Ethylene Oxide Sterilizer

Model: BCS-L-138

Operation Manual

Note: Please read this manual carefully before use.

Zhejiang Bocon Intelligent Equipment Co., Ltd

STATEMENT

Thank you for choosing to use the "Ethylene Oxide Sterilizer" produced by Zhejiang Bocon Intelligent Equipment Co., Ltd.

We remind you:

- ✧ Before installing and using this EO sterilizer,please read “Instruction Manual”carefully, preserve it properly for easy access.
- ✧ Sterilizing food is strictly prohibited.
- ✧ This EO sterilizer must be maintained regularly.

CONTENT

1、Brief introduction and scope of application

A、Scope of application of Ethylene Oxide Sterilizer

For sterilization of medical devices that are resistant to ethylene oxide.

B、Brief introduction of ethylene oxide

1 Property of ethylene oxide

Ethylene oxide is a very effective low temperature sterilizer.When the temperature is higher than 10.73 ° C, ethylene oxide is a colorless transparent gas, heavier than air, and easy to liquefy. At low temperature, it is a colorless transparent liquid with chemical structure formula: H2C-CH2 = O. When volatilized, it has an ether taste and can be dissolved in water and organic solvents.

2 Principle of ethylene oxide sterilization

Ethylene oxide molecules can react with carboxyl groups (-COOH), amino groups (-NH2), hydrogen groups (-SH) and hydrogen groups (-OH) on the gene proteins necessary for metabolism in bacterial cells, resulting in alkylation reaction, replacing the unstable hydrogen atoms on the above groups, and forming a compound with hydroxyethyl root (-CH2CH2OH). Because this compound destroys the necessary reaction bases in the important metabolic reactions of microorganisms, it affects the role of bacterial enzymes, and causes the death of microorganisms.

3 The sterilization effect was tested using Bacillus subtilis black variant spore.

C、Implementation standard of this sterilizer

YY0503-2016	Ethylene Oxide Sterilizer
GB4793.1-2007	Safety requirements for measuring, control and laboratory electrical equipment (Part I: General Requirements)
GB18279-2000	Confirmation and routine control of ethylene oxide sterilization of medical devices
GB/T18268.1	Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use
GB 4793.8-2008	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-042: Specific requirements for the treatment of medical materials with toxic gases and for pressure sterilizers and sterilizers intended for laboratory use

2、Composition, basic parameters and performance of sterilizer

2.1、Composition

The ethylene oxide sterilizer consists of a sterilizing box, a heating device, a vacuum device, a humidifying device, a dosing device, a sealing device, a residual gas treatment device and a control system.

2.2、Basic parameters

Installation information:

a） Door type: fixed rotary, non-removable.

b） The maximum noise that the sterilizer can produce 65dB（A）

c） Vacuuming time: < 30min

Information for use:

a）Working temperature: 30~55℃.

b）Relative humidity: 40%～80%RH.

c）Working pressure: -40～-65Kpa (BCS-L-138)

d）Rated working pressure: -65Kpa

e）Type of sterilizing agent: 100% ethylene oxide

Other parameters are listed in the following table:

Model	Internal bladder dimension W*H*D（mm）	Nominal volume（L）	Total volume W*D*H（mm）	Equipment weight（kg）	EO gas（g）	Power（kVA）	Power supply
BCS-L-138	**430*380*840**	**138**	**960*1000*1600**	**280**	**100**	**2.3**	**220V/50Hz**

2.3、Performance

1 The temperature of the surface of the sterilization chamber does not exceed the set temperature of the sterilization stage by ±5℃..

2 The temperature in the empty sterilization chamber during the sterilization stage does not exceed ±3℃ of the set temperature..

3 When the temperature in the sterilization chamber exceeds the set temperature by 3°C during the sterilization stage, "Temperature abnormal" displays in the message area.

4 At the stage of vacuuming, the vacuum system can evacuate empty sterilizing chambers to -65Kpa or lower; the time required to evacuate from atmospheric pressure to -65Kpa is less than 30 minutes.

5 The leakage rate of the sterilization chamber complies with the following:

a）Sterilization chamber leakage is an important indicator of sterilizer safety and sterilization effectiveness, leakage rate of negative pressure measurement, test pressure -65Kpa (BCS-L-138).

b）Determination of leakage rate should be carried out under the conditions of no load, constant temperature of the sterilization chamber, and measurement time t≥1h.

c) Average leakage rate ≤ 0.1Kpa/min during determination time.

d) Indoor ethylene oxide residues<2PPM.

3、Characteristics of sterilizer

A 、 Negative pressure sterilization, negative pressure cleaning, negative pressure residue removal, the whole process of negative pressure to ensure safety!

This sterilizer belongs to class B sterilizer, the sterilization temperature can be adjusted in 30℃~55℃.

Sterilization, cleaning and residue removal processes, the sterilizer always maintains a relative negative pressure to ensure that ethylene oxide does not leak. Even if leakage occurs, the control system will automatically detect the leakage, and automatically abort the sterilization process to send an alarm, and automatically discharge the ethylene oxide gas.

B、Residue removal and aeration

When the sterilization process reaches the end of the cleaning process, it automatically enters the residue removal (to fully ensure that the EO residue of the sterilized articles is minimized).

C、Continuous temperature monitoring

Sterilization stage temperature is maintained within the selected temperature ± 3 ℃, once the temperature sensor detects a deviation from the predetermined temperature of 3 ℃, then the over-temperature protection device is automatically activated, and the text prompts the temperature abnormality and alarm, and interrupt the heating.

D、Humidity control

The humidity sensor is open and displayed throughout the sterilization process. According to the set humidity value, humidification is uniformly applied several times to ensure the right humidity level.

F、Automatically control of puncturing EO gas cartridge

Only when the dosing process is entered normally will the system automatically activate the dosing unit, puncturing the EO gas cartridge and releasing the ethylene oxide gas.

