Large Scale Ethylene Oxide Sterilizer

Model SDEO2.0

USER'S MANUAL

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Product Introduction

SD series large ethylene oxide sterilizer is the latest computer-controlled fully automatic sterilization equipment developed and produced by our company. Its technical level and manufacturing process are in the leading position in China. This product is composed of a microcomputer PLC control system, a vacuum sterilization chamber system, a constant temperature system, and a residual gas treatment system. When in use, only one button is needed to realize complex processes such as automatic heating, vacuuming, vaporization, sterilization, and residual discharge. It is very convenient and safe, with a sterilization rate of 100%. At the same time, this equipment has a single tank dosing (small) and ethylene oxide mixed gas, which has the characteristics of * flame retardant, * explosion-proof, * strong penetration, * efficient

broad-spectrum sterilization, * short sterilization time, * no corrosion, * no residual toxicity, * no pollution to the environment, etc. This product has unique advantages in sterilizing and disinfecting items that are afraid of moisture and heat. At present, it is widely used in the fields of medical and health, industry, foreign trade, commerce, banking, archaeology, archaeological archives management and cultural relics management.

Installation Requirements & Precautions

1. 1. Installation Requirements

1. The sterilizer should be installed in a Class A medical device workshop. The workshop should be connected to power supply, water source, drainage, explosion-proof ventilation, lighting and electrical facilities. There should also be a dedicated grounding device.

2. The installation location of the sterilizer should ensure a certain amount of space around it. It is generally recommended that the two sides and the back be 80-100CM away from the wall for installation and maintenance. There should be enough space in front of the sterilizer door to ensure that the sterilized items can be easily entered and exited.

3. The sterilizer should be placed as horizontally as possible.

4. The power supply should be connected to a three-phase four-wire AC 380V-50HZ power supply and equipped with a dedicated explosion-proof distribution box.

5. The water source and steam source should be connected with a pressure gauge or a corresponding manual valve to ensure safe use. The diameter of the residual discharge pipe should not be less than 55MM.

6. Gas cylinders should be installed with fixtures, kept away from heat sources, and not exposed to the sun. The storage temperature should be less than 30°C. Good ventilation.

7. Special EO dosing room and equipment room should be set up. The equipment room mainly places auxiliary electrical equipment such as air pressure pumps and steam generators. There should be a special gas cylinder storage device in the EO room. Ensure that the gas cylinders are firm and do

not shake. And install explosion-proof air inlet and exhaust devices. The equipment room should be equipped with a water source and a power distribution cabinet to meet the needs of equipment operation. And install explosion-proof air inlet and exhaust devices.

8. Ethylene oxide sterilizers should be placed in a separate sterilization workshop. They should not be used together with other functional workshops, office buildings, etc. The distance between two or more ethylene oxide sterilizers used at the same time should be greater than 4 meters.

9. The sterilization workshop is equipped with air supply and exhaust systems. Explosion-proof fans should be used. Ensure that the space in the workshop is circulated at least 5 times per hour.

10. The lighting and electrical switches used in the ethylene oxide sterilization workshop should be explosion-proof.

11. .Ethylene oxide sterilization workshops and sterilization areas should have obvious fire prevention and no smoking signs. The sterilization workshop should be a key fire protection area, with sufficient fire fighting and fire extinguishing equipment. Static dischargers should be installed at the door.

12. Installation environment: The installation environment temperature is 5~40℃, the highest temperature is 40℃ and the lowest temperature is 5℃.

13. It should be relatively dry and ventilated, with air humidity not exceeding 80% and no other corrosive gases present.

1. 2. Precautions

1 . Ethylene oxide is flammable and explosive, so safety is very important. Therefore, the sterilization workshop should be equipped with fire prevention measures. In addition, smoking and other open flames are prohibited, and the workshop should be kept ventilated.

2 . Ethylene oxide is toxic to a certain extent. If a person inhales an excessive amount at one time, he or she may feel uncomfortable, or even suffer from headaches, vomiting, and other poisoning symptoms. If the above symptoms occur, you should leave the scene immediately and breathe fresh air in an open and cool place until the symptoms disappear. If the skin or eyes of a person come into contact with ethylene oxide, they should be rinsed with clean water for 10-15 minutes and seek medical attention as soon as possible.

3. Installation requirements for ethylene oxide sterilizers: The ethylene oxide sterilizer must be placed in a well-ventilated area and should not be placed near a fire source. For easy repair and regular maintenance, a space of 80 cm should be reserved on each side (including the top) of the ethylene oxide sterilizer. A dedicated exhaust duct should be installed and completely isolated from other exhaust ducts.

