CORALAB® Touch

CLINICAL CHEMISTRY ANALYZER

MANUAL

Index

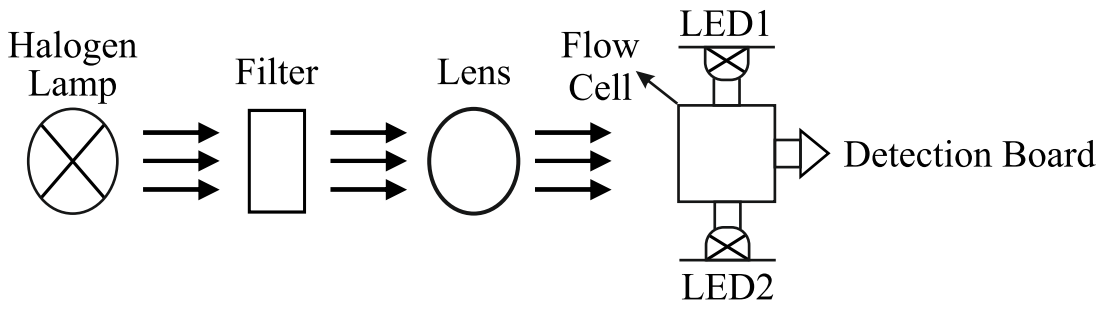
		Pg. No.
1.	General Description	1
2.	Installation	2
3.	Test Functions & Operation	4
4.	Device Maintenance	12
5.	Trouble Shooting	13
6.	Transportation & Storage	17

1. GENERAL DESCRIPTION

Coralab Touch semi-automatic biochemistry analyzer is a microcomputer-based in-vitro diagnostic instrument uniting optics, mechanics and automation control in one. It is used together with reagents for quantitative determination of biochemical products, widely applied to various hospitals and research institutes, with the characteristics of high precision, excellent repeatability, and complete function

1.1 Configuration and Structure

Coralab Touch mainly consists of Control System (single chip microcomputer, touch screen), Samples and Reagent Incubation system, Optical and Measuring System, Peristaltic Pump Suction system, Built-in Thermal Printer, etc.



1.2 Main features and technical parameters

The wavelength of transmitted light	**:** 340nm, 405nm, 492nm, 510nm, 546nm, 578nm, 620nm
Light source	**:** 6V, 10W halogen lamp
Absorbency	**:** 0.000～3.500 OD
Temperature for reaction cuvette	**:** 37℃
Test plate configuration	**:** Flow cell
Analytical Method	**:** end point, fixed time, kinetic, multi-point, serum blank
Interference light	**:** ≤3.5A

Linearity of absorbency:

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 absorbency

Less than 0.002A within 20minsat 340nm

Repetition of absorbency

Coefficient variance(CV)≤1.0%

Cross Contamination Rate:

When reaction liquid volume is 1ml, the cross contamination rate should be less than 1% by flow cell test.

2. INSTALLATION

In order to ensure the normal operation of equipment, it must be installed and debugged by the engineers who are authorized by Tulip Diagnostics (P) Ltd. For any reason to reinstall or debug the analyzer, only trained personnel from Tulip Diagnostics (P) Ltd. should do the needful.

Attention

- If any unauthorized installation other than Tulip Diagnostics (P) Ltd. causes damage to the equipment, it will not be under free warranty.

2.1 Requirement of installation

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

2.1.1 Requirement of space

To ensure enough space for releasing heat, repairing, maintenance, keeping the pipeline and the fluid to flow freely, the space must meet the requirements as follows:

1. Keep the analyzer not less than 100mm distance away from the wall and other objects on each side (left, right and back)
2. Ensure enough space for the equipment to place distilled water and waste containers.

2.1.2 Power supply

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

Attention

- The power supply socket should be within 1m from the analyzer in order to pull out the plug timely during any malfunction or breakdown.
- Check if network voltage is the same to the equipment 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. The area of installation should be clean and the instrument should be kept away from dust, noise, X-ray machine, CT, centrifuge and radio interference devices.
8. Avoid direct sunlight and ultraviolet rays and keep the instrument away from hot and cool sources and outlet of air conditioners.

2.2 Open Package

2.2.1 Steps:

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

1) Unpack the package and check whether the packing contents are complete or not referring to packing list
2) Check whether the outer appearance is damaged or not
3) Check whether the serial number is in accordance with the packing list and outer package.

2.3 Steps for installation

1. Place the instrument on stable work table.
2. Connect power supply line to the appointed power supply slot.
3. Put the waste pipe behind the instrument into the waste bottle.
4. Open the side cover and install the peristaltic pump.
5. Install the microswitch button.
6. Switch on the main machine before testing.
7. Install the printing paper
   - Open printer cover of the instrument
   - Load the new printing paper into the paper slot
   - Put the paper to the Feed form and press" FEED"
   - Cover printer cover

Attention

- While installing a thermal printing paper, pay attention to the direction of the paper
- Before installing the printing paper, do not print, or else it will cause the system to crash
- The probe or waste fluid joint may carry some serum, control, calibrator and reagent, which is of potential biological risk. Therefore, it is dangerous to touch the probe directly.