G、Sterilization process status display

Located in front of the liquid crystal display real-time continuous display of the sterilization process status. (e.g. temperature, humidity, pressure, time, sterilization process, etc.)

4、Installation requirements and working conditions

1） environmental conditions:

- Use indoor.
- The altitude is below 3000m.
- Environment temperature within the range of 5°C to 40°C
- Maximum relative humidity of 80% at environment temperature below 31°C and a linear reduction of 50% at 40°C.
- Transient overvoltage facility category (overvoltage category) according to Class II

2) Installation room requirement：

A clean, non-humid, non-corrosive gas, well-ventilated special room, the area should be >10m2.

In order to make the sterilizer smooth and not tilted, the floor level where the sterilizer is placed should be kept horizontal. In order to facilitate maintenance, the sterilizer should be placed 1 meter away from the obstacle (wall) at the back, left and right sides, and the front should be kept at a distance of more than 2 meters from the obstacle, with a floor load of ≥1500kg/㎡.

The room where the sterilizer is placed should be ventilated, and the back of the sterilizer is reserved for the network interface.。

3）Water supply requirement：

If floor drain discharge: there should be water and independent drainage pipes, pipes should be stainless steel, aluminum-plastic, PPR, PVC and other corrosion resistant pipes, pipe connections must be sealed well, do not allow leakage.

If directly discharge: it should be equipped with special inlet and exhaust pipes, and the pipes should be made of stainless steel, aluminum-plastic tubes and other ethylene oxide-resistant pipes, and the pipe connections must be well sealed without leakage, and the back of the equipment should have reserved water inlet, drain and exhaust port.

4）Power requirement：

a separate power supply: socket with ground protection; Adapt to the equipment specified current and voltage interface, shall not be mixed with the power supply of other equipment, the equipment 50CM within the debris or other flammable items are not allowed.

voltage: 220V

frequency: 50Hz：

power: 2.3KW

5） water requirement: water source pressure value of not less than 0.1MPa, flow rate of not less than 1m/s.

6） after the sterilizer is placed, do not move it casually; there is a humidified water tank underneath the equipment, and distilled water needs to be added regularly.

7） service life

Because the sterilizer is mainly composed of sterilization chamber and electrical control system. Electrical control system, parts can be updated in time, so its safe use cycle is mainly determined by the sterilization chamber. The material selected for the sterilization chamber is SUS304, which has good corrosion resistance to EO, so it can be safely used for 2400 sterilization cycles (8 years) under timely replacement of parts, good equipment maintenance and good working environment. After the sterilizer is scrapped, it should be recycled by qualified recycling company.。

8） production date:see label for details

5、How to use the sterilizer

1 Introduction of sterilization cycle

When the sterilization temperature exceeds the high temperature, the system over-temperature protection device is forced to interrupt the heating power supply.

◆ The sterilization temperature range is 30℃~55℃ based on kinds of items. The sterilization temperature can be set before sterilization process begins. Once the sterilization process has started, it cannot be set again.

◆This sterilizer is a full-automatic sterilizer, as long as the system starts normally after the door is closed, the system will be sterilized automatically according to your pre-selected sterilizing parameters without human intervention until the sterilization is completed; all abnormal conditions will have information and alarm prompts.

◆Sterilization process: heat→keep warm→ pre-vacuum→ dwell pressure→ humidification→ EO inject →sterilization→ clean→ residual remove→end.

1）heat：

（a）Heat is supplied to the sterilizer through an electric heating belt, and the system is controlled by full thermostatic PID control. The operator can observe the pre-heating situation through the display on the LCD touch screen (the temperature shown on the screen is the temperature in the sterilization chamber);

（b）When the sterilizer temperature reaches the preset value, the system automatically enters the "keep warm" process;

（c）When the sterilizer heating failure, the alarm interface has text prompts "heating abnormality" and alarm, the system automatically cuts off the sterilization process; "status display" changes to "abnormal alarm" and flashing.

2）keep warm:

（a）In the "keep warm" process, the system can automatically according to the pre-set heat preservation time heat preservation and ultra-low temperature check to meet certain process requirements;

（b）Time range of keep warm: ≥5 min;

（c）When the holding time reaches the preset value, the system automatically enters the "pre-vacuum" process;

（d）When the sterilizer temperature control failure, the system alarm interface has text prompts "temperature abnormality" and alarm; "status display" becomes "abnormal alarm";

（e）When the human abort the sterilizer "heat preservation" process, the system has a text message "Push the "OK" button to break off the current cycle, are you sure?", push the " OK" button after the system to cut off the sterilization process.

3）pre-vacuum：

（ a) Vacuuming time varies depending on the preset pressure value,Time from atmospheric vacuum to -65Kpa should be ≤30min;

（b）Pre-vacuum preset pressure: -55or -65Kpa;

（c）When the vacuum level in the sterilization chamber reaches the preset value, the vacuum pump stops working. The pressure is maintained for a period of time and then automatically enters the pressure preservation state;

（ d ） In case of pre-vacuum failure, the alarm interface will indicate "pre-vacuum abnormality" and alarm, and enter residual removing process;

（e）When the human abort the sterilizer "pre-vacuum" process, the system has a text prompt "Push the "OK" button to break off the current cycle, are you sure?", push the "OK" button after the system to cut off the sterilization process and enter the residue removal process

4）dwell pressure：

（a）In the "dwell pressure" process, the system can start to detect leaks according to the pre-set dwelling pressure time to meet certain process requirements;

（ b) When the preset pressure is reached, all valves connected to the sterilization chamber are closed and at the same time the vacuum pump stops working. The pressure in the sterilization chamber is monitored for a preset time of at least 3 min, during which the pressure rise does not exceed 0.3 Kpa/min;

（c）When the dwelling pressure time reaches the preset value, the system automatically enters the humidification process;

（d) Set the permissible fluctuation range of sterilization pressure, the system detects the pressure change every five minutes, set the pressure leakage rate in the user settings, and the value shall not be less than 0.3Kpa, calculate the permissible difference in pressure after five minutes through the set pressure leakage rate to determine whether the pressure leakage is abnormal, and output the "abnormal pressure" alarm.;

（e) When the human abort the dwelling pressure process, the system prompts "Push the "OK" button to break off the current cycle, are you sure?", after pushing "OK" the system to cut off the sterilization process and enter the residue removal process.