4. Ethylene oxide protection principles and precautions:

5. Keep the ethylene oxide sterilizer and gas cylinders or tanks away from fire and static electricity.

6. The place where ethylene oxide is stored should be free of fire sources, rotating motors, sunlight, good ventilation, and the temperature should be below 30°C, but it should not be placed in a refrigerator. It should be handled in strict

accordance with the storage requirements for flammable and explosive items formulated by the state.

7 . Do not use too much force when administering the medicine or opening the bottle to avoid spraying the medicine.

8 . The air concentration of ethylene oxide working environment is monitored annually.

9 . Ethylene oxide workers should be trained in professional knowledge and emergency accident handling. After excessive exposure to ethylene oxide, the patient should be quickly moved away from the poisoning site and breathe in fresh air immediately; after skin contact, rinse the contact area with water for at least 15 minutes and take off the dirty clothes at the same time; if the eyes come into contact with liquid ethylene oxide or high-concentration ethylene oxide gas, rinse the eyes for at least 10 minutes. In the above cases, you

should see a doctor as soon as possible.

10 . Clean, maintain and debug the ethylene oxide sterilization equipment regularly according to the manufacturer's requirements.

11 . Ethylene oxide can form toxic ethylene glycol when it comes into contact with water, so it cannot be used to sterilize food.

12 . The cargo volume of the ethylene oxide sterilizer should not exceed 80% of the total volume. Leave 20CM from the top of the cargo. Leave 5CM from the left and right walls. Be careful not to collide with the sterilizer sensor during loading and unloading. Check whether the sensor pipeline is damaged before sterilization.

How to operate

1. 3. Operation flow chart

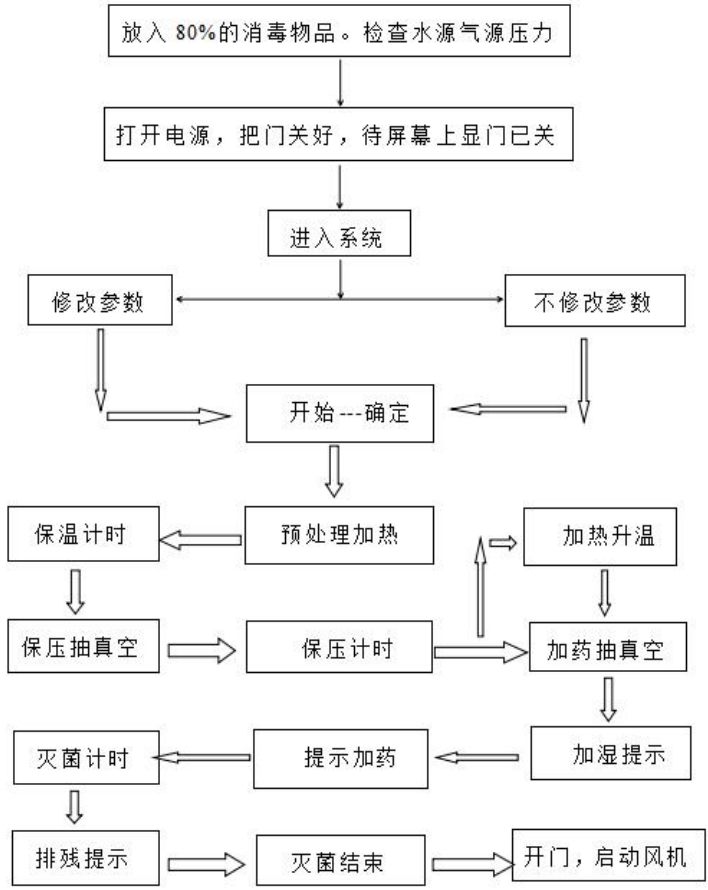
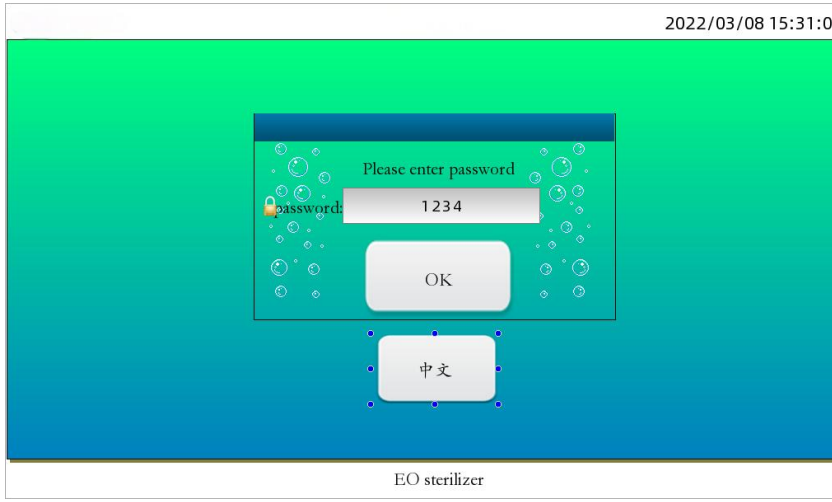