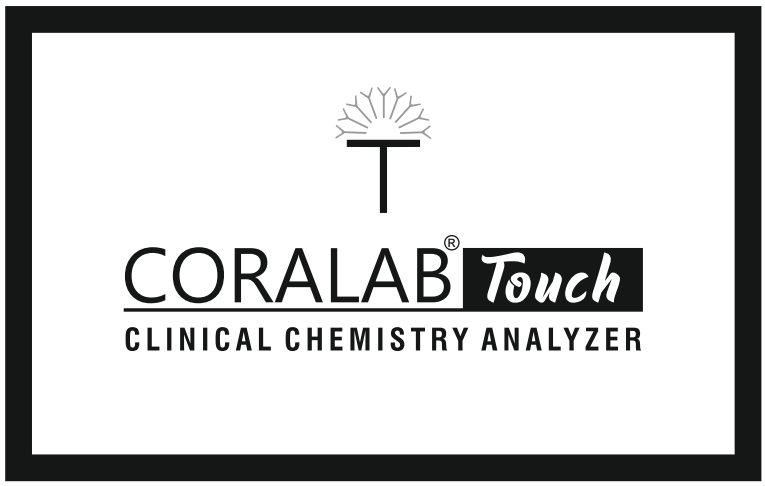
3. TEST FUNCTIONS AND OPERATION

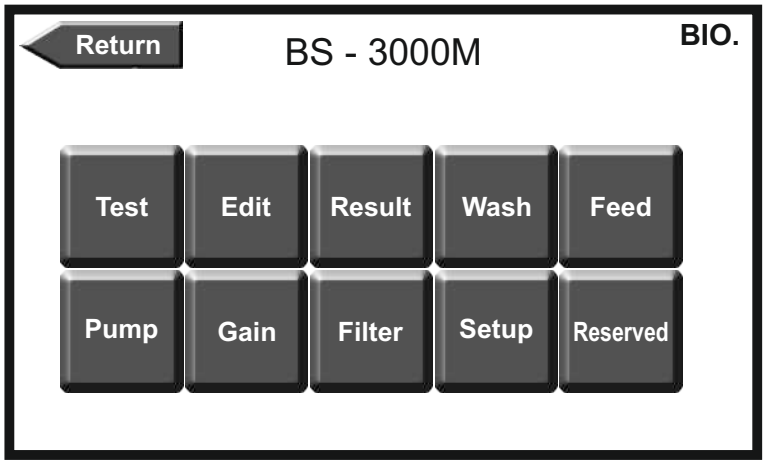
3.1 Working Principle

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

3.2 Operation

After switching on the instrument, it will show the below screen



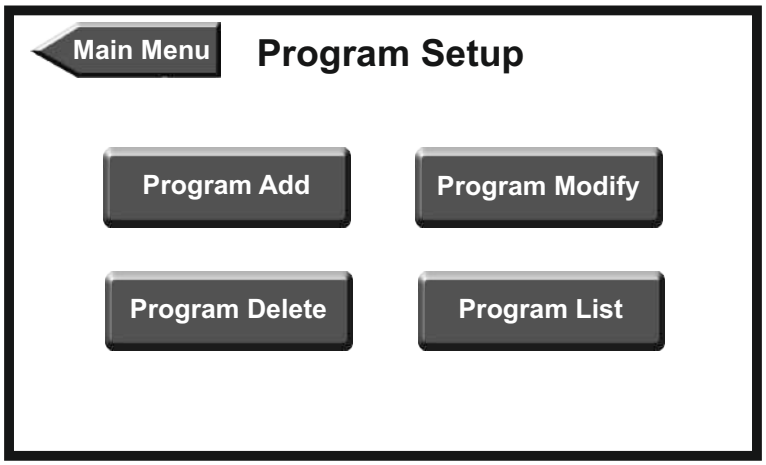


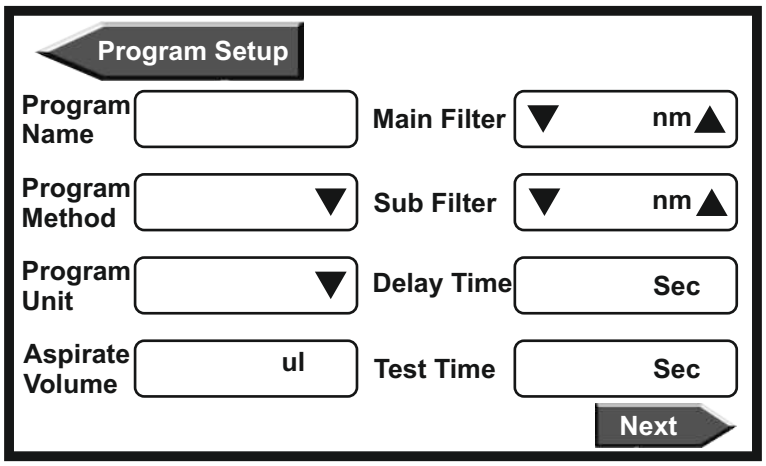
Test:

To select the well-edited biochemical items to do sample test, after testing, the instrument will show the test results and print it automatically

Edit:

To add, modify, delete and print biochemical items.



