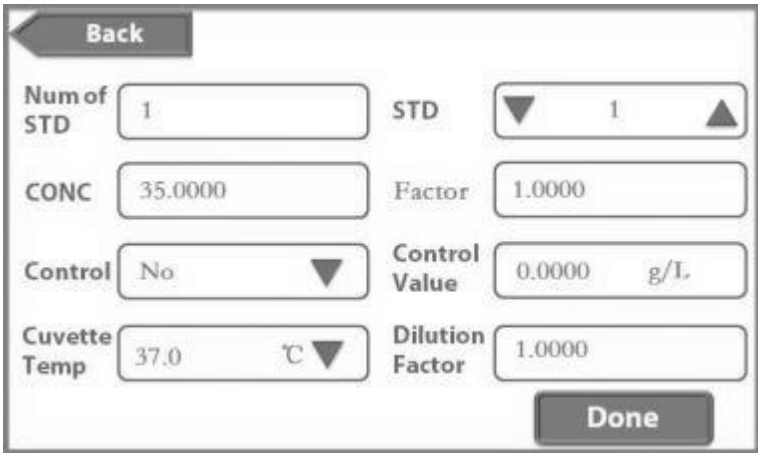


Figure 3-7

Num of STD: It is used for multi-standard method.

STD: Select 3 to 6 for multi-standard method, select 1 to 2 for other methods.

CONC: Concentration of standard corresponding to each standard number. Input value via number key.

Factor: This value could be input by user referring to reagent manual(Kinetic) or automatically obtained by calibration(End point, Two points).

Control: Four options (Control H, Control M, Control L, No) can be selected.

Control Value: Input value according to reagent manual.

Cuvette Temp: Four options

Dilution Factor: When sample is diluted, input the dilution ratio, then test result will be multiplied by the corresponding dilution ratio. Default value is 1.

Figure 3-8

Select "YES", new added item will be saved.

Select "NO", new added item will not be saved.

3.3.2Program Modify

Click “Program Modify” to modify biochemical item. Take “ALT” as an example.

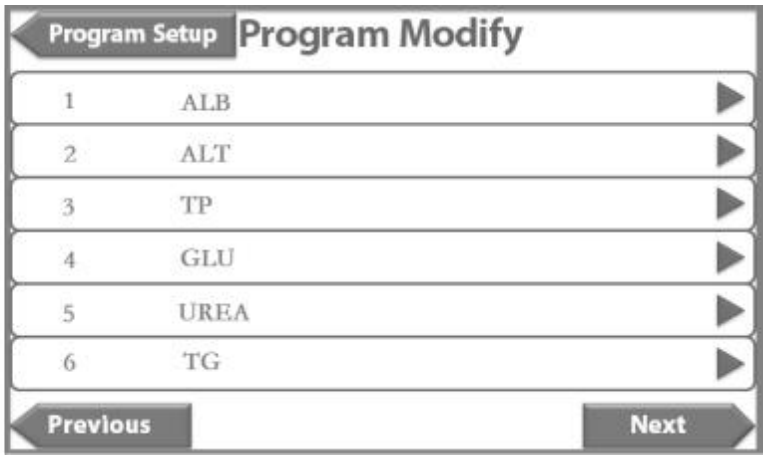


Figure 3-9

Select and click biochemical item (ALT) to modify.

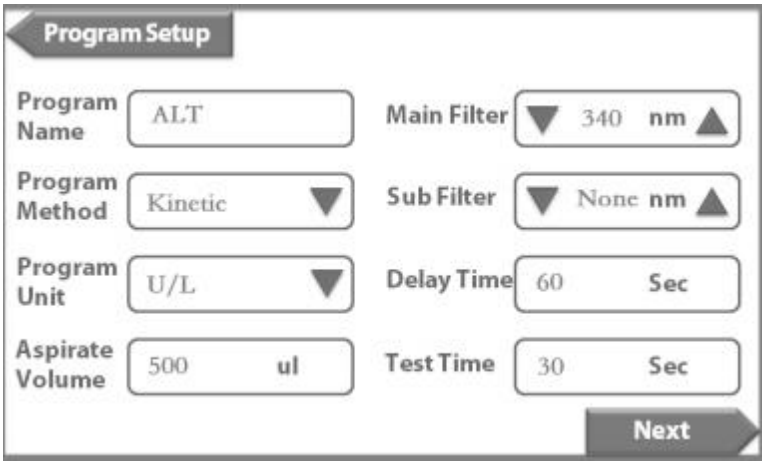


Figure 3-10

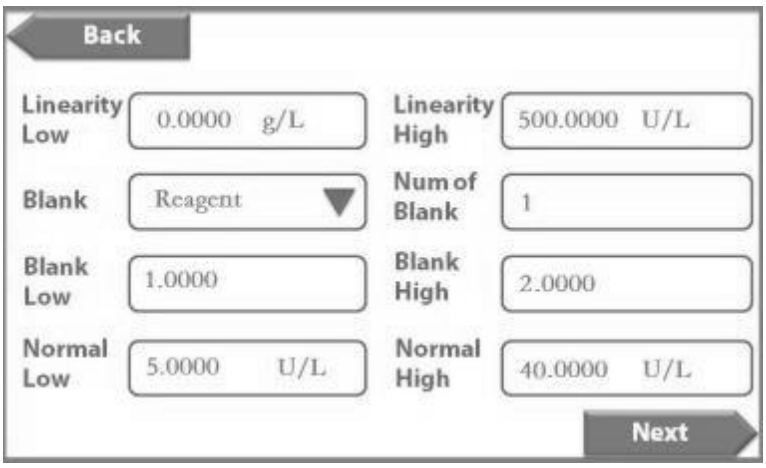


Figure 3-11

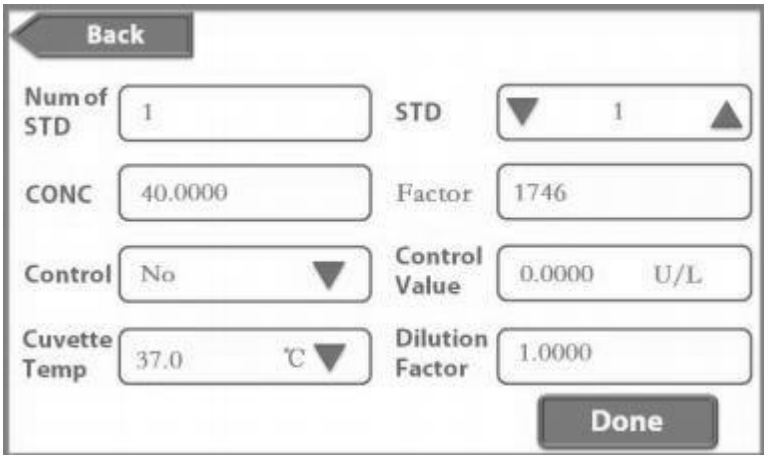


Figure 3-12

Figure 3-13

Select "YES", modified item will be saved.

Select "NO", modified item will not be saved.

3.3.3Program Delete

Click "Program Delete" to delete biochemical item.

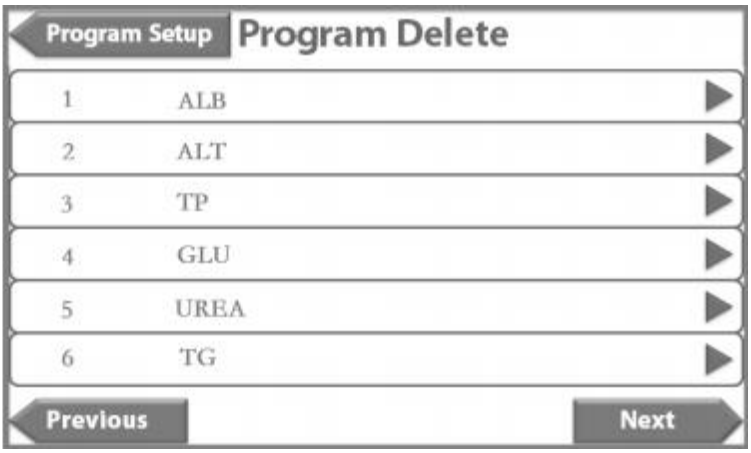


Figure 3-14

Figure 3-15

Select “YES”, biochemical item will be deleted.

Select “NO”, biochemical item will not be deleted.

3.3.4 Program Print

Click “Program Print” to print biochemical list and parameters.