Figure 1 Operation flow chart

1. 4. Sterilization operation

Operation function keys and display block description

1. The password input screen will be displayed when the computer is turned on! Enter the password and click Enter.



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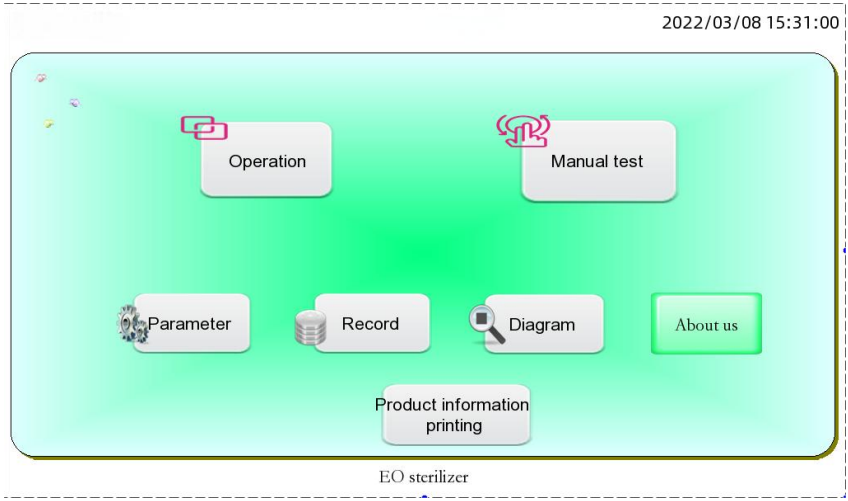
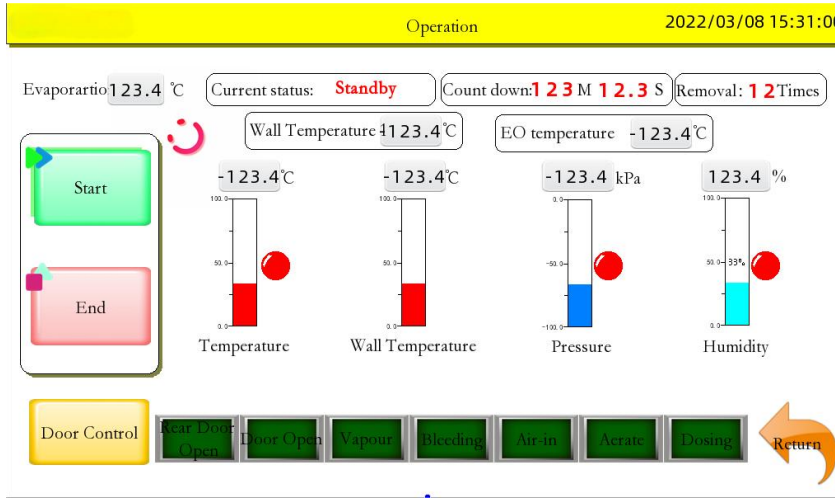
2. Select the interface. You can choose

"Parameter Setting", "Manual Test", "History Record", "Graph", or " Run Interface"!



