SINNOWA®
英诺华

BS-3000M

User’s Manual

Sinnowa Medical Science & Technology Co., LtD

1. General Description

BS-3000M semi-automatic biochemistry analyzer is a microcomputer-based in-vitro diagnostics instrument uniting optics, mechanics and automation control in one. It is used together with the related reagents for quantitative determination of biochemical items, widely applied to various hospitals and research institutes, with the characteristics of high precision, excellent repeatability, and complete function

1.1 Configuration and Structure

BS-3000M 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; no cross contamination by using separated cuvette inspection.

2. Installations

In order to ensure the normal operation of equipment, it must be installed and debugged by the engineers who are authorized by Sinnowa or Sinnowa authorized organization. For any reason to reinstall, debug the analyzer, only the authorized engineer can do the works.

Attention :

- No authorized installation may make wrong or damage to the equipment, the problem or damage is not in term of 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 not squeezed and ensure the fluid can flow freely, the space must meet the requirements as follows:

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

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 when accident happens.

- 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: F2AL250V
6. Input power: 150VA
7. the 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 Package

2.2.1 Steps:

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 immediately with the carrier and our local dealer. If no outer damage, please open it by following steps:

-- unpack the package and check whether the packing contents are complete or not referring to packing list

-- check whether the outer appearance is damage or not

-- check whether the serial number is in accord with packing list, outer package.

2.3 Steps of installations

1. Place the instrument on stable worktable
2. Connect power supply line to the appointed power supply.
3. Put the waste pipe at the back of the instrument into waste bottle
4. Open the side cover and install 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 :

- 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 cost system 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 probe directly.

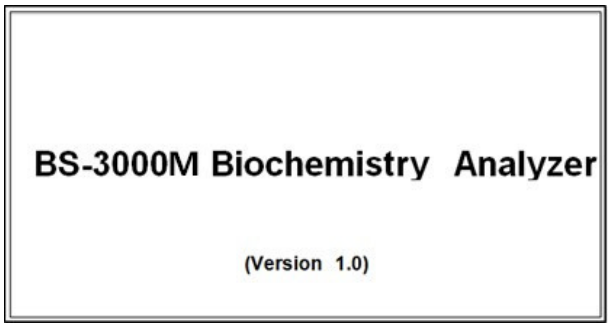
3. Test Functions and Operation

3.1 Working Principle

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

3.2 Operation

Turn on the instrument, it will show as below figure



Click on the screen, it will enter function menu as shown below:

Select keys you need

Test: To select the items to do sample test, after testing, the equipment will show the test results and

print it automatically

Edit: To add, modify, delete and print test items.

Result: Result print, 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

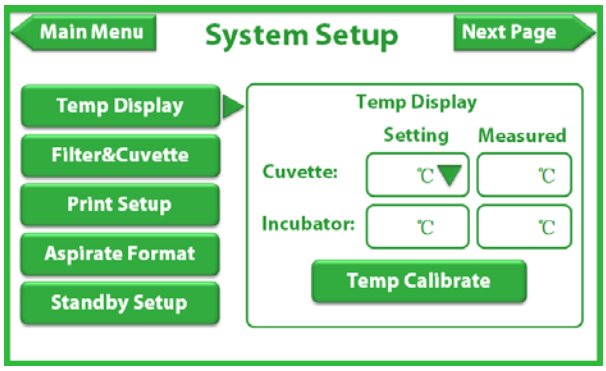
Gain: AD Auto Zero to confirm whether the instrument is in the regular test status.

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

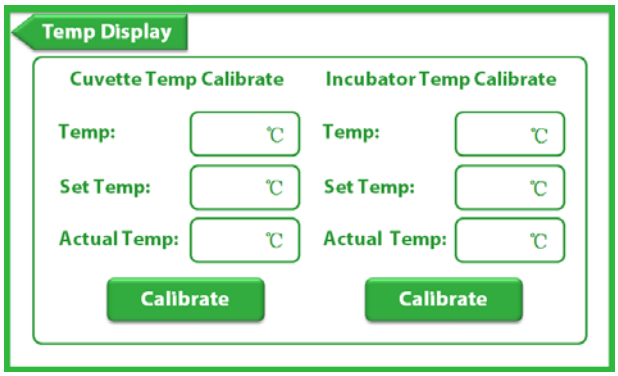
Setup: Show cuvette temperature; set filter number, cuvette diameter, language, aspiration mode, sleep mode; Hospital and instrument model title Settings; time format and date/time Settings; screen brightness settings, etc.