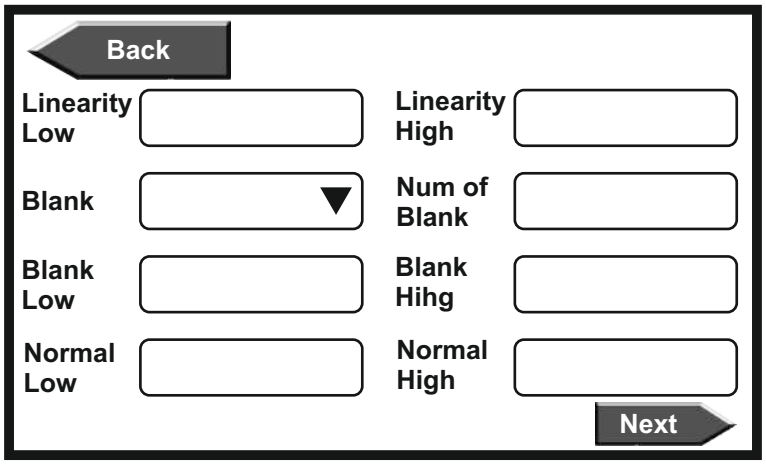


For “Program Name”, “Main Filter”, “Program Method”, “Sub Filter”, “Program Unit” setup, please follow reagents user manual.

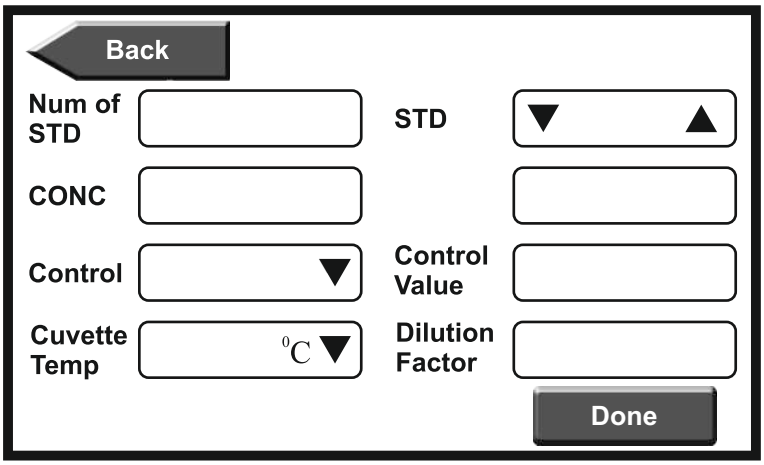
Aspirate Volume : 500ul (recommended to set this value, no modification)

Delay Time: Kinetic (60S recommended), Endpoint (3S recommended), Two Points (30S recommended)

Test Time: Kinetic (30S recommended), Endpoint (3S recommended), Two Points (30S recommended)



The Above parameters setup, please follow reagents user manual, if no low value of linearity, input 0



Num of STD : STD numbers

STD : Select corresponding Standard solution and input its concentration in "CONC"

Control : Select control

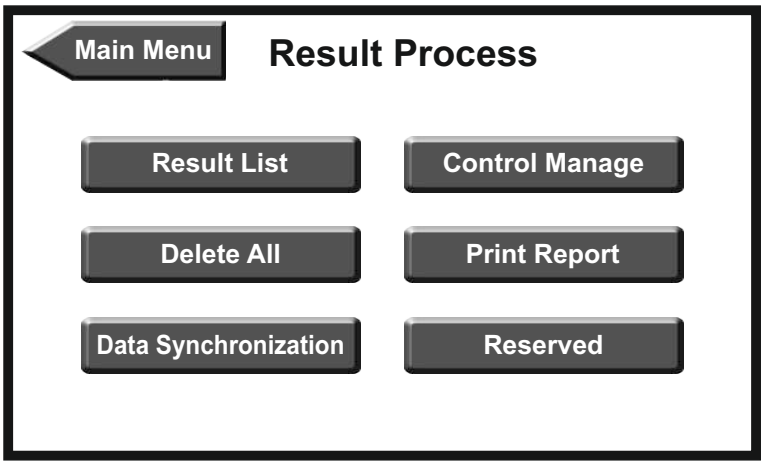
Control Value : Setup control concentration

Cuvette Temp. : 25℃, 30℃, 37℃ selectable

Dilution Factor: default value 1

Result:

Enter result storage database for data query, print, delete, QC management, QC statistics and printing general report, etc.