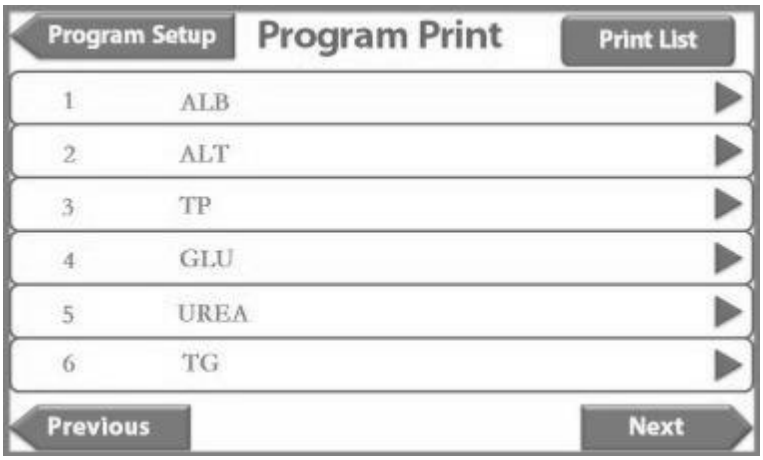


Figure 3-16

NO	Name
0001	GLU
0002	CREAT
0003	sgpt
0004	ua
0005	TG
0006	CHOLESTE
0007	HDL
0008	UREA
0009	CRE
0010	SGOT
0011	ALP
0012	AMY
0013	CK MB
0014	TO PROTE
0015	ALB
0016	CALCIUM
0017	MAGNESIU
0018	BILLU
0019	HGB
0020	GAMMA GT
0021	glu
0022	GLU

Figure 3-17

HOSPITAL
RS 3000M
002
Program Name: ALT
Program Method: Kinetic
Program Unit: U/L
Main Filter: 340 nm
Sub Filter: None nm
Delay Time : 060 Sec
Test Time : 030 Sec
Blank: Reagent
NUM of Blank: 1
Blank Low: 1.0000
Blank High: 2.0000
Normal Low: 5.0000
Normal High: 40.0000
Linearity Low: 0.0000
Linearity High: 500.0000
Dilution Factor: 1.0000
NUM of STD: 1
CONC of STD: 40.0000 U/L
Factor: 1746.0000
Control: No
Cuvette Temp 37.0 deg

Figure 3-18

3.4 System Settings

Click "Setup" on main menu (Figure 3-2) to perform system settings.

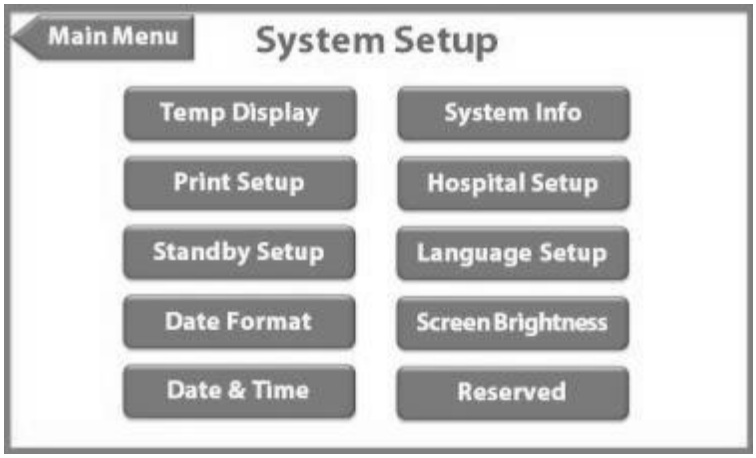


Figure 3-19

3.4.1Temperature Display Settings

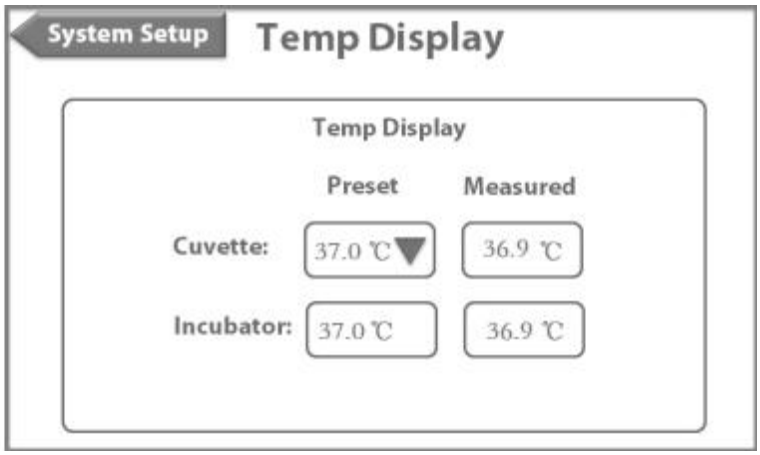


Figure 3-20

"Preset" -- preset temperatures; "Measured"-- actual temperatures.

Four options of preset cuvette temperatures (37 ℃, 30 ℃, 25 ℃).

One option of preset incubator temperature (37℃.)

Select preset temperature for cuvette, "Measured" will show actual temperature when device is stable. Temperatures of "Preset" and "Measured" should be same or similar.

3.4.2 Print Settings

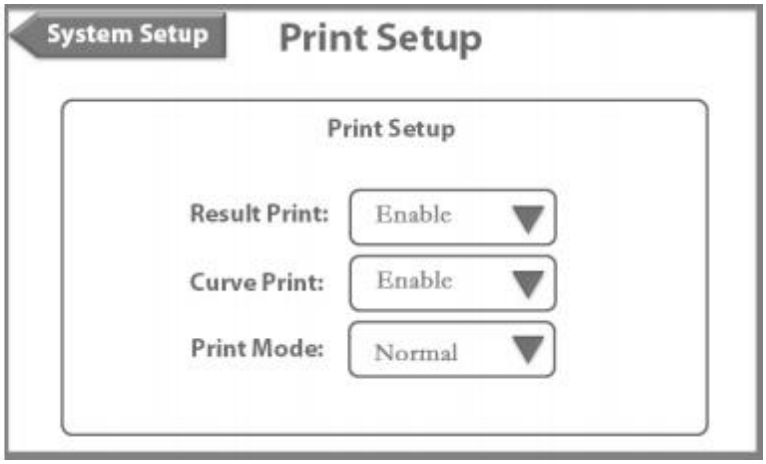


Figure 3-21

Result Print: Enable or Disable. Print result after testing automatically or not.

Curve Print: Print reaction curve after testing automatically or not (For Kinetic method only).

Print Mode: Select print mode (Normal or Concise).

3.4.3 Standby Settings

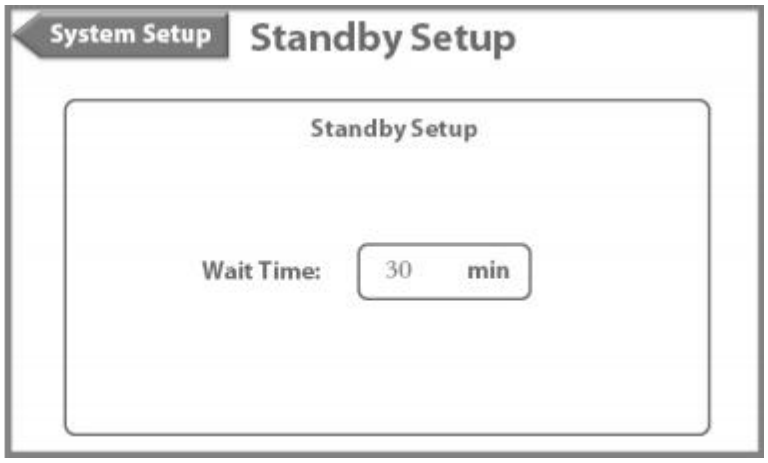


Figure 3-22

Touch screen will be in standby state after Wait Time, tap screen to wake up again.

3.4.4 Date Format Settings

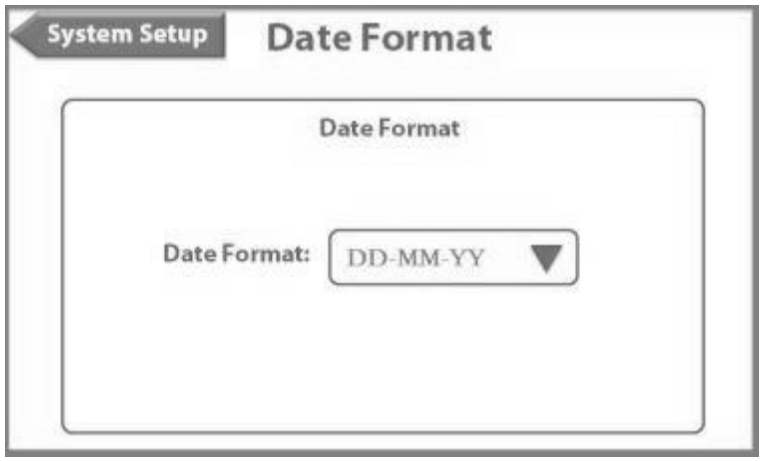


Figure 3-23

Select date format (YY-MM-DD, MM-DD-YY or DD-MM-YY).