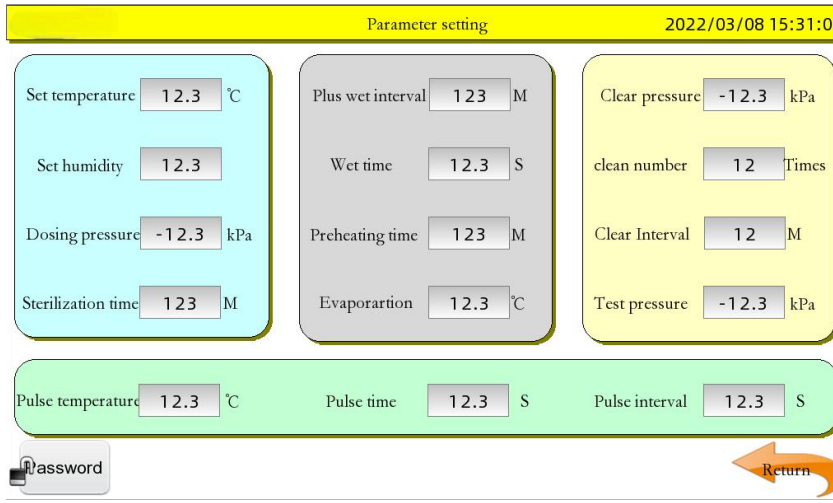
1．The "Automatic Interface" equipment is loaded with sterilized items and sterilization consumables are placed. Click the start button to run automatically, and click the "open door" or "close door" button to operate the equipment to open and close the door. The program flow is as follows. Open the door - put in the sterilized load - put in the sterilizer - close the door - click the start button - start preheating - the temperature reaches

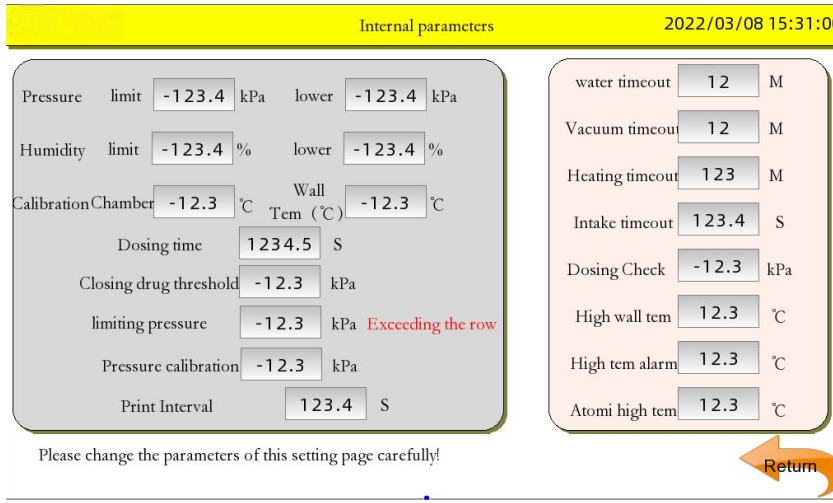
the set temperature (the standard is 50°C) - enter the preheating countdown (preheating time set by parameters) - leak test - add medicine and vacuum (pump to the set pressure) - add medicine - sterilization (maintain to the set sterilization time) - exhaust (air intake, vacuum cycle to the set number of times) - sterilization is completed. When the equipment prompts that the sterilization is completed, click OK, and then you can open the door to take out the items.



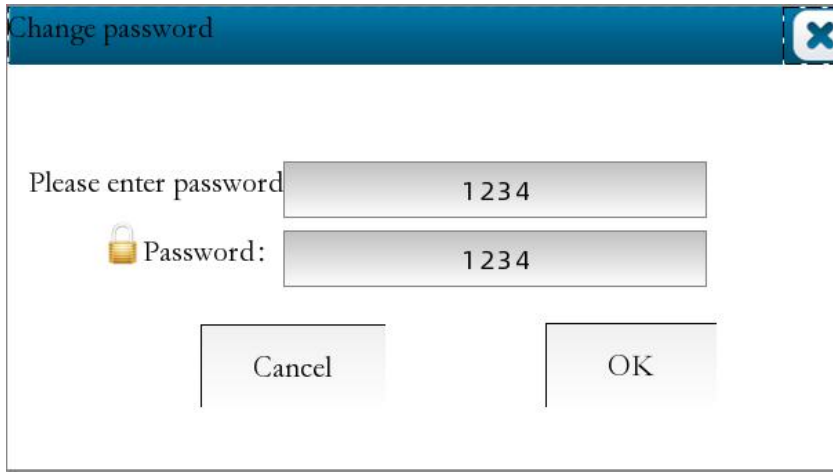
4. Parameter setting interface. The main

parameters of the equipment are set. This interface is generally not recommended for customers to modify. If you need to modify it, you can only modify the "set temperature", "set pressure" and "sterilization time" on the first page. If you modify other parameters by yourself, it will affect the operation of the equipment.