Wash:

The shortcut key for cleaning, aspiration volume is 1.5ml per keystroke, used to clean flow cell.

Feed:

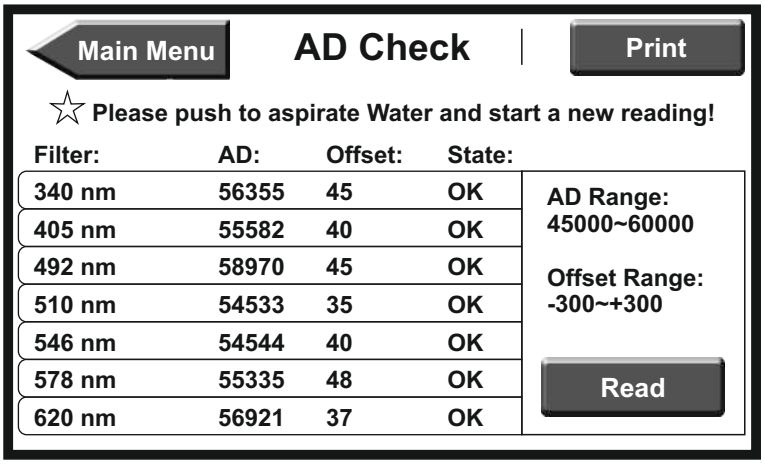
Used for printer to load papers, pass papers and cut papers

Pump:

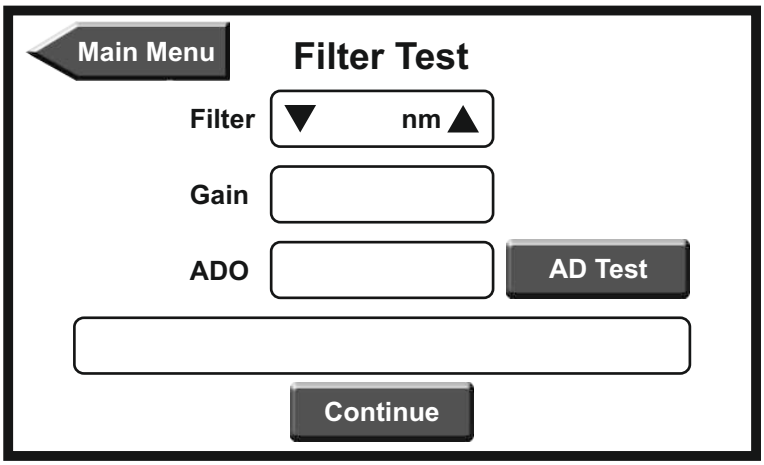
Calibration for Peristaltic pump aspiration volume (refer to 3.3.2)

Blank:

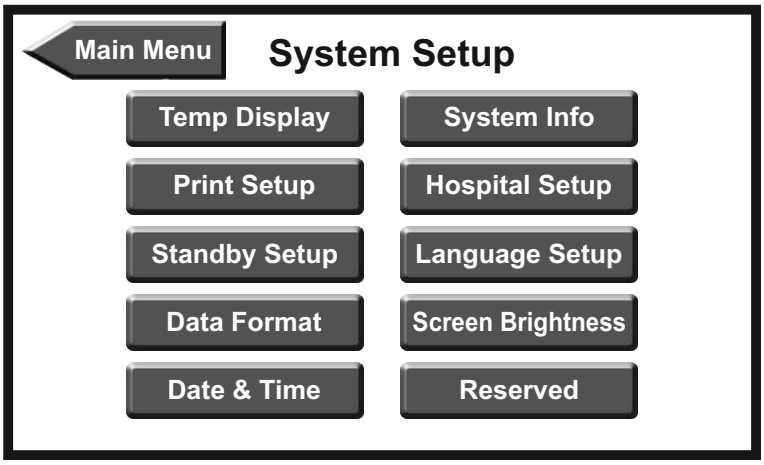
AD Auto Zero to confirm whether the instrument is in good status or not.



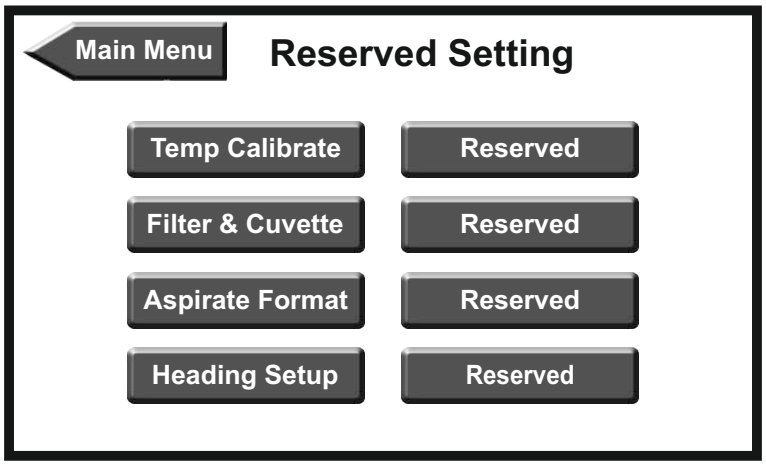
Filter:
Measure and adjust each filter's AD value, blank value and absorbance



Setup:
Shows cuvette temperature; sets filter number, cuvette diameter, language, aspiration mode, sleep mode; Hospital and instrument model title Settings; time format and date/time Settings; screen brightness settings, etc.