3.4.5 Date and Time Settings

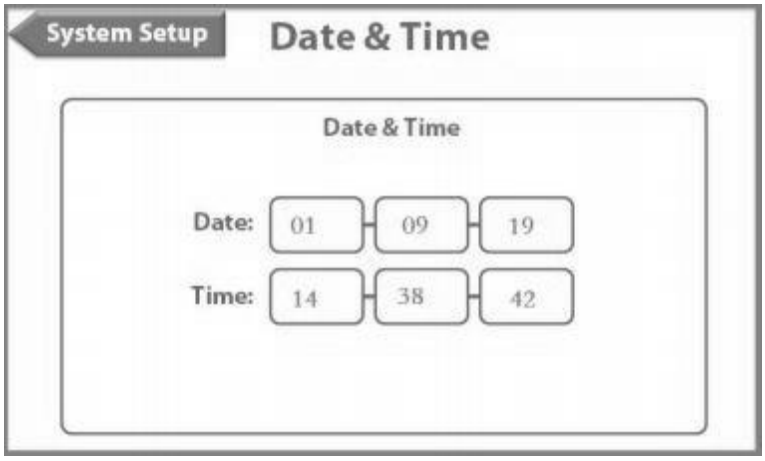


Figure 3-24

Input the actual date and time.

3.4.6 System Information Settings

Figure 3-25

Browse version and issue date of software.

3.4.7 Hospital Settings

Figure 3-26

Input hospital, clinic's name and it will be printed on the report.

3.4.8 Language Settings

Figure 3-27

Select required language as per the different version (such as English, French, Spanish, Russia etc).

3.4.9 Screen Brightness Settings

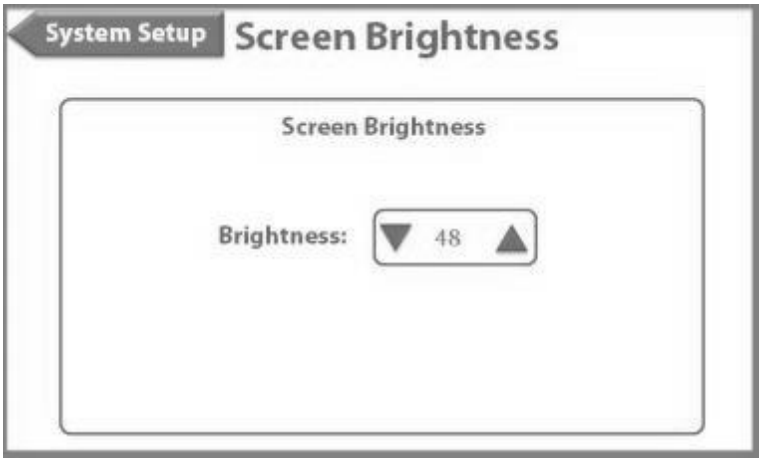


Figure 3-28

Increase or decrease screen brightness. Default value is 48.

3.5 Reserved Settings

Click "Reserved" on main menu (Figure 3-2) to perform reserved settings. Password of entering reserved settings is 123456.

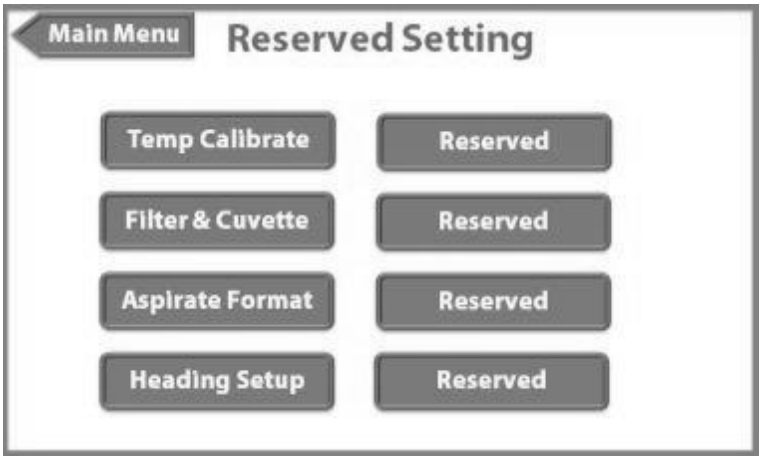


Figure 3-29

3.5.1 Temperature Calibrate Settings

Temperature calibration must be performed by professional engineers. Password of entering temperature calibration is 123456.

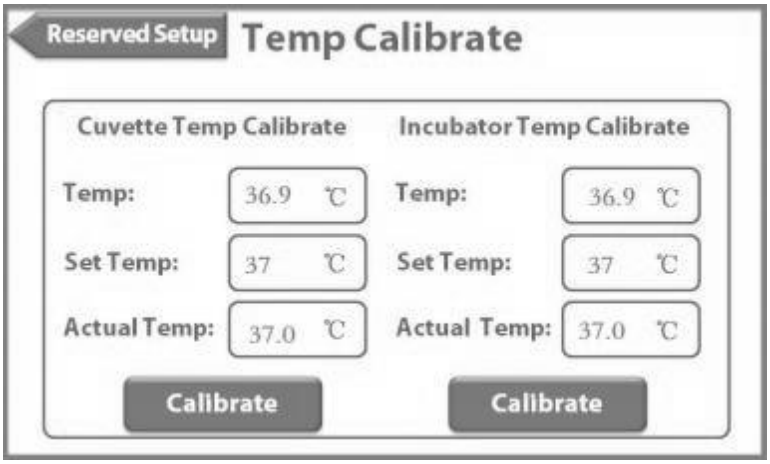
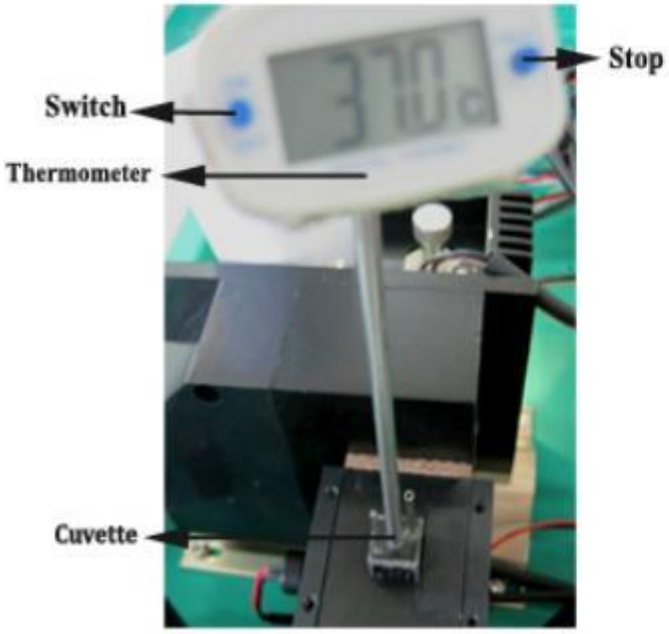


Figure 3-30

Temp: Displayed temperature

Set Temp.: Set temperature (Default value is 37 ℃)

Actual Temp: Actual temperature (Measured by the thermometer)



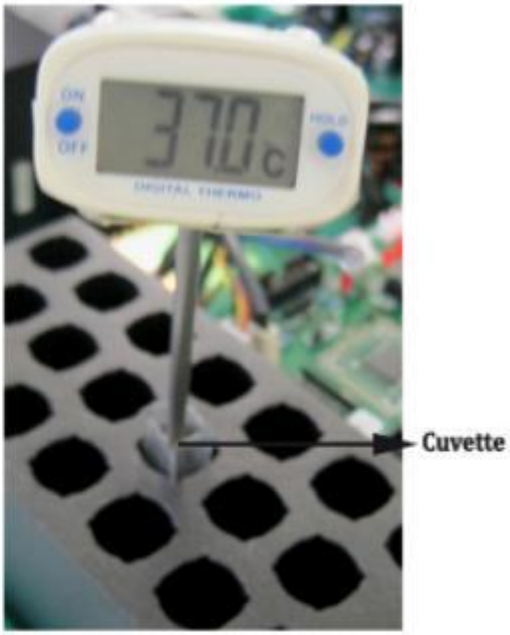


Figure 3-31 **Figure 3-32**

Cuvette Temperature Calibration:

Put thermometer and cuvette inside the position as Figure 3-31 shown, wait until the temperature keeps stable(about 10 minutes), input the value showing in thermometer to “Actual Temp” in “Cuvette Temp Calibrate” interface, then click “Calibrate” and “Reserved Setting” to exit.