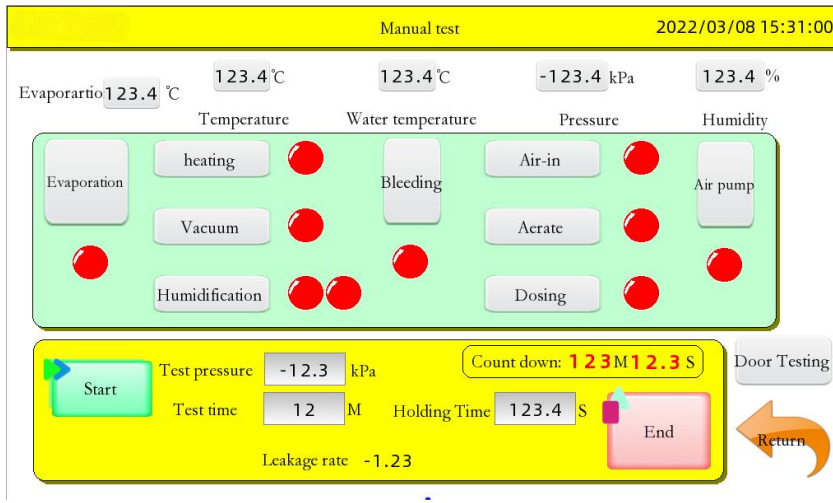




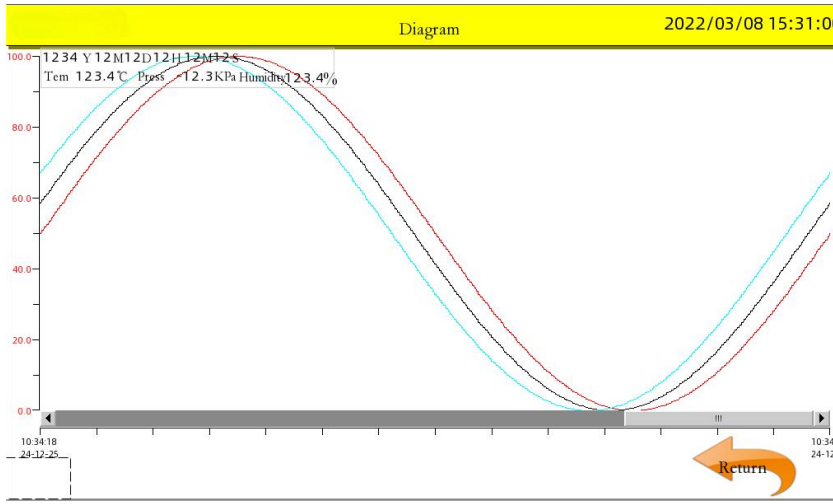
5. Password setting, enter the parameter setting interface in the sub-interface background parameter interface. Click password modification, enter the second password to enter the password and time setting interface. The power-on password is the password to be entered when the device is turned on! The set password is the password required for the password modification interface.



6. Manual test interface. This interface is generally only used for testing or in emergency situations. It is used when the device has stopped automatic operation.

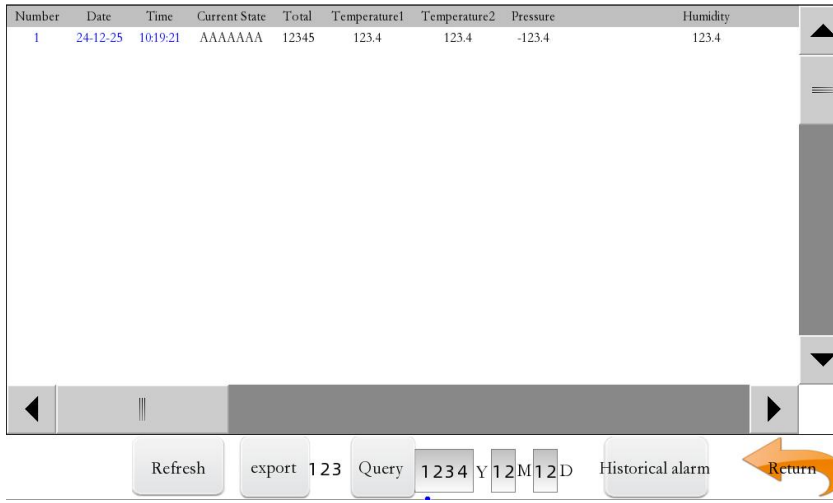


7. Curve graph interface. Displays the parameter curve of this pot operation. Blue is pressure. Red is temperature and black is humidity.



8. Alarm record interface, mainly records equipment failure situations.

9. The history record interface displays historical operation data, which can be exported to a USB flash drive. After export, the data will be automatically cleared. The history record is basically synchronized with the printed receipt record.