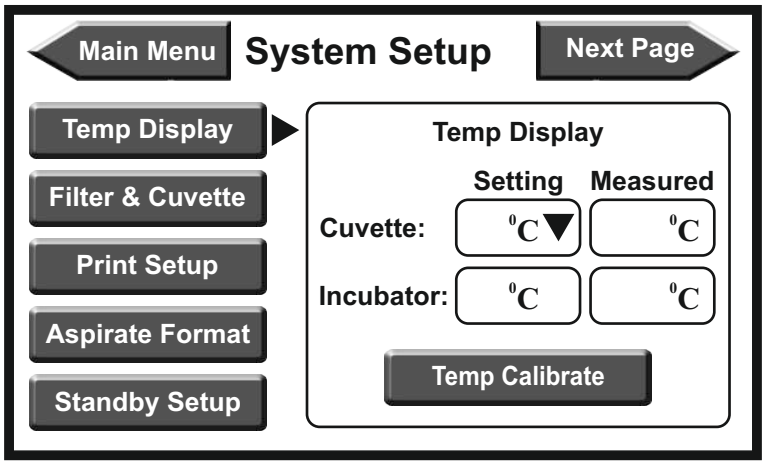


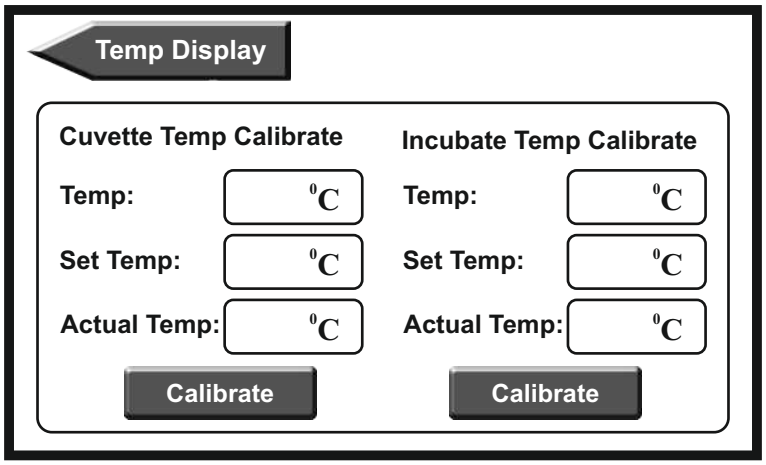
Reserved:
Temperature calibration, set filter numbers & cuvettes light path, aspiration mode, model & headline set, etc. (This interface is an encrypted interface, Password 123456)



3.3 Parameters settings

3.3.1 Temperature display Settings



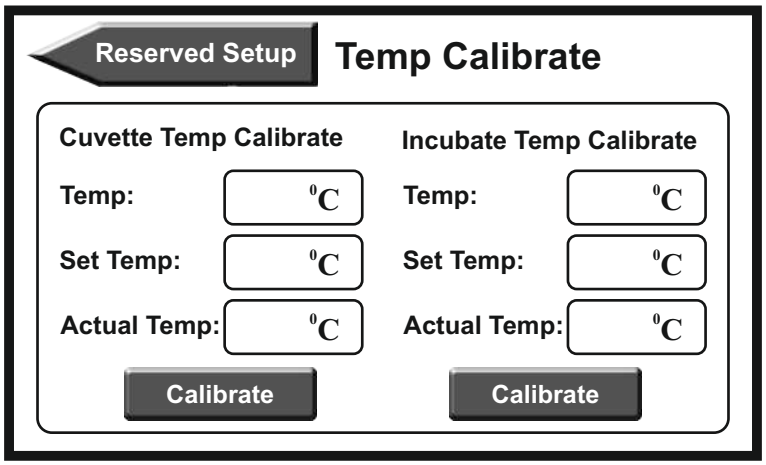


Choose "Setup" in the main menu and choose "Temp. Display", default temp. is 37℃.

Use to choose Temperature, click main menu to save. This function can only provide the confirmation on whether temperature is right or not. When testing sample, the temperature will be shifted automatically according to the test program.

Temperature calibration should be operated by professional engineers or guided by Tulip Diagnostics (P) Ltd personnel.