Incubator Temperature Calibration:

Before calibration, please prepare for thermometer, put thermometer and cuvette to an incubator position as Figure 3-32 shown (There should be 1ml distilled water in cuvette). Wait until the temperature keeps stable (about 20 minutes), input the value showing in thermometer to "Actual Temp" in "Incubator Temp Calibrate" interface, then click "Calibrate" and "Reserved Setting" and exit.

3.5.2 Filter and Cuvette Settings

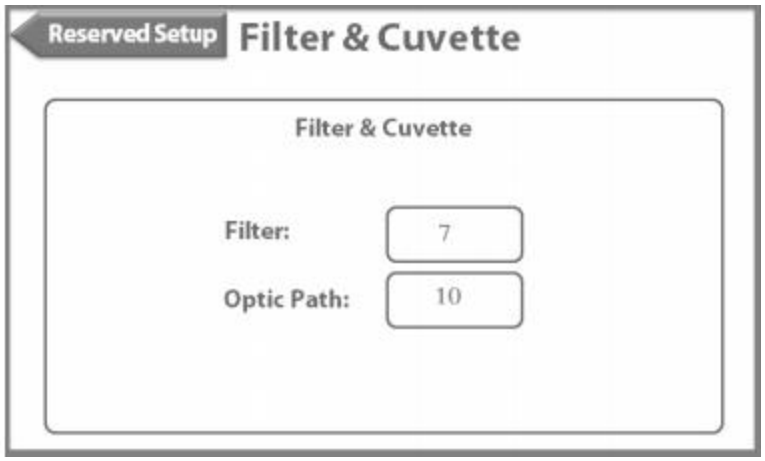


Figure 3-33

Filter: Set up filter numbers (e.g. 7 pieces of filter in total).

Optical Path: Set up optical path (e.g. the optical path is 10mm).

3.5.3 Aspirate Format Settings

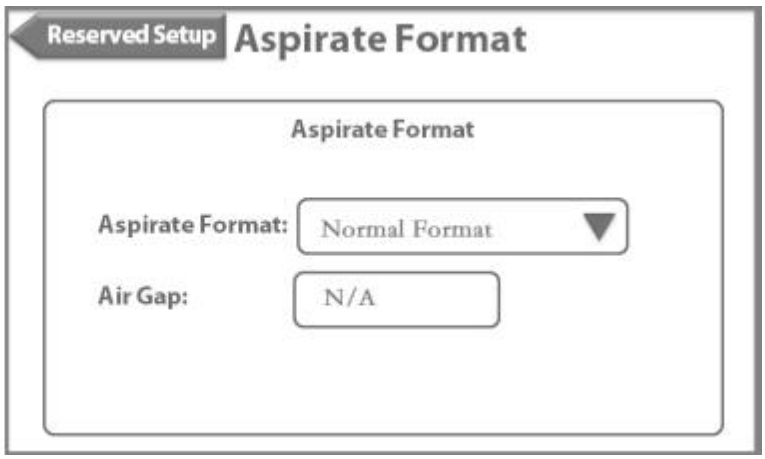


Figure 3-34

Two aspirate formats: Normal format and Express format.

Normal format means device aspirates fixed volume setting by program in advance when testing, peristaltic

pump remove the waste liquid after testing.

Express format means device pause for 1 second after aspirating fixed volume setting by program in advance when testing, then peristaltic pump re-aspirate volume of "AIR GAP", peristaltic pump doesn't work until next sample was aspirated meanwhile remove the waste liquid . Default value of air gap is 100ul.

3.5.4 Heading Settings

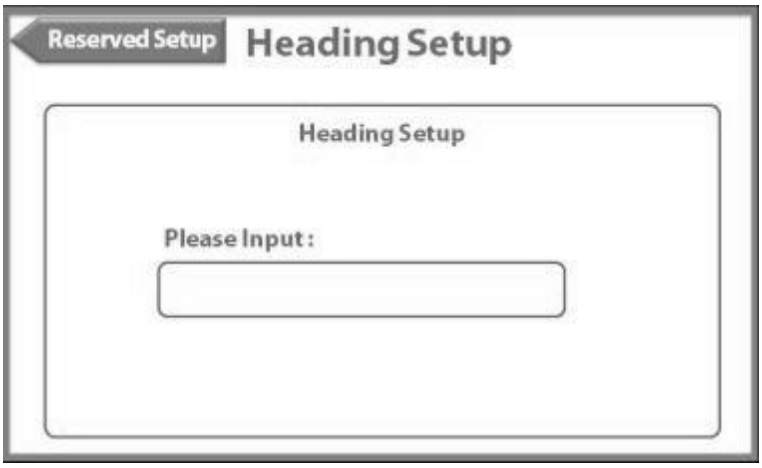


Figure 3-35

This is initial model ofthe analyzer.

3.6 Pump Calibration Settings

Click "Pump" on main menu (Figure 3-2) to perform pump calibration.

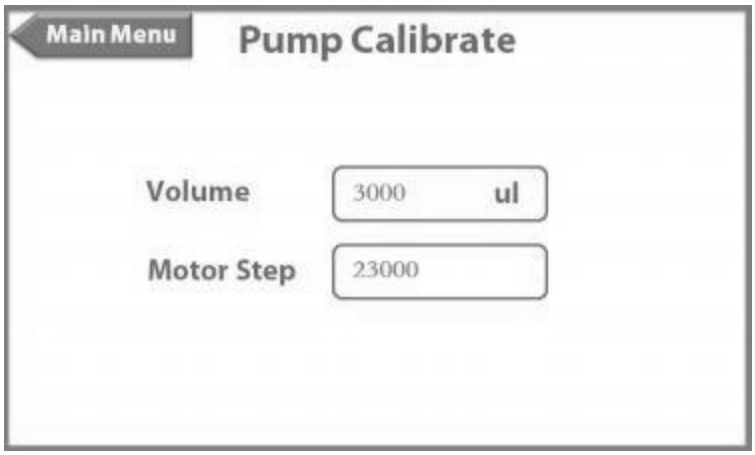


Figure 3-36

Default value of the device is that 3000ul aspiration sample volume corresponds to 22000 motor steps.

When aspiration volume of peristaltic pump is not correct, it's necessary to calibrate motor step. Enter the pump calibrate page, input pump calibrate volume (3000ul), then pour corresponding distilled water into the container, insert aspiration probe into water, press PUSH button to aspirate. After the distilled water was aspirated completely, press PUSH button again. The device will display motor step and exit pump calibration to save step.

Ifthe aspiration volume is still not right, repeat the above operation or input motor step (22000) directly.

Figure 3-37

Select “YES”, pump calibration will be saved.

Select “NO”, pump calibration will not be saved.

3.7 Operation

3.7.1 Device Preheating

Connect to the power supply and turn on the switch, the device should be preheated in 10-30 minutes.

3.7.2 Pipeline Washing

Clean the flow cell before testing, enter the main menu (Figure 3-2), insert the aspiration probe into distilled water, and then click “WASH” to start washing, run 5-10 times.

Attention:

---It’s better in a dust-proof and moisture-proof room, and with air conditioning is better, room temperature is the best in 18-25 ° C.

---When external power is not stable, device must be connected to stable power supply.

---Can’t open the cover when device working to avoid user or device damaging.

---Leakage and electrostatic prevention, device should be in good grounding. Line power socket must have a reliable grounding line to guarantee in steady state and security.

---Wash the device 3 to 5 times at least immediately after testing to keep the cuvette and pipeline away from waste liquid.

---Blood samples should be collected and disposed as medical waste liquid after testing.

---End joint ofwaste liquid pipe should not be dipped into waste liquid to avoid poor drainage.

---Use qualified reagent within the period of validity.

3.7.3 AD Auto Zero

Click "Blank" on main menu (Figure 3-2) to AD auto zero.

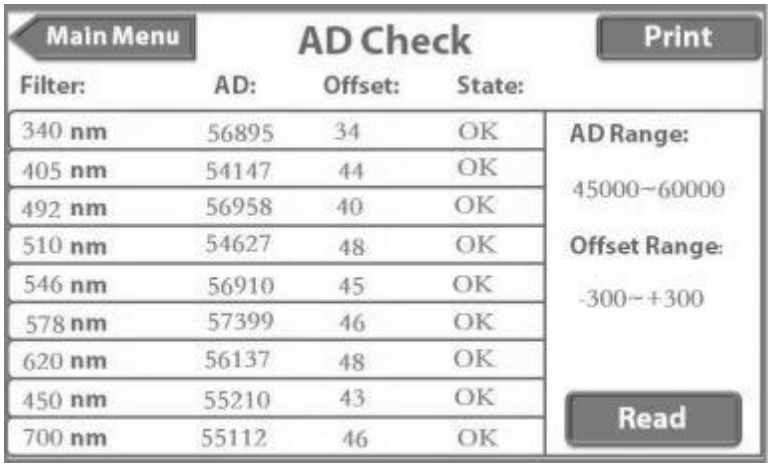


Figure 3-38

When AD auto zero, put the aspiration probe into distilled water, click PUSH button to aspirate distilled water, then device start to AD auto zero, software will show AD value, Offset value and State. If the value is out of range, there will be alarm reminding.