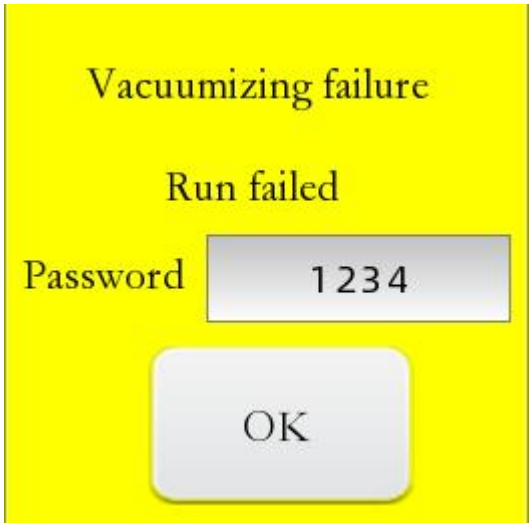
Precautions for sterilization operation

Sterilizer Common Tips and Instructions

1. The sterilization is complete display, prompting that the equipment is complete. You can open the door to take out the items.

2. Water filling timeout display. It indicates that the water filling time is too long and the water level in the water tank has not been reached when the equipment is running. It is necessary to check the water source, water inlet valve and water tank float.

3. Vacuum timeout display. It indicates that the vacuum time is too long and the vacuum degree of the inner tank does not meet the set requirements. First, check whether the door is closed and the seal is normal. Second, check whether the sound of the vacuum pump is working to ensure that the vacuum pump is not damaged.

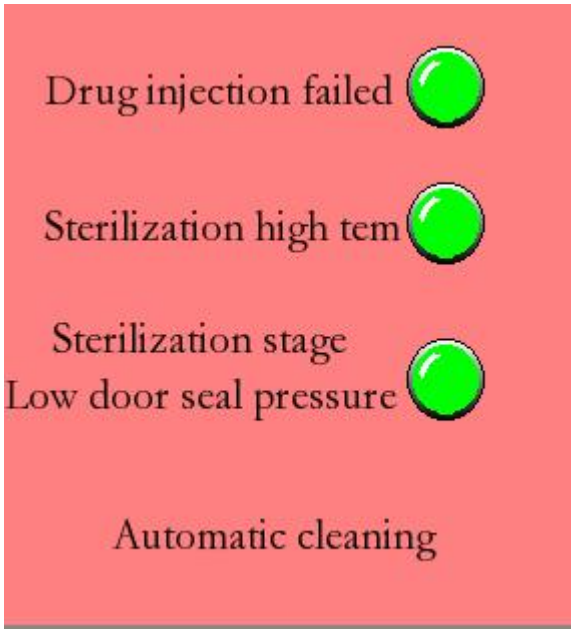


4. Heating timeout display. Prompts that the temperature of the inner tank has not reached the

set temperature requirement within the set time. It is necessary to check whether the heating tube is damaged, and also check the water level of the water tank and whether the water temperature of the water tank is consistent with the displayed water temperature.

5. Insufficient injection display. The device has detected that the medicine bottle is punctured but the pressure in the inner tank has not reached the set requirement. The device will automatically

discharge the residual. Do not turn off the power or operate. Wait until the automatic operation is finished before checking. Check whether the medicine bottle has been replaced. Whether the medicine bottle has been left for too long and has been missed. If there is no problem, replace the medicine bottle and test it again.



6. High temperature alarm display. It indicates that the temperature of the inner tank or water tank

is too high. The device will automatically end the work. If the medicine has been added, it will automatically enter the residual discharge program. First, check whether there is a problem with the set parameters. Second, check whether there is a problem with the water tank and water source. Third, check whether the heating relay is burned out.

All the above alarms are closely related to the alarm parameter values in the parameter settings!

Please do not change the above parameter values without the guidance of the manufacturer!

1.5. Technical Parameters

Set temperature:-------- -- Sterilization chamber temperature

Set pressure: --------- -- Sterilization chamber pressure

Set humidity: --------- -- Sterilization chamber humidity

Preheating pressure: ---------- -Pressure set for leakage holding pressure

Heating cycle: ---------- Total time of pulse phase

Heating time: --------- - The heating time in the pulse stage. For example, if the heating cycle is set to 10 seconds and the heating time is set to 5 seconds, it means heating for 5 seconds in 10 seconds and pause for 5 seconds. One cycle.