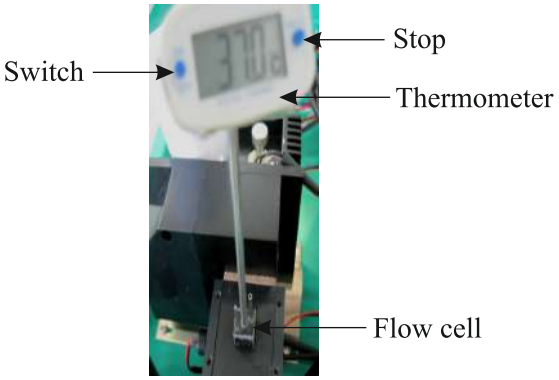
Click "reserved", input password "123456" to enter temp. calibrate interface

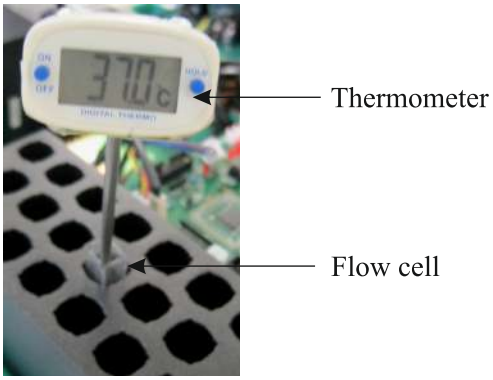


Temp: displayed temperature

Set Temp.: Set temperature (default 37℃)

Actual Temp: Actual temperature (measured by the thermometer)





Flow cell (Cuvette) Temperature calibration:

Put the thermometer and flow cell inside the position as shown in figure-4 shown, wait until the temperature becomes stable (about 10 minutes), input the degrees showing in the thermometer to "Actual Temp" in "Temp Calibrate" interface, then click "calibrate" and "Reserved Setting" and exit.

Incubation temperature calibration:

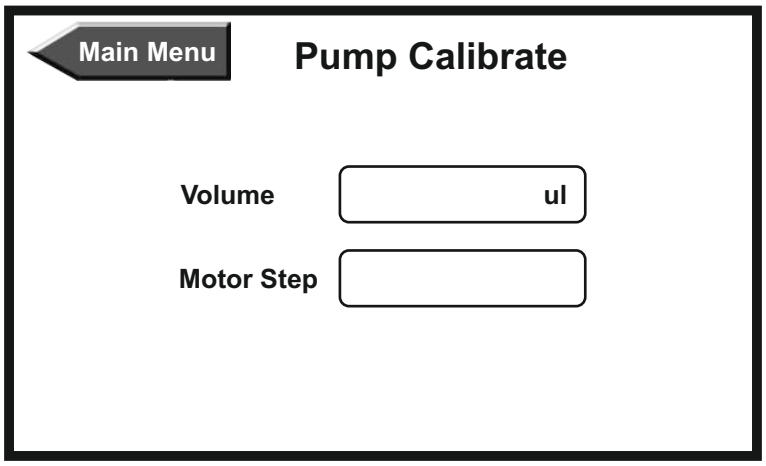
Before calibration, please prepare the thermometer by placing the thermometer and the flow cell in an incubation position as shown in figure-5 (there should be 1ml distilled water in flow cell).

Wait until the temperature is stable (about 20 minutes), input the degrees showing in thermometer to "Actual Temp" in "Temp Calibrate" interface, then click "calibrate" and "Reserved Setting" and exit.

Attention

Please run this operation twice.

3.3.2 Pump calibration



Motor step is calibrated corresponding to 3000ul aspiration volume as default.

If the aspiration volume is incorrect, please re-calibrate the motor step.

Enter into the calibrate interface,

1) Input pump calibrator volume (recommended 3000ul),
2) Take 3000ul distilled water into the tube, insert the aspiration pipe into the tube, press PUSH to aspirate.
3) After the distilled water is aspirated, press PUSH again immediately.

The instrument will display motor step and exit pump calibration to save step. If the aspiration volume is still not right, repeat the above operation or input motor steps directly.

3.4 Instrument Operation

3.4.1 Instrument preheating

Connect to the power and turn on the switch, the instrument should be preheated in 10-30 mins.