Attention:

---AD auto zero means that the device based on water to measure the initial absorbance to different wavelength light. AD value and offset value are calculated together to obtain absorbance. This step is important; user should perform this step before testing after device turn on.

---Flow cell needs much distilled water when AD auto zero, it is recommended that the aspiration probe should insert into distilled water to ensure no bubble when AD auto zero.

3.8 Program Test

After preparing for sample and reagent, click "Test" on main menu (Figure 3-2).

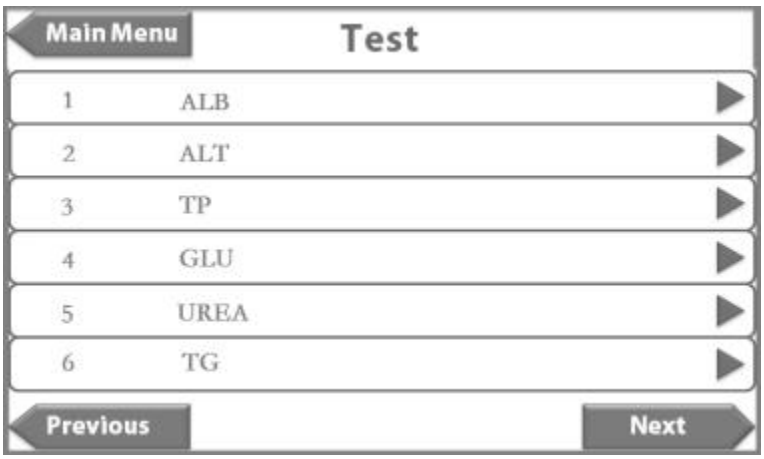


Figure 3-39

Take “ALB” (End point method)as an example to show the test process.

Figure 3-40

If cuvette temperature reaches 37℃, device will enter next page automatically. Ifnot, user needs to select.

Skip: Device enters next page to start testing.

Wait: Device waits for cuvette temperature reach 37℃.

Exit: Device back to last page to check.

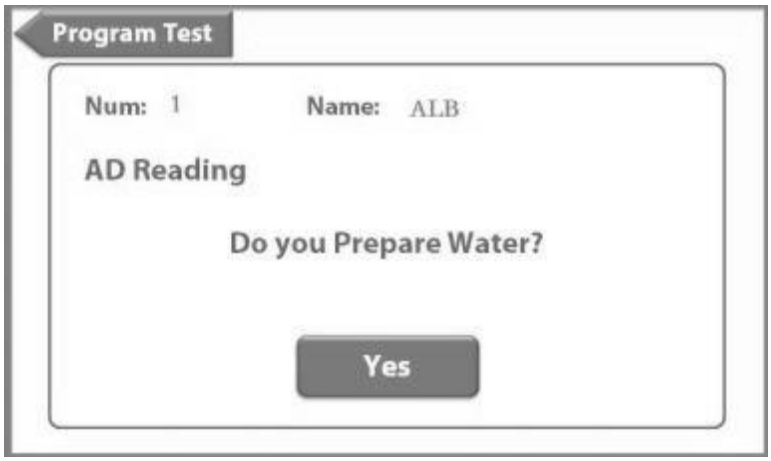


Figure 3-41

Prepare for distilled water for AD reading.

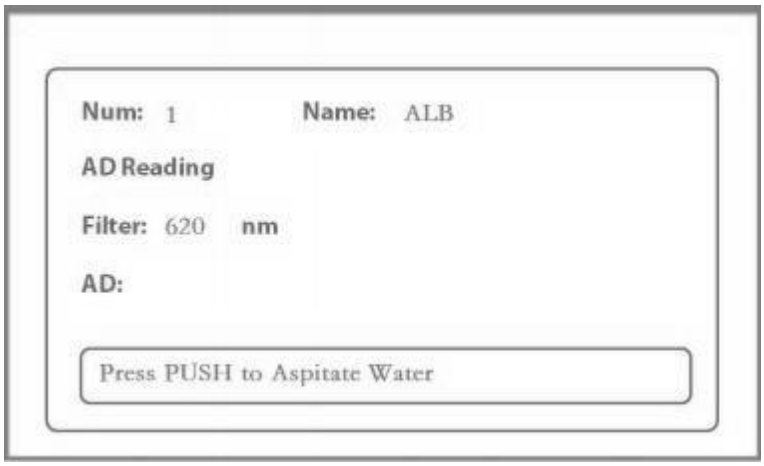


Figure 3-42

Press PUSH button to aspirate distilled water, device will calibrate AD value and enter next page automatically.

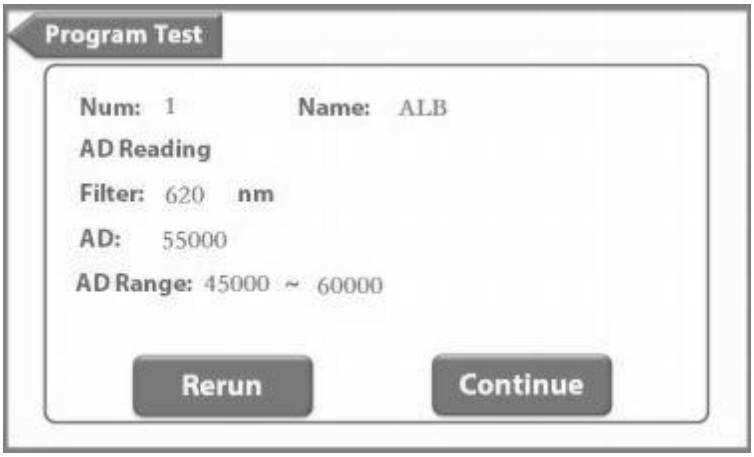


Figure 3-43

AD value should be 45000 to 60000. Click “Continue” to test reagent blank.

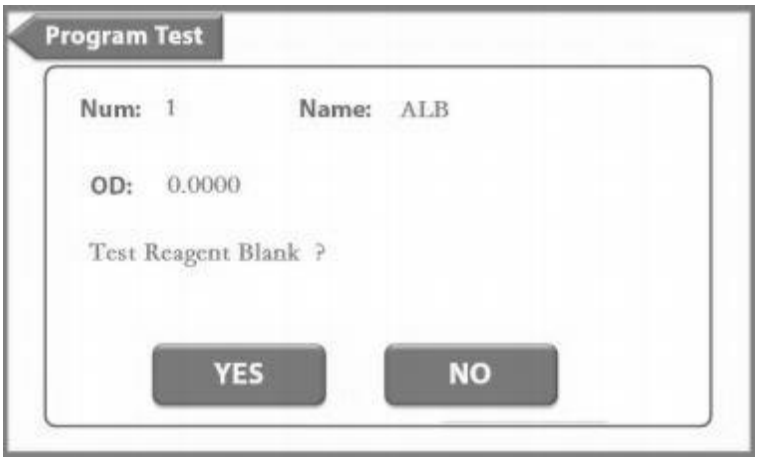


Figure 3-44

Select “YES” to aspirate reagent blank to test reagent blank absorbance.

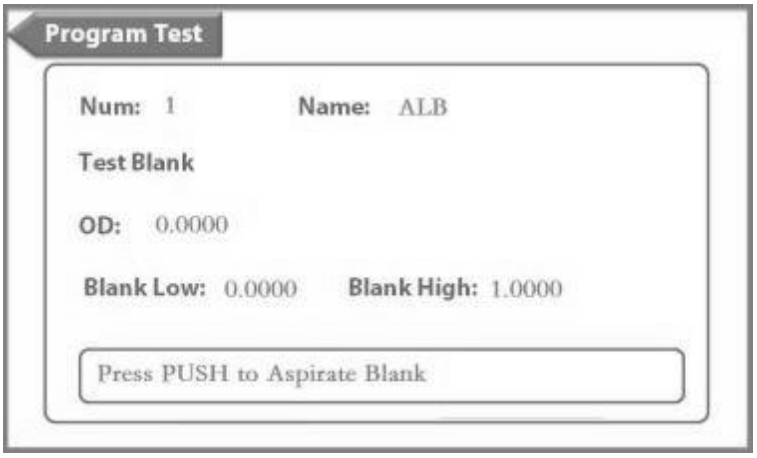


Figure 3-45

Press PUSH button to aspirate reagent blank to test reagent blank absorbance.

Figure 3-46

Click “Continue” to test STD.