Pulse temperature: ---------- -When this temperature is reached, pulse heating begins. The value must be lower than the set temperature .

Preheating time: ----------The time to maintain a constant temperature after reaching the set temperature.

Print interval time--------The printing interval time during the operation cycle .

Set the sterilization time--------that is the sterilization time

Humidity detection interval time - the interval time of humidity detection in the operation cycle. For example, if it is set to 60 minutes, check whether the humidity

reaches the set value after 60 minutes. If it is not, humidify. If it is, do not humidify. Generally, 50 minutes is a good setting.

Residue discharge pressure: ----------vacuum pressure during residual discharge

Set the water adding time--------the time for quantitative water replenishment each time the machine is turned on, generally 3-8 seconds.

Set the humidification time--------fixed humidification time, usually about 10 seconds.

Set the dosing time--------the time to add ethylene oxide gas. When the internal timer is up, close

the dosing pneumatic valve to indicate the start of sterilization.

Vacuum pump no water alarm------If no water flow is detected within the set time, an alarm will be sounded.

Set the number of residual cleaning times.

Set the residual discharge time--------the interval between the last residual discharge and the next one

Faulty residual extraction time------If the air pressure is low during sterilization, it usually takes 3-5 minutes to start the vacuum pump to extract the residual .

Sterilization programs 1 and 2 are quick selection mode parameters, one is 50

degrees and the other is 35 degrees

Temperature, humidity and pressure printing-------the upper and lower limits are exceeded. The printed numbers are black with white characters.

Circulation fan operation interval-----optional

Circulation fan running time-----optional

Leak test stabilization time-----the time it takes for the vacuum to reach the set value and stabilize, after which the leak timing starts .

Vaporization chamber temperature ---------- -- EO vaporizer temperature

Leak test time---------pressure holding time

Leakage rate--------------Leakage rate setting value

EO gasification alarm temperature-------EO gasification exceeds the secondary value and alarms

Vacuuming timeout time ------- Vacuuming timeout time

Automatic dosing time----------Automatic dosing time (optional)

Waiting time after injection--------waiting time after adding medicine

Maximum pressure after drug injection--------The pressure after adding the drug cannot be greater than this value. If it is greater, an alarm will be triggered to terminate sterilization.

The upper limit of positive pressure is the positive pressure protection of the sterilization chamber. When this value is exceeded, the

vacuum pump starts to evacuate and reduce the pressure .

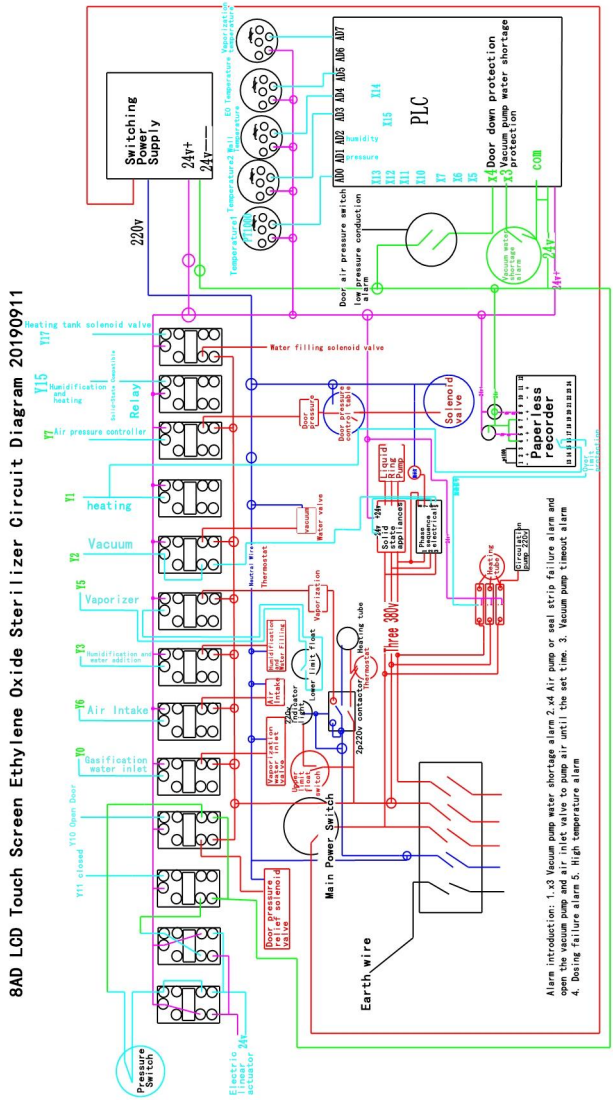
Negative pressure when the door is open ---------- - the value of vacuum when the door is open