5）humidification：

(a) As humidity will have a certain lag, before humidification to confirm that the humidity setting is not too high, and do not exceed 80%RH (humidity setting range:

40%RH ～ 80%RH);

（b） After entering the "humidification" process, the system will automatically start the automatic humidification system automatically humidified, when the humidity reaches the preset value, the system automatically enters the "EO injection" process;

(c) Steam generator for humidification systems that automatically generates steam and adds it to the sterilization chamber;

(d) Humidification process failure, the system information area text prompts "humidification abnormality" and alarm, and at the same time cut off the sterilization process, transfer to residue removal process;

(e) When the humidification process of the sterilizer is suspended artificially, the system has a text prompt "Push the "OK" button to break off the current cycle, are you sure?", after pushing the "OK" button the system cuts off the sterilization process and and enter the residue removal process.

6）EO injection:

（ a ） "EO injection" system is also a fully automatic dosing method, the system automatically starts the "dosing" program dosing; when the first dosing fails the system tries to carry out the second dosing, if the second dosing fails, it enters the "clean"process;

（ b ） When the cartridge puncture is successful, the system will prompt "Perforating succeeded!"; After the puncture is successful, the EO release process will be automatically entered for 10 minutes. When the timing is over, the system will prompt "EO injection succeeded!";

（c）If the dosage is successful, it automatically enters the "sterilization" process;

（d） When the dosage fails, the system information area text prompts "dosage failure, cleaning..." and alarm, at the same time cut off the "sterilization" process, into the "cleaning".

7）sterilization：

(a) Sterilization time≥1hour, time to the minute；

(b) Continuous monitoring of all parameters during the sterilization process via LCD touch screen;

(c) In the sterilization process, temperature, pressure and humidity for the whole process of detection, once abnormal, the system has the corresponding text prompts and alarm;

(d) Sterilization process after the start is not allowed to stop artificially, if an accidental power failure occurs after the power to continue the unfinished sterilization process;

(e) When sterilization is finished, the system will prompt "Sterilization succeeded!".

8）clean:

(a) This process is to remove the remaining ethylene oxide from the sterilization chamber;

(b) The number of cleaning times n ≥ 3, the maximum set number of times is 99, before the number of cleaning times less than three times for the mandatory cleaning process, the process can not be artificially aborted.;

(c) washing pressure: -30Kpa ～ -65 Kpa;

(d) When "cleaning" is complete, proceed to the "residual remove" process.

9）residual remove:

（a）time of residual removing≥3hours;

（b）When the sresidual removing is completed, the system has a message prompt. If the system has completed normal sterilization, the text message in the system information area will read "Sterilization complete";

（c）If the equipment malfunctions during the sterilization process and displays an alarm, it does not display "Sterilization complete" after the removal of residues is completed.

Requirement of sterilization cycle:

（1） The fault handling and alarm measures during the sterilization process please see 7、Fault handling and alarm.

（2）Intervals between any of the processed should not exceed one hour during the sterilization process。

（3） Residual gases from the cleaning and residue removal process must be treated in water and through a residual gas treatment unit before being discharged to the sewer.

（4）Residual gas treatment is set below the sterilizer, where the operator can not easily access, to ensure operator safety.

（5）Each time, a "cycle" is recorded after equipment startup (including startup in the event of a malfunction).

10）air lead-in:

Air is introduced into the sterilizing chamber through a filter until the pressure in the sterilizing chamber is within ±10Kpa of the environment pressure.

11）end of cycle:

When the pressure inside the sterilizer is close to atmospheric pressure, wait for 5 minutes, the door of the sterilizer will automatically pop open the gap, at this time you can open the door to take out the sterilized load.

2 Preparation before operating the sterilizer

 note: Please follow the operating procedure strictly to operate the sterilizer!

1) prepare sterilized items

Sterilized items are sorted and thoroughly cleaned and rinsed to remove mucous membranes, blood stains, or other organic matter. Items are also dried and water droplets are removed.

2）packaging

Before sterilizing, sterilized items are sealed and packaged in paper-plastic bags (or other packaging).

3）placement

Place the packaged items to be sterilized in the basket with gaps between the items. For paper-plastic bags, be sure to place them in a regular and orderly manner with the paper side facing the plastic side.

Basket loading rate of not more than 80%.

4）placement of bio-indicators

Each batch of sterilized items should be placed with biological and chemical indicators to test the effectiveness of the sterilization process.

5）door open

Observe the LCD touch screen pressure display at atmospheric pressure, click on "open door".

6) install EO gas cartridge

Note: a）Replacement of a specific cartridge is required for each sterilization.

b）Only after the LCD touch screen displays the operation interface, the cartridge can be installed.

Insert the cartridge with ethylene oxide into the cartridge tank and rotate the cartridge locking device to press the cartridge tightly.

! Attention
Don't press the cartridge down too hard. Otherwise, the cartridge will be

punctured prematurely and the ethylene oxide will leak. If it is still difficult to place the cartridge, remove the cartridge and check for blockage in the tank.
Visually, the tip of the needle should be about 10 mm lower than the plane of the needle base 。

7) placement of basket

Place the basket, already loaded with items, into the chamber and close the door.

8）liquid level indication

If the touch screen prompts "water level in the tank is low, please check the water level", the operator needs to add a certain amount of distilled or purified water to the water cup, otherwise the equipment can not run normally (note that the water level in the water cup should not exceed 6/5 of the volume of the water tank, and should not overflow the water tank when adding water).