3.4.2 Pipeline Washing

Clean the flow cell before using, enter the main interface, insert the pipe into distilled water, and then press wash to start washing, run 5-10 times**.**

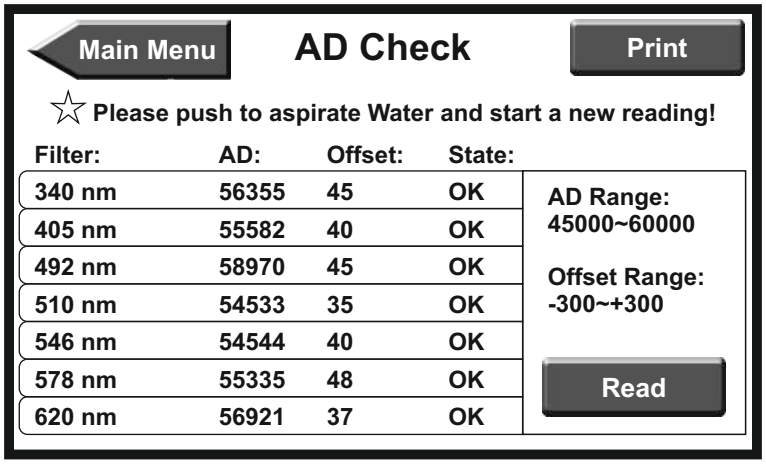
Attention

- Pay attention to use environmental dustproof, moisture proof, and installation air conditioning is better, environment temperature in 18-25 ° C is the best working temperature.
- When external power is not stable, instruments must be connected to a regulated power supply.
- The cover of the instrument in the process of operation shall not be open, so as not to cause damage to the equipment or operator.
- To prevent leakage and electrostatic prevention, the instrument should be in good grounding. The Power socket must have a reliable grounding line to guarantee a steady state and security.
- After work, wash the instrument 3 times immediately to keep the cuvettes and pipeline free of liquid waste.
- After finishing the testing, the waste should be collected and disposed according to the medical waste.

- The waste pipe end should not be dipped into the waste to avoid poor drainage.
- Use qualified reagent within the period of validity.

3.4.3 AD Auto Zero

After selecting AD Auto Zero from the main menu, the below shown screen will apprear



Press **Push** to aspirate distilled water and click **Read**

During AD auto zero, put the aspiration pipe into distilled water, press push, the instrument will begin auto zero. The interface will show Gain coverage, AD value and offset value, if the value is out of range, there will be an alarm.

Attention

- AD auto zero means that the instrument is based on water to measure the initial light intensity of different wavelengths. The gain coverage, AD value and offset value are calculated together to obtain absorbance. This step is very important; users should carry out this step whenever the instrument is switched on.
- AD auto zero for flow cell need more distilled water, it is recommended that the aspiration pipe be inserted into distilled water to ensure no bubbles are formed when AD auto zero is being carried out.
- It is also recommended to use cuvette for AD auto zero; the distilled water in the cuvette should reach more than 10mm away from the bottom of the cuvette.

4. DEVICE MAINTENANCE

4.1 Daily Maintenance

Daily maintenance is mainly for washing the flowing cuvette to keep it clean. Before testing, 10 times washing is necessary. After each test a wash is essential for 4-5 times. If there are bubbles in flowing cuvette, you may aspirate ethanol to soak and flush firstly, then wash it by distilled water. When all tests are done, please use distilled water flush.

4.2 Weekly Maintenance

Weekly maintenance is on washing the flow cell cuvette by detergent. Keep detergent in cuvette for 5-10 mins before draining. Then flush it repeatedly by distilled water.

Recommended detergent:

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

4.3 Monthly Maintenance

Daily maintenance is mainly about cleaning dust and stains on the casing, correct sample absorption amount of peristaltic pump.

5. TROUBLESHOOTING

This chapter explains all kind of malfunctions, which often happen in the routine operations. Besides, it analyzes the related reasons about malfunctions and supplies some methods against the malfunctions.

⚠ WARNINGS:

- You must turn off the analyzer, cut off the power, and then remove the power plug from the socket. The repair work must be taken by Tulip Diagnostics (P) Ltd. professional trained men.

= The analyzer must use suited power supply and voltage. Or else, the damage which is caused against this order is out of Tulip Diagnostics (P) Ltd. responsibility.

⚠ CAUTION:

- Analysis of samples may give incorrect test results in the case of instrument malfunction. If there is a fault detected in the sample, be sure to troubleshoot before use.
- Sample, quality control samples, calibration samples, wasted liquid and so on have potential biochemistry risk. The operator must comply with the laboratory regulations about the safety operator to wear personal protective device (like: laboratory protective clothing, gloves etc.), and accordance with local government regulations to dispose the waste materials generated by the instrument detection.

5.1 Malfunction phenomenon and maintenance

Please take measures to eliminate the malfunctions which occur in use or before use according to relevant troubleshooting. If the malfunctions still exist, please contact the after service of Tulip Diagnostics (P) Ltd. or our local franchiser as soon as possible.

5.1.1 Malfunction phenomenon: There are mistakes with auto zero

Possible cautions:

There is no distilled water in Cuvettes;
Cuvettes are dirty (need to wash);
There is air bubble in Cuvettes (need to wash);
Pipette is connected wrongly, leaks or blocked;
Peristalsis pump hitch;
Filter is aging or damaged;
Instrument bulb burned out.