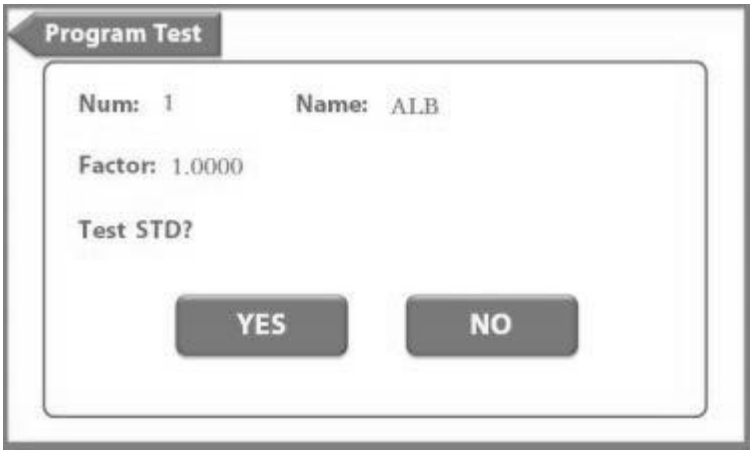


Figure 3-47

Select “NO”, device will use last factor and perform the sample test directly.

Select “YES”, device will aspirate standard to test STD.

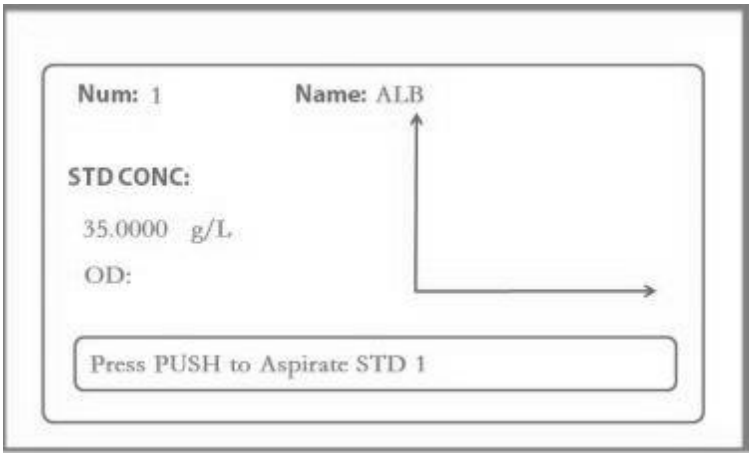


Figure 3-48

Press PUSH button to aspirate standard, then device will test standard absorbance and calculate factor automatically.

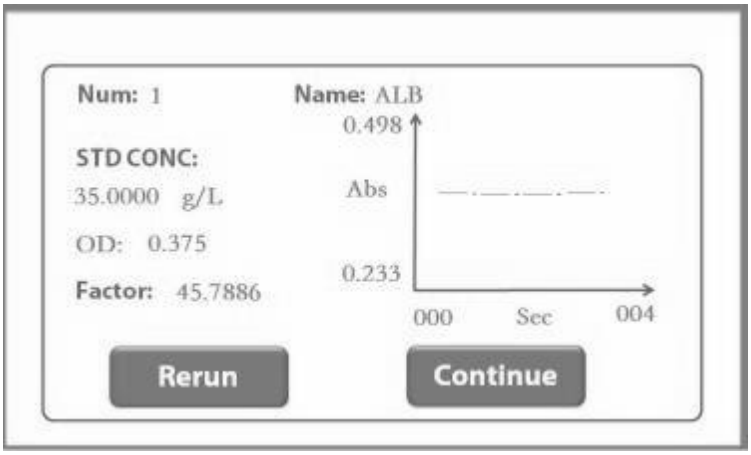


Figure 3-49

Click "Continue" to next page. Test the sample directly or perform control test.

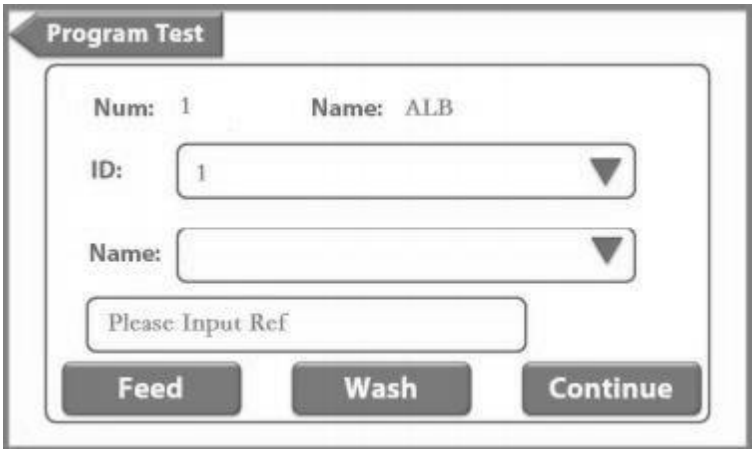


Figure 3-50

ID: Sample Number

Name: Sample Name

Feed: Feed printer paper

Wash: Clean flow cell to reduce carry over

Continue: Move to next page

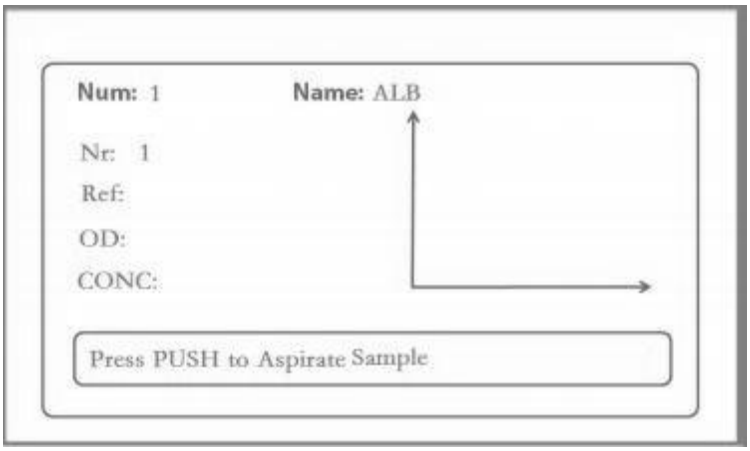


Figure 3-51

Press PUSH button to aspirate sample, then device will test the sample and display test result automatically.

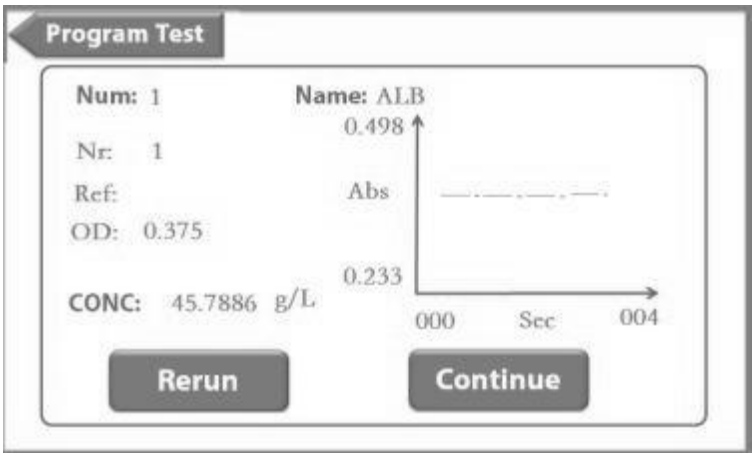


Figure 3-52

Click “Continue” to test next sample.

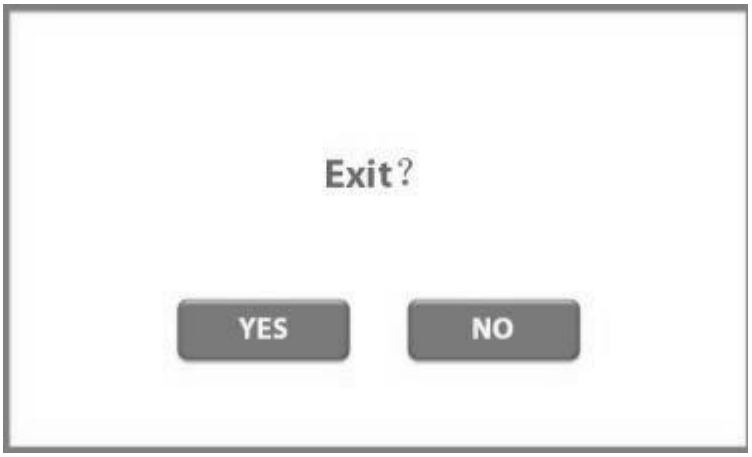


Figure 3-53

Select “YES” to exit.

Attention:

---If program method is Kinetic, the device will display test result and reaction curve.