3 Operation of sterilizer

1) turn on the power

The power switch is in the upper left corner of the equipment panel。

Turn on the sterilizer power switch. The power indicator at the lower left end of the LCD touch screen lights up. The system enters the power-on interface, e.g., (Fig. 2). Note: The sterilizer should always be powered on during the sterilization cycle.

2）operation interface

The operation interface displays the parameters of the equipment, operation status, alarm records, data, as well as the start and stop of the sterilization process, and the opening and closing operations of the sterilizer door. Such as: sterilizing temperature, sterilizing humidity, sterilizing pressure, sterilizing time， and the status of the sterilization process. The "door open" and "door closed" display is the current real-time position of the sterilizer door, double-door equipment will have an additional back door switch button indicator, and the front and back doors can not be opened at the same time (Fig. 1).

Fig. 1

3）parameter setting

Click the "set" button at the bottom right of the "operation interface", and select the "User Parameters" option. Enter the "User Parameter Setting" setting interface (please refer to Fig. 2 and Fig. 3). Note: Manufacturer's parameters require a password to access. User is not allowed to modify.

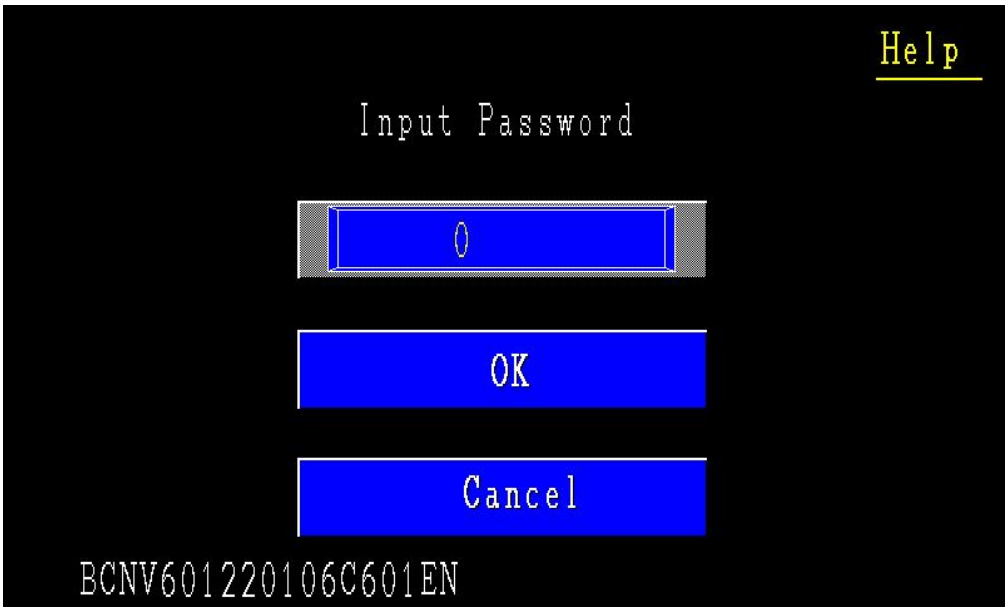

Fig. 2

After entering passing word, the user can set the "user parameter" according to the actual use situation.

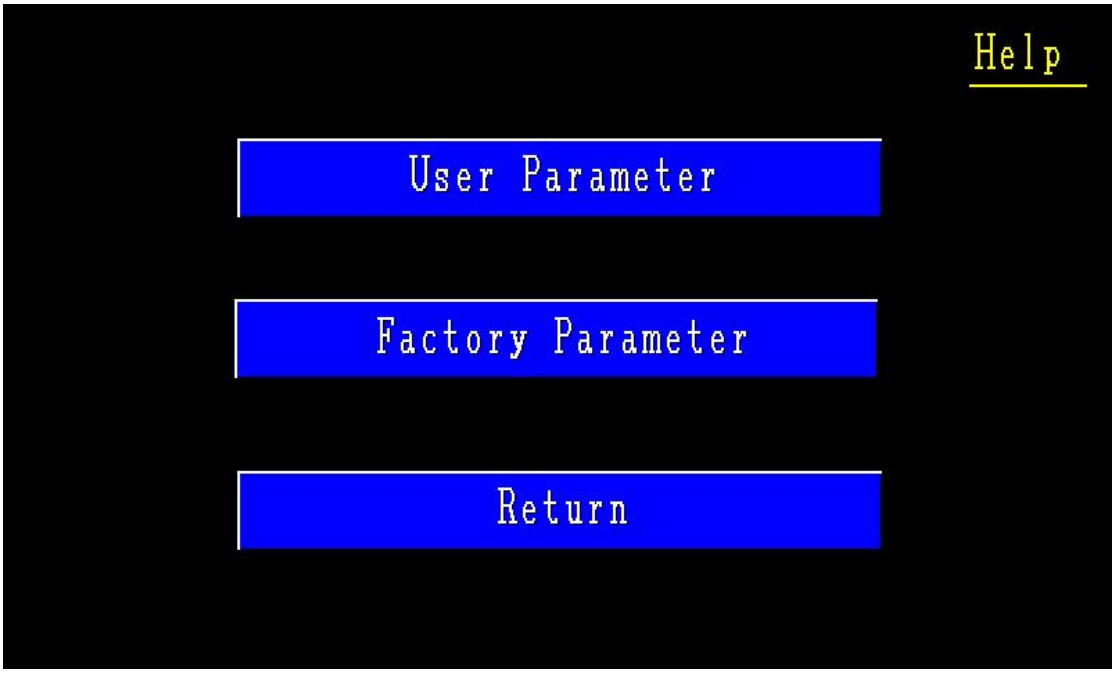

Fig. 3

The users can set the parameter in the interface of “user parameter” (Fig.4)