5.1.2 Malfunction phenomenon: Wrong result or bad repetition

Possible cautions:

There is air bubble in Cuvettes (need to wash);
Peristalsis pump pipe is not installed properly or leaks; Aspiration is abnormal, need to recalibrate the pump;
Voltage is not stable, need to connect regulated power;

Whether the sample is hemolytic or whether the reagent is invalid.

5.1.3 The instrument does not work

Cause: Fuse burn-out or behind power interface is poor connected.

Maintenance: Replace the fuse, check the interface.

5.1.4 Screen definition changes

Cause: Due to the local ac voltage is different; Led display voltage is not the same, but in general all in the visible range

Maintenance: Open the instrument, find the cable of main board connecting with the display, you can see a blue 203 potentiometer; adjust the potentiometer 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 instrument, 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 long

Cause:

a) Effect of ambient temperature (Especially in winter), increase indoor environment temperature, keep the environment temperature to 10℃～30℃;

b) The heating voltage is insufficient which could lead to a longer heating time. Please open the instrument, use the digital multimeter to test the voltage of incubator heating rod, if there is no voltage, then replace the heating rod.

Maintenance: Against the possible reasons check the maintenance individually.

5.1.7 Testing time slightly long

Cause: Serum and reagent do not have enough incubation time. Or Instrument needs calibration again.

5.2 The corrections and replacements to common parts of analyzer

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

Attention

- The user must be trained by our professional engineers before they take up maintenance and replacements alone.

5.2.1 The replacements of fuse

The concrete steps of replacement are as follows:

1. Turn off the power of analyzer and pull out the power cord.
2. Pull the power wire from the power socket of mainframe 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.

Warning:

- The operator must use fuse of appointed specification.

5.2.2 The replacement to light source

The standard configuration of the instrument 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 if the lamp is damaged or has been working for 2 years.

The steps as follows:

1. 15 minutes after analyzer's turnoff
2. Open the analyzer
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 switch, enter into the instrument interface, enter into the interface of A/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.

Attention

- After changing the lamp and LED, please check and confirm the light source and cable are securely connected, and after calibration can be put into normal use.

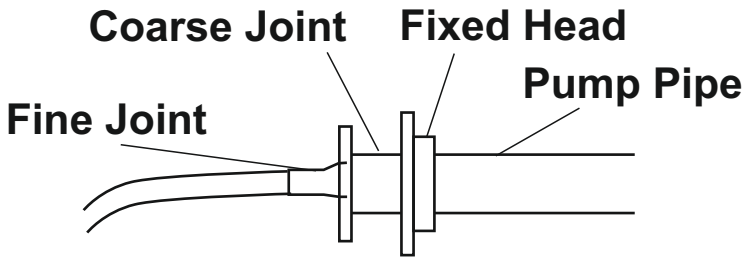
Warnings:

- Do turn off the power supply before replacing the lamp.
- It is dangerous to take replacement when the analyzer has been shut just now. Because, the temperature is very high. Wait for the temperature to decrease, then only replace the lamp.
- Do not touch the new lamp surface; it could change the characteristics of the lamp. If it is found that the lamp surface has fingerprints or other stains, it can be canceled using a cloth dipped in alcohol.
- Do not touch the new lamp surface; it could change the characteristics of the lamp. If it is found that the lamp surface has fingerprints or other stains, it can be canceled using a cloth dipped in alcohol.

5.2.3 The replacement to peristalsis pump

The steps are as follows:

1. Open the covering on the instrument side face
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 peristalsis pump on the coarse joint through the set screws
5. According to the Figure 4 connect pump pipe



Attention:

- Unplugging the pump pipe should be done very carefully, 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 Tulip Diagnostics (P) Ltd., do not use other types of pump pipe to replace

5.2.4 Replacement to printing paper

The steps as follows:

1. Open printer covering, take away the old printing paper
2. Load the new printing paper into the paper slot
3. Cut paper port to flat, put the paper to the formfeed, push tight
4. Press FEED, look the paper port to the appropriate position
5. Cover printer cover

6. TRANSPORTATION AND STORAGE

6.1 Transportation

The transportation of instruments should be done according to the contract. Transporting with poisonous, harmful and corrosive substances is not allowed.

It should be prevented from severe shocks, rain and exposure to direct sunlight, overturning should not be permitted during transportation.

6.2 Storage

It should be stored in environment temperature 5℃～50℃, Relative humidity should be not more than 80%, use well-ventilated indoor. It shouldn't be stored with toxic, harmful, corrosive materials.

CE

ISO 9001:2008 & ISO13485:2003 Certified Manufacturer

Marketed by:

Coral Clinical Systems

A Division of

TULIP DIAGNOSTICS (P) LTD.

a PerkinElmer company

CIN: U85195GA1988PTC005717

Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex Post Office, Goa - 403202, INDIA.
Tel.: +91 832 2458546-50 **Fax :** +91 832 2458544 **E-mail :** sales@tulipgroup.com **Website :** www.tulipgroup.com