---If program blank is serum, sample test has two steps (After testing AD, blank, standard and control).

Firstly, insert aspiration probe into serum blank then press PUSH button, device will test OD1 (absorbance of serum blank).

Secondly, Insert aspiration probe into sample then press PUSH button, device will test OD2 (absorbance of sample), then calculate result.

3.9 Wash

It's necessary to wash flow cell and pipeline before and after sample tests. Click"Wash" to aspirate distilled water or detergent to wash device. To wash 3 to 5 times after testing is recommended.

3.10 Result Process

The device can store 6000 test results and update by new test results automatically. Click "Result" on main menu (Figure 3-2)

Figure 3-54

3.10.1 Result List

"Result List" is for browsing and printing test results.

Figure 3-55

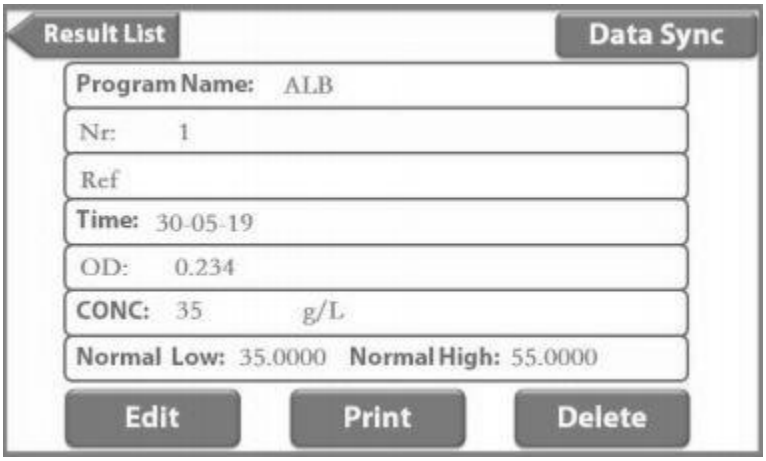


Figure 3-56

Click “Print” to print test result.

3.10.2 Delete All Result

Click “Delete All ” to delete all test result.

Figure 3-57

Select “YES” to delete all test result, Select “NO” to last page.

3.10.3 Data Synchronization

All test result can be uploaded to the PC through online software.

Figure 3-58

3.10.4 Control Manage

Click "Control Manage". Perform control statistic; query and delete control results; delete all control.

Figure 3-59

3.10.4.1 Control statistic

Click "Control Statistic" to select test program.

Figure 3-60

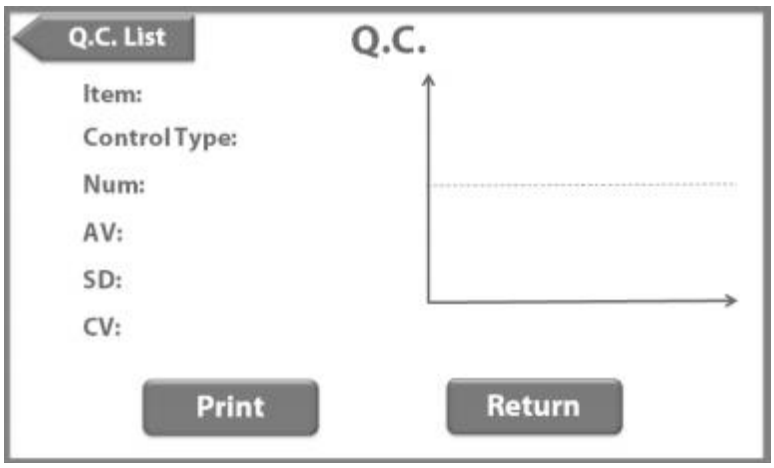


Figure 3-61

AV: Average value of control test

SD: Standard deviation of control test

CV: Control variation rate of control test

Print: Print QC curve

3.10.4.2 Control result

Click “Control Result” to select control result.

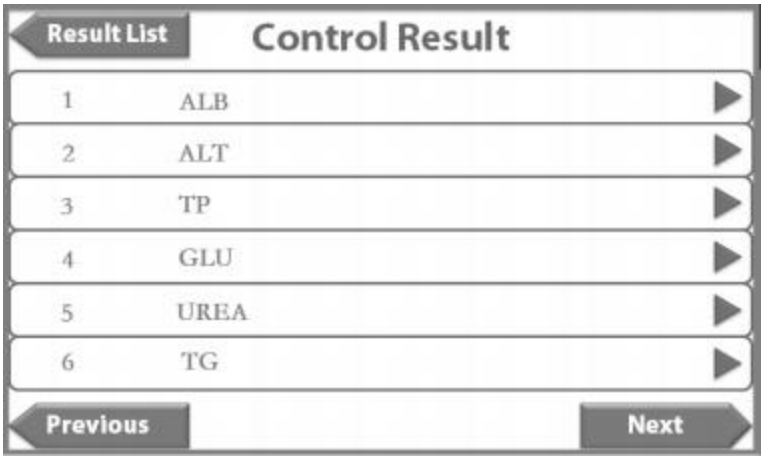


Figure 3-62

3.10.4.3 Delete control result

Click “Delete Control Result” to delete control result.

Figure 3-63

Select "YES" to delete control result, Select "NO" to last page.

3.10.4.4 Delete control all result

Click "Delete Control All Result" to delete all control result.

Figure 3-64

Select "YES" to delete all control result, Select "NO" to last page.

3.10.5 Print Report

Click "Print Report" to input sample ID (Default value is 001) and date, then click "Print" to print the report.

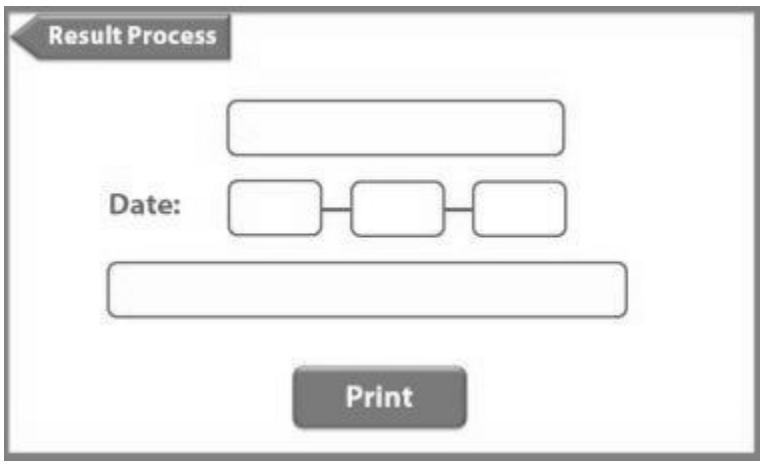


Figure 3-65

3.11 Filter Test

"Filter Test" is for testing sample real-time absorbance directly.

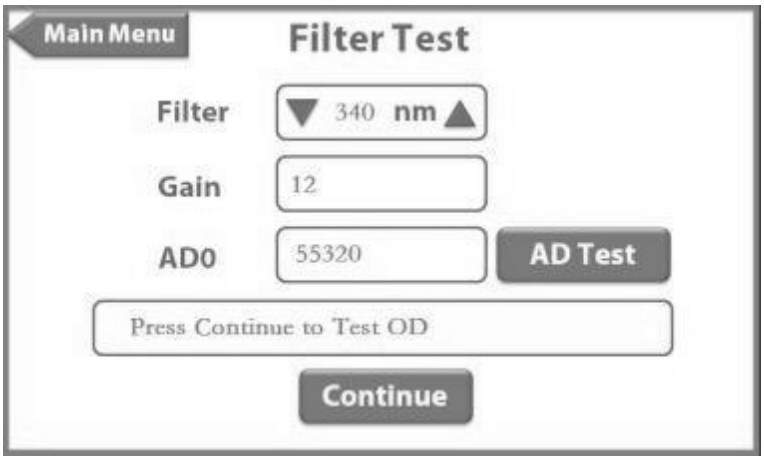


Figure 3-66

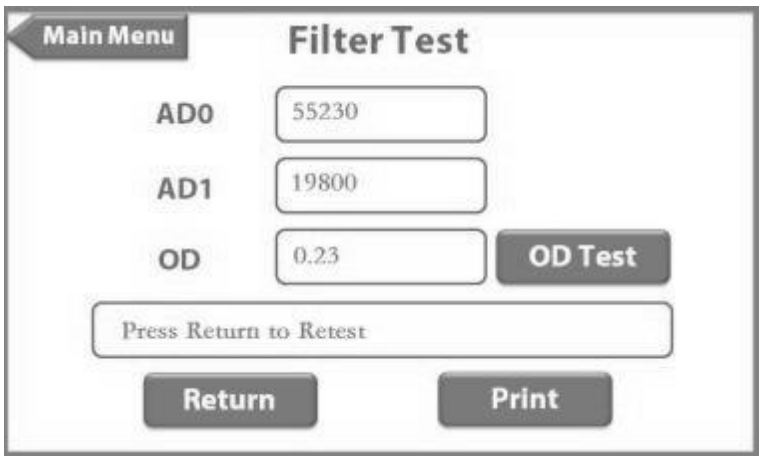


Figure 3-67

Testing steps:

-- Select filter wavelength.