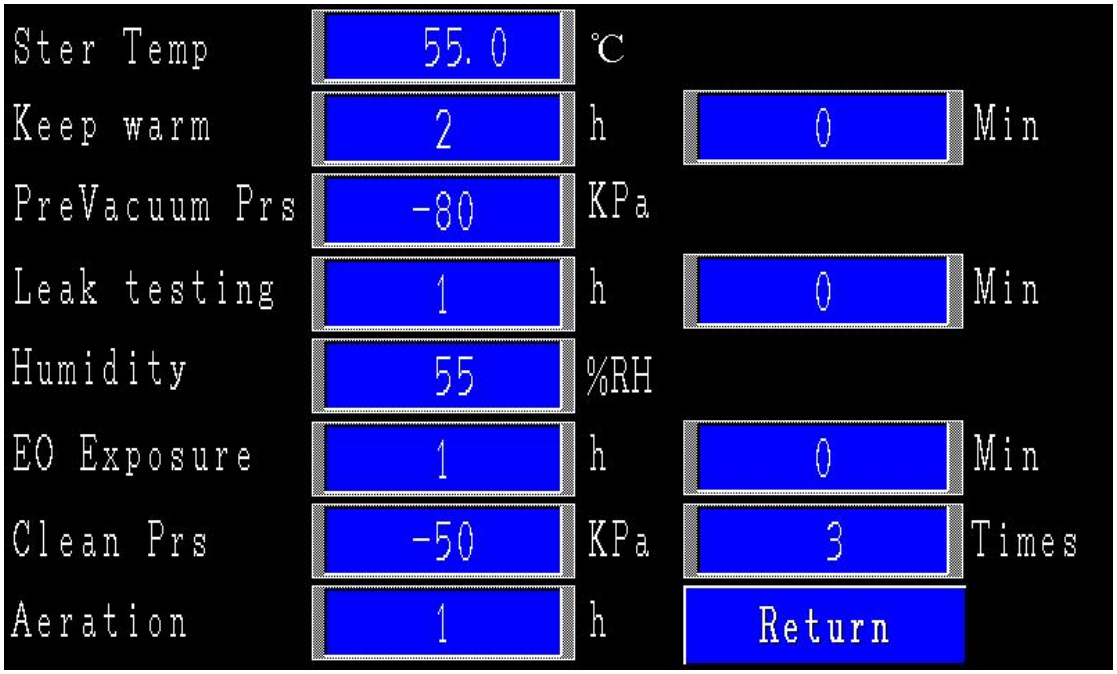

Fig. 4 Interface of “ user parameter

Recommended reference values are as follows:

set sterilization pressure: -40 Kpa ～ -65Kpa;

set humidification value: 40%RH～80%RH;

set clean pressure: -30 Kpa ～ -65Kpa;

set clean times: 3～99 times;

set time of residual removing: 3h～99h;

set 55℃ sterilization time: 1h～24h;

set 37℃ sterilization time: 1h～24h;

3) After confirming the setting of the above parameters, return to the operation interface.(Fig. 2)

4）Start and stop

Ensure that all user parameters are correctly set.

Push the " open" display, the door is automatically locked, at this time the red "open" display changes to grenn "closed" ; Press the "start" button and the sterilization system automatically enters the working process.The normal sterilization sequence is: heat→vacuum→humidify→ EO inject→EO dwell→flush→aerate. Every time the "start" button is pressed, the system automatically records one "cycle".

After the system is up and running, if the users want to terminate the sterilization process, press the "Stop" button, a prompt box will pop up to confirm the shutdown (Fig. 5), click on the "OK" button to terminate the operation of the system. Note: Sterilization processes are not allowed to be terminated from the "dosing" stage to the "cleaning" stage. In the " residual remove", the equipment can be stopped. By clicking the "Cancel" button the system continues the previously unfinished sterilization process. Once the prompt box disappears, the users can unlock the sterilizer and take out the sterilized items.

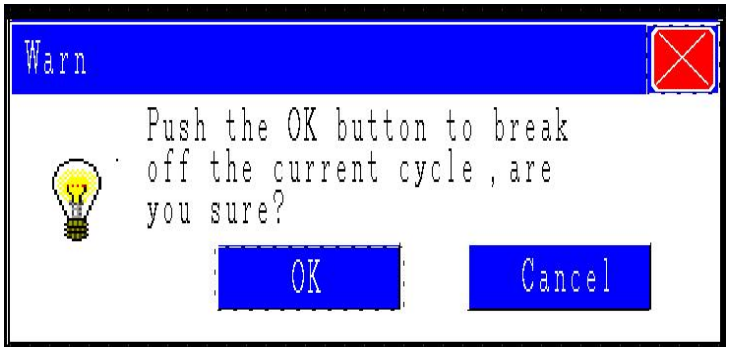

Fig. 5

5）Sterilization completed and take out items

After the sterilization cycle is successfully completed, the words "heated time" in the

down left corner of the Run screen will change to "completed" (Fig.6) and an alarm will sound. The door would not open automatically which requires operators to touch "Closed" button to open the door.