Vacuuming and waiting in pressure holding mode - the time the negative pressure is maintained during the residual discharge stage

Humidification interval ---------- -Humidification detection interval time

Humidification time ----------The time to turn on the humidification during the humidification cycle

Circuit diagram



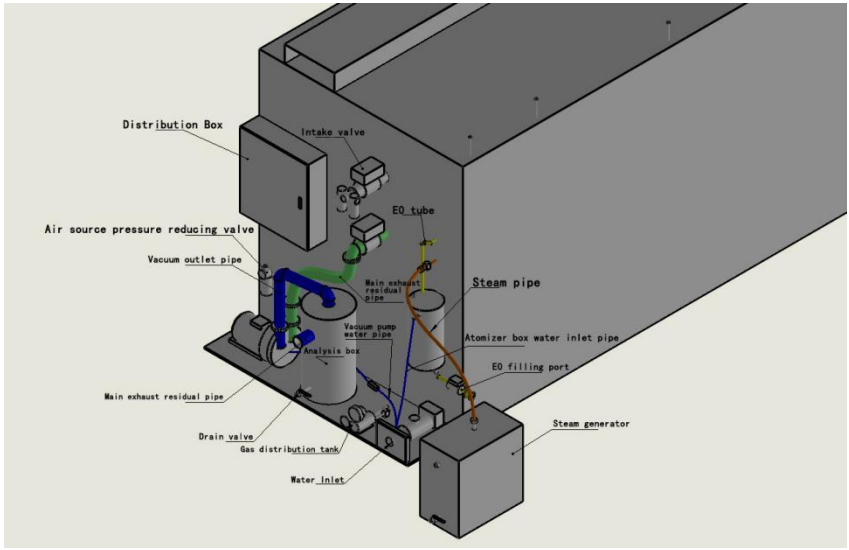


Figure 15 External structure diagram

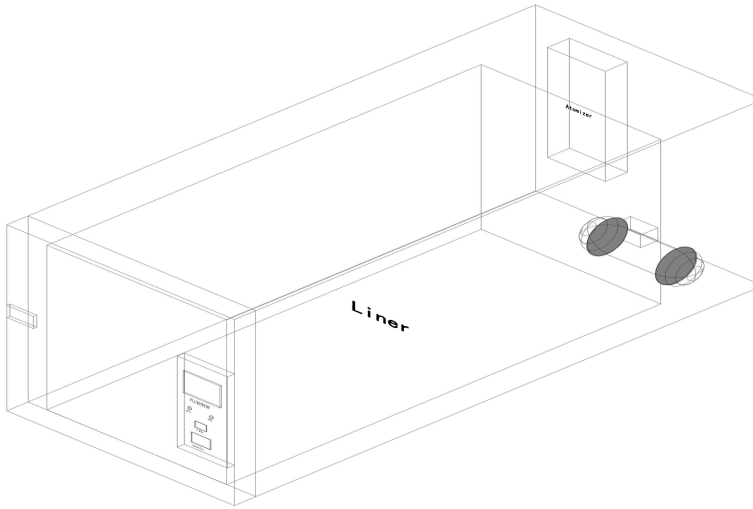


Fig.16 Overall perspective

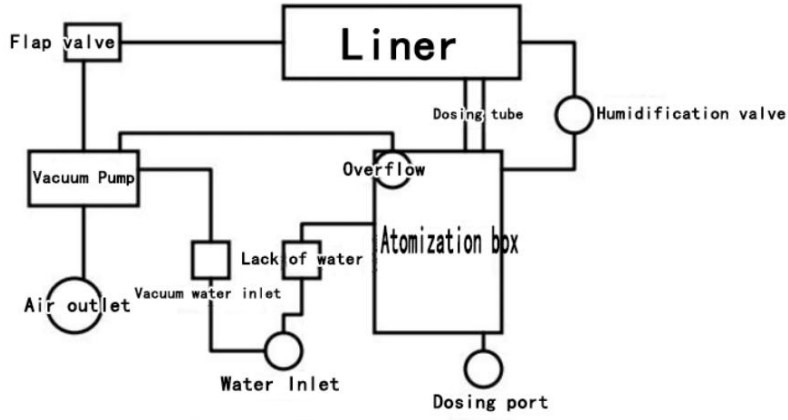


Figure 17 Gas flow chart