3.3 Parameters settings

3.3.1 Temperature display Settings



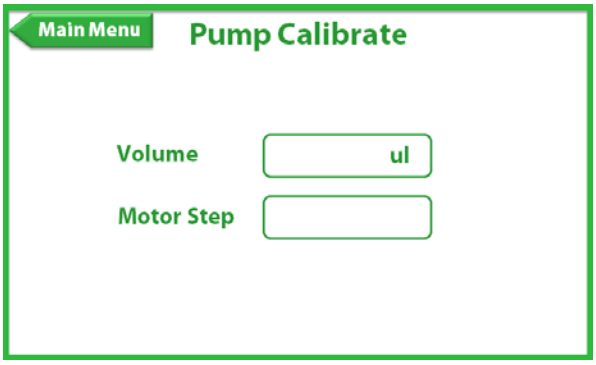
Use ▽ to choose Temperature, click main menu to save. This function can only provide the confirmation on whether temperature is right or not. When testing sample, the temperature will be shifted according to the test program. Input the password and then input calibration temperature (for professionals only). Password: 123456.



Attention:

Filter wheel, cuvette, aspiration mode, language setting, screen brightness settings, the password are all 123456.

3.3.2 Pump calibration



The default values of the instrument is that 3000ul aspiration sample volume corresponds to 20000 motor steps. When the aspiration volume is not correct, adjusting is necessary. Enter into the calibrate interface, input pump calibrate volume, then pour corresponding distilled water into the tube, insert pipette into water, press PUSH to aspirate. After the distilled water was sucked done. Press PUSH again, 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 moter steps directly.

3.4 Instrument operation key process

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 it, enter into the main interface, insert the pipette into distilled water, and then press wash to start washing, last 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 connect regulated power supply
- Instruments in the process of operation shall not open the cover, so as not to cause damage to equipment or operator
- Leakage and electrostatic prevention, the instrument should be in good grounding. Line power socket must have a reliable grounding line to guarantee in a steady state and security
- After work, wash the instrument 3 times at least immediately to keep the cuvette and pipeline from

liquid waste.

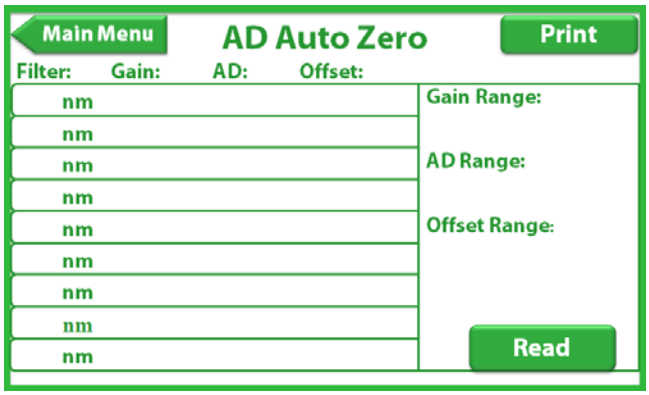
- After finish the testing, the used should be collected and disposed according to the medical waste.

- 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

Select AD Auto Zero from the main menu, the screen will show as below:

Press Push to aspirate distilled water and click Continue



And then click read

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

Attention:

- AD auto zero is that the instrument is based on water to measure the initial light intensity of different wavelength. The gain coverage, AD value and offset value are calculated together to obtain absorbance. This step is very important; users should do this step at each starting the instrument.

- AD auto zero for flow cell need more distilled water, it is recommended that the aspiration pipe should insert into distilled water to ensure no bubble when AD auto zero.
- It is also available 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 on washing the flowing cuvette, keep it clean. Before testing, 10 times washing are necessary. After each test, wash 4-5 times is essential. If there are bubbles in flowing cuvette, you may draw ethanol to soak and flush firstly, then wash it by distilled water. When all tests done, please use distilled water flush.

4.2 Weekly Maintenance

Weekly maintenance is on washing the flowing cuvette by detergent. Keeps detergent resting in cuvette 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 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 SINNOWA 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 SINNOWA's 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 SINNOWA or our local franchiser as soon as possible. We are pleasure to serve you.

5.1.1 Malfunction phenomenon: There are mistakes with auto zero

Possible causations: 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 causations: 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 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, and replace the heating rod.
Maintenance: Against the possible reasons check and maintenance individually.

5.1.7 Testing time slightly long

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

Maintenance: Serum and reagent incubate more than 3 minutes in winter it should around 5 minutes. Or reference to the manual, run the calibration procedure to calibration.

5.2 The corrections and replacements to common parts of analyzer

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:

- The user must be trained by our professional engineers before they take 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 while 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 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.

⚠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. 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 The replacement to peristalsis pump

The steps 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

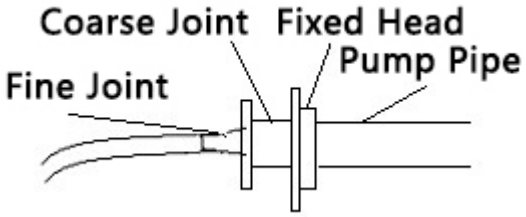


Figure 4

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 SINNOWA, 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, 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.