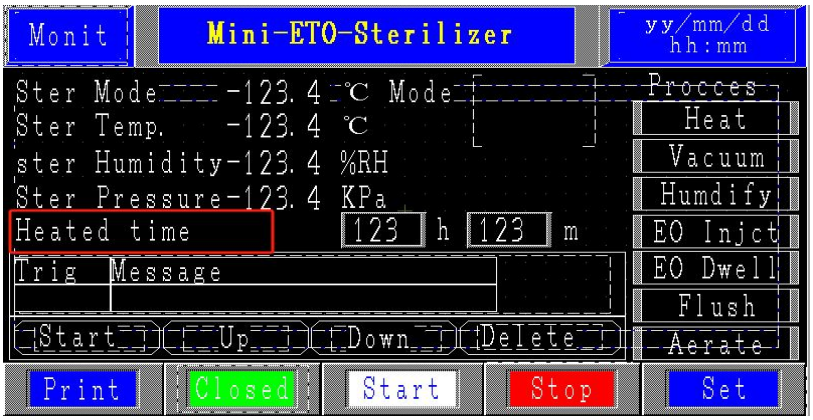

Fig. 6

6）Alarm and view progress records

A red light blinks at this position on the screen, and the alarm message is displayed in the message..(Fig. 7)

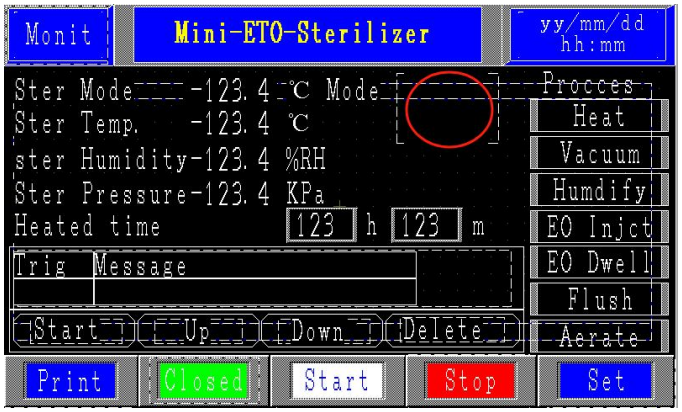

Fig.7

In the Fig.8, theplace circled in red is the message area

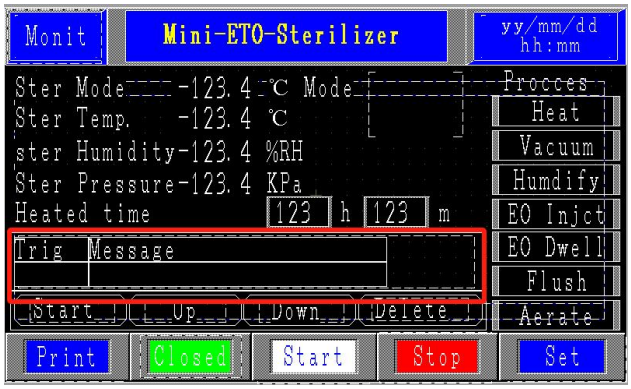

Fig. 8

7）Data record

Click "print" in the lower left corner of the main interface to enter the print interface, there are two choices for the print content Select the current batch and the last batch.(Fig. 9)

Fig. 9

Push"Monit" in the upper left corner of the main interface to enter the curve interface.(Fig. 10)

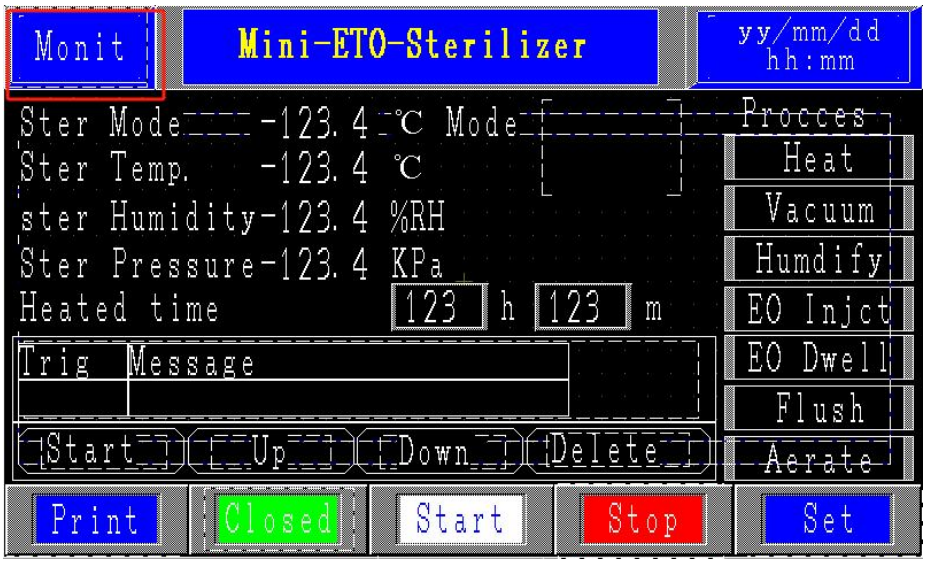

Fig. 10

6、Maintenance

- The inner chamber, door and seal of the sterilizer should always be kept clean and clear of other foreign matter. Especially the door seal ring should be wiped well with a damp dry cloth every week. Door sealing ring daily if broken should contact the manufacturer in time.
- Please frequently check the water cup level indication (if the touch screen prompts "abnormal level, please add water...", the operator needs to add water to the water tank in time). Please note that the water level of the water tank shall not exceed 5/6 of the volume of the water tank, and the water shall not overflow the water tank when adding water.
- The use of units should be in accordance with the relevant provisions of the National Measurement Law on a regular basis on the calibration of measuring instruments, and the daily operation of measuring instruments found to be inaccurate should be sent to the test in a timely manner.
- Check wires, screws, grounding terminals, etc. monthly for secure contact to prevent loosening.
- Air filters should be cleaned every year of operation.
- Regularly check the condition of water storage tank piping connections.
- Please contact the manufacturer for the component replacement。

  Note: maintenance should be carried out with the equipment disconnected from the power supply and in a safe condition.

7 、Fault handling and alarm measures

In the sterilization process, if there is a malfunction, it will be indicated in the text and alarm on the screen.

Fault before dosing: should be timely troubleshooting, restart sterilization.

Fault after dosing: the system automatically enters the cleaning process.

Fault 1: abnormal abort heating

Check that the temperature display is rising and that the set parameters are correct.

Check if the heating timeout is not exceeded and if the setting parameters are correct.