-- Insert aspiration probe into distilled water, then press PUSH button to aspirate water. The device will test the water blank (AD 0 value). Click "AD Test" until the AD value is stable.

-- Click "Continue" to OD test.

-- Insert aspiration probe into sample, then click "OD test", the device will test and display sample real-time absorbance.

-- Click "Return" to last page.

4. MAINTENANCE

4.1 Daily Maintenance

Daily maintenance is mainly on washing flow cell and pipeline, keep them clean. Before testing, 10 times washing are necessary. After each test, wash 3-5 times is essential. If there are bubbles in flow cell, you may draw ethanol to soak and flush firstly, then wash it by distilled water. When all tests done, please

use distilled water flush several times.

4.2 Weekly Maintenance

Weekly maintenance is on washing the flow cell by detergent. Keeps detergent staying in flow cell 5-10 min before draining. Then flush it repeatedly by distilled water.

Recommended detergent:

1. 20% sodium hypochlorite solution
2. 95% absolute ethanol
3. Dedicated Detergent for biochemistry analyzer

4.3 Monthly Maintenance

Monthly maintenance is mainly about cleaning dust and stains on the cover, calibrate volume and motor step for peristaltic pump.

5. TROUBLESHOOTING

This chapter explains all kind of malfunctions, which often happen in the routine operations. Besides, it analyses related reasons about malfunctions and provides some methods to solve these malfunctions.

Attention:

---Must turn off the device and cut off the power supply, then remove the power plug from the socket. The repair work must be taken by professional engineers.
---The device must adopt to suitable power supply and voltage.

Attention:

---Testing sample may give incorrect test result in the case of device malfunction. If there is fault detection in the sample, please mare sure to solve malfunctions before testing.
---Sample, control, calibration, waste liquid etc. have potential biochemical risk. User must comply with the laboratory regulations of the safety to wear personal protective device (like: laboratory protective clothing, gloves etc.), and accordance with local government regulations to dispose the waste materials during testing.

5.1 Malfunction Phenomenon and Maintenance

Please take measures to eliminate the malfunctions which occur before and during the testing according to relevant troubleshooting. If the malfunctions still exist, please contact your local dealer as soon as possible. We are pleasure to serve you.

5.1.1 There are mistakes with AD auto zero

Possible causations: There is no distilled water in flow cell;
Flow cell is dirty (need to wash);
There is air bubble in flow cell (need to wash);
Pipeline is connected wrongly, leaks or block;

Peristaltic pump hitch;
Filter is aging or damaged;
Device bulb burned out.

5.1.2 Wrong result or bad repeatability

Possible causations: There is air bubble in flow cell (need to wash);
Peristaltic pump pipe is not installed properly or leaks;
Aspiration is abnormal, need to calibrate the pump;
Voltage is not stable, need to connect regulated power supply;
If sample is hemolytic or the reagent is invalid.

5.1.3 Device does not work

Cause: Fuse burn-out or behind power supply interface is poor connected.
Maintenance: Replace the fuse, check the behind power supply interface.

5.1.4 Screen definition changes

Cause: Due to the local AV voltage is different; Led display voltage is not the same, but in general all in the visible range.
Maintenance: Open the device's cover, find the cable of main board connecting with the display, you can see a blue 203 potentiometer; adjust the potentioneter to change the definition.

5.1.5 Printer keeps walking

Cause: The cable of printer head connecting with control panel is loose.
Maintenance: the cable of printer head connecting with control panel is white, open the device, take off the printer head, and compress the interface.

Attention:

---Be careful about the white cable and the printer head cable do not drag too hard.

5.1.6 Heating time is too long

Cause:
a) Effect of ambient temperature (Especially in winter), increase room temperature, keep the room temperature at 10 ~ 30 ℃;
b) Insufficient heating voltage could lead to longer heating time. Please open the device, use the digital multi-meter to test the voltage of incubator heating rod, if there is no voltage, and replace the heating rod.
Maintenance: Against the possible reasons check and maintenance individually.

5.1.7 Testing time is a little long

Cause: Serum and reagent do not have enough incubate time. Or device needs calibration again.
Maintenance: Serum and reagent incubate more than 3 minutes in winter it should around 5 minutes. Or refer to user's manual, run the calibration procedure to calibrate.

5.2 Corrections and Replacements of Regular Spare Parts

In order to make the analyzer's running reliable, it's necessary to proofread or replace some parts of analyzer and take effective maintenance.

Attention:

---User must be trained by professional engineers before they take maintenance and replace spare parts alone.

5.2.1 Replacements of fuse

The concrete steps ofreplacement are as follows:

1. Turn offthe power supply and pull out the power supply line.
2. Pull the power supply line from the power socket ofmainframe and elicit the fuse housing.
3. Take out the fuse housing and install a new fuse into fuse housing.
4. Plug the fuse housing into original position.

Attention:

---User must replace appointed specification fuse.

5.2.2 Replacements of light source

The standard configuration of device has a halogen lamp set in the opposite position of detector; Two LED light sources are disposed on two adjacent sides of the detection position and the detector.

It needs replacing while the lamp is damaged or has been working for 2 years.

The steps as follows:

1. 15 minutes after turning offthe device
2. Open the device's cover
3. Unload cuvettes pallet
4. Unplug the Plugin of the lamp connected to power
5. Unscrew the screws, remove the lamp
6. New lamp fitted in accordance with the above order
7. Loosen the screws on the side of the lamp bracket
8. Turn on the power supply, enter the device's system, enter into the interface ofA/D signal detection, select any one wavelength, and test the signal value, at this time up and down to adjust the position of the lamp to fix it until the A/D value at the maximum signal value points.

The replacement to LED: when instrument scattering detection is in abnormal, the LED light source should be checked or replaced.

After change the lamp and LED, Please check and confirm the light source and cable are secure connected, and after calibration, then it can put into normal use.

Attention:

---Turn off the power supply before replacing the lamp.
---It is dangerous to take replacement when device has been shut down just now. Because, the temperature is very high. It should wait for the temperature decrease then replace the lamp.
---Do not touch the new lamp surface; otherwise it could change characteristics of the lamp. If it is found that the lamp surface has fingerprints or other stains, it can be canceled by cloth with rubbing alcohol.

5.2.3 Replacements of peristaltic pump

The steps as follows:

1. Open device's cover
2. Pull out two pump pipe
3. Take the coarse joint from the set screws, pull out the pump on the coarse joint
4. Inset the new peristaltic pump on the coarse joint through the set screws
5. According to the Figure 5-1 connect pump pipe

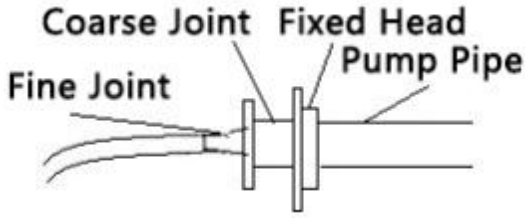


Figure 5-1

Attention:

---Unplug the pump pipe should be very careful, to prevent break incoming point and outlet point
---In order to guarantee the reliability of the test, need to inspect the peristaltic pump pipe every month
---Replacement of the pump pipe must be provided by manufacturer, do not use other types of pump pipe to replace

5.2.4 Replacements of printer paper

The steps as follows:

1. Open printer cover, take away the old printer paper
2. Load the new printer paper into the paper slot
3. Cut paper port to flat, put the paper to the form feed, push tight
4. Click "FEED", look the paper port to the appropriate position
5. Cover printer cover, paper was finished

6. TRANSPORTATION AND STORAGE

6.1 Transportation

Transport should be in accordance with the regulations implementing of order contract, Away from the toxic, harmful, corrosive substances

It should be to prevent severe shocks, rain and exposure, overturned not be permitted in transportation.

6.2 Storage

It should be stored in environment temperature −5℃～50℃, Relative humidity no more than 80%, well-ventilated indoor. It shouldn't storage with toxic, harmful, corrosive materials stored.

ISO 9001:2015 & ISO13485:2016 Certified manufacturer

CLINDIAG SYSTEMS CO., LTD.

ADD: 29 ZHIYUAN ROAD, JURONG ECONOMIC DEVELOPMENT ZONE, CHINA.

TEL：86 0511 80775555

FAX: 86 0511 80770077