Fault 2: abnormal abort keeping warm

Check whether the system is stopped and the device is powered off.

Fault 3: abnormal abort pre-vacuuming

Check whether vacuuming times out and the parameters are set correctly.

Fault 4: abnormal abort leakage

Check the cabinet for air leakage.

Check whether the pressure sensor value is correct

Fault 5: abnormal abort humidification

Check whether the humidity is displayed and the Settings are correct.

Check the water level of the cup and the temperature rise of the humidifier.

Check whether humidification times out and the parameters are set correctly.

Fault 6: abnormal abort EO injection

Check that the gas cartridge is placed in the correct position.

Check the dosing puncture device for failure.

Check the tightness of the inner cavity of the sterilizer.

Fault 7: burst abort

Check whether the system is stopped and the equipment is powered off.

Fault 8: abnormal abort removing residual

Check whether the system is stopped and the equipment is powered off.

Fault 9: abnormal abort cleaning

Check the fluctuation range of sterilization pressure.

Check the tightness of the inner cavity of the sterilizer.

Fault 10: the temperature sensor in the cabinet is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 11: the pressure sensor in the cabinet is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 12: the humidity sensor in the cabinet is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 13: the heating plate temperature sensor of the cabinet is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 14: the temperature sensor on the interlayer is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 15: the temperature sensor of the steam generator is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 16: the temperature sensor of the cabinet door is faulty

Check whether the sensor works properly.

Check whether cables to the sensor are correctly connected.

Check whether the PLC module and transmitter are working properly.

Fault 17: the liquid level is too low and alarm

Check whether the liquid level sensor and cables are normal.

Fault 18: the door is not closed well and alarm

Check whether the limit switch of the door lock works normally and whether the feedback signal of the limit switch is normal.

Fault 19: temperature abnormal alarm

Check whether the temperature deviation has exceeded the set range and whether the set value is correct.

Fault 20: pressure abnormal alarm

Check whether the pressure deviation has exceeded the set range and whether the set value is correct.

Check the tightness of the inner cavity of the sterilizer.

Fault 21: humidification abnormal alarm

Check whether the humidification deviation has exceeded the set range and whether the set value is correct.

Check whether the humidification and water absorption time is reasonable.

Check whether the humidifier liquid level is too low.

8、Notice

Sterilization load must be placed in the basket, the basket can be sterilized in the sterilization chamber, it is strictly prohibited to directly put the sterilization load into the sterilization chamber！

Loading of sterilized items

The walls and doors of the sterilizing chamber should not be touched when loading sterilizing items. Sterilized items should be placed in a sterilized basket made of metal.

Loading of sterilized baskets

Sterilized items should be placed loosely in the basket. The maximum volume cannot exceed 75% of the basket volume.

The kit should be placed vertically or diagonally so as to avoid shielding each other (ensuring that the paper side of the package is in full contact with the sterilizing medium). Large horizontal items should avoid condensation. Packaging items are best placed on the side, paper and paper face, film face and film face, so that the film will not cover the paper.

Ethylene oxide gas is flammable, explosive and toxic, and should be used especially in strict accordance with the specified requirements to prevent accidents!

1 Safety requirements for ethylene oxide use

1) The sterilization room shall be equipped with fire prevention facilities.

2) Ethylene oxide cartridges should be stored separately in a dry and well-ventilated room, and no fireworks are allowed.

3） Sterilization room lighting should be explosion-proof lamps to eliminate all electrical appliances that may spark, and open flame is strictly prohibited.

4） At the end of sterilization, the explosion-proof axial flow fan should be opened before opening the door to pick up the material to ensure that the door is opened to pick up the material in a ventilated environment.

5）If the ventilation system in the worKplace fails, the equipment should be turned off and cannot be started. If the worKplace ventilation system fails when the operation cycle is in the process where the gas sterilizer has entered the sterilization chamber, contact with the sterilizer should be made after the sterilization agent elimination process and

the flushing process are all completed.

6）After use, the ethylene oxide cartridge bottle should be treated as medical waste.

Users in the worKplace there is a possibility of sterilization gas fugitive accumulation of local areas, such as the door of the sterilizer, has been sterilized articles storage area, sterilization agent storage area and other areas should be configured with local exhaust system, exhaust system emissions should not cause danger.

2 Disposal of ethylene oxide leaks

In the sterilization process, if there is a significant change in the pressure of the sterilization chamber, indicating that there is leakage or leakage in the sterilization chamber, the vacuum pump should be started immediately, all the ethylene oxide gas in the sterilization chamber should be extracted, and then the power supply should be cut off for inspection and disposal. If necessary, open the window for ventilation, open the axial fan, and then dispose.

3 Disposal of personnel after exposure to ethylene oxide

1) respiratory contact:

Excessive inhalation of ethylene oxide can cause respiratory irritation, dizziness, weakness, nausea and vomiting (either immediately or afterwards), chest pain, and neurotoxic reactions. If excessive exposure to ethylene oxide, go outside immediately to inhale fresh air and go to the hospital as soon as possible.

2) eyes contact:

Liquid ethylene oxide splashed into the eyes can cause serious eye injury, high concentrations of ethylene oxide gas can cause serious eye irritation. If the above situation occurs accidentally, immediately rinse the eyes with water for at least 10 minutes, and then go to the hospital for treatment.

3) skin contact:

Liquid ethylene oxide can cause skin irritation, dermatitis and blisters. In case of skin contact with liquid ethylene oxide, immediately wash with water for at least 15 minutes, at the same time take off clothes, wash the contaminated area with water and soap, and go to the hospital as soon as possible.

4) Digestive tract contact

Digestive tract contact with ethylene oxide is an uncommon contact route. Liquid ethylene oxide enters the digestive tract and is corrosive, which can cause severe irritation and burn to the digestive tract mucosa. If this is the case, you should drink 1 to 2 glasses of water, touch the back of the throat to cause vomiting (delirious people can not cause vomiting), and go to the hospital immediately.

4 Storage environment of ethylene oxide

——cool, low temperature (≤25℃), ventilation;

——avoid light, sun, collision;

——keep away from fire;

——explosion-proof appliances should be used in the storage area;

5 Please read the relevant contents on the nameplate carefully before use!

Warning: Operators should avoid contact with dangerous live parts!

Sign：

protective conductor terminal

read the operation manual before use

electric shock carefully

see the instructions for other details

6 Power supply precaution:：

Wires with yellow and green outer layers are used to connect the protective conductor terminals.

Protective switches or fuses should be selected with reference to the rated current of the equipment more than two times. The switch or fuse is for disconnecting the power supply 220V and is installed in a fixed place and must ensure that the protective ground wire is not disconnected.

The socket must fit the sterilizer plug, no unauthorized plug changes. That is, specialized plugs and sockets!

If the power cord needs to be extended, its plug and socket need to match.

7 Precautions for humidifying water tank

1）When adding water, do not top up, do not exceed 600mL.

2）If there is any spillage when adding water, sassafras should be cleaned up immediately with a dry cloth.

3）The water tank should be kept empty during handling.

4）Distilled water for humidification.

5）When adding water, be careful not to spill water on electrical parts.

6） When adding water, the operator should be careful not to come into contact with electrically charged parts.

7）Check the cup level indicator before using the equipment. If the touch screen displays "abnormal liquid level, please add water..." The operator needs to add water to the water cup, otherwise the equipment cannot operate normally (pay attention to the water cup must not be >600mL).

8 Precautions for operators:

1) Sterilizer operators, maintenance personnel and sterilization process monitoring personnel must be trained by the plant's personnel before they can operate the sterilizer independently. Operators, maintenance personnel and process monitors should be familiar with the safe operation of the sterilization process and the sterilizer as well as the measures to be taken in the event of sterilant leakage.

2) After the installation of the sterilizer, the installer of the plant is responsible for the training of the equipment operation and maintenance personnel of the use unit and the monitoring of the sterilization process.

3) Ethylene oxide sterilization procedures must be monitored by personnel knowledgeable in the safe use of ethylene oxide sterilizing agents.

4) Sterilizer operators, maintenance personnel and sterilization process monitoring personnel must read the operation manual in detail before starting work.

5) The users should be used annually for ethylene oxide sterilizer operators, maintenance personnel and sterilization process monitoring personnel for ethylene oxide sterilization process and equipment overhaul training and records.

9 Other notes

1） Observe the pressure display on the touch panel when opening the door, do not open the door immediately if positive pressure is present.

2） Before starting the program, open the settings to see if the parameters meet the process need.

3） After dosing, it must be cleaned three times before entering and removing residue for one hour before opening the door.

4） Residual gases from the sterilizer must be passed through a residual gas treatment unit.

5） The residual gas treatment device provided by our factory is a special device of the equipment, so it cannot be disassembled for other purposes.

6） Contact the manufacturer for replacement of any parts.

7） If the users do not work in the manner specified by the manufacturer and does not follow the instructions for normal operation, the protection of the equipment may be damaged.

8） The operators take care to avoid contact with dangerously energized parts!

9） Sterilized items should be placed in the analysis room for forced analysis if they need to be further analyzed.

10） Battery type LR6-1.5V, mercury-free alkaline battery.

11） Do not leave the equipment in a location where it is difficult to disconnect the power plug.

10 Operator

1) Sterilizer operators, maintenance personnel and sterilization process monitoring personnel must be trained by the plant's personnel before they can operate the sterilizer independently. Operators, maintenance personnel and process monitors should be familiar with the safe operation of the sterilization process and the sterilizer, as well as the measures to be taken in the event of leakage of the sterilizing agent.
2) After the installation of the sterilizer, the installer of the plant is responsible for the training of the equipment operation and maintenance personnel of the using unit and the monitoring personnel of the sterilization process.
3) Ethylene oxide sterilization procedures must be monitored by personnel knowledgeable in the safe use of ethylene oxide sterilizing agents.
4) Sterilizer operators, maintenance personnel and sterilization process monitoring personnel must read the operation manual in detail before starting work.
5) The users should be used annually for ethylene oxide sterilizer operators, maintenance personnel and sterilization process monitoring personnel to carry out ethylene oxide sterilization process and equipment overhaul training and make records.
6) If the users are testing temperature/pressure/humidity, please use the wireless sensing equipment that has been measured by the national metrology department.
7) Ethylene oxide concentration alarm instrument alarm first open the ventilation device, indoor concentration of ethylene oxide is less than 2PPM personnel can enter the scene.
8) Adopt the ethylene oxide concentration alarm instrument that meets the relevant

national requirements.

9) Regular training on the overhaul of the process must be conducted and a record kept of each person's attendance and accomplishments.

10) Regularly check the various connections, screws and other components.

9、Accessories list

Model: BCS-L-138

No.	description	model
1	button switch	LB22C-P20Z/E+DYG220V/S(L)
2	miniature circuit breaker	C10/C16
3	switching power supply	LRS-50-24
4	miniature relay	MY2N-GS AC220/240
5	axial fan	QA12038HBL
6	PLC	6ES7288-1SR60-0AA1
7	air compressor	built-in/external
8	solenoid valve	Air Tac/SMC
9	vacuum unit	DA-20D/EV-10
10	electric heating tape	CYS-1000
11	buzzer	5-36V
12	two-position five-way solenoid valve	4V220-08
13	touch screen	GP4402WW
14	temperature transmitter	PT100
15	PLC Expansion Modules	DT08/AE04

16	temperature sensor	PT100
17	humidity sensor	TRH-100/4～20mA
18	pressure sensor	±100Kpa/4-20mA

Appendix

Sterilizer EO cartridge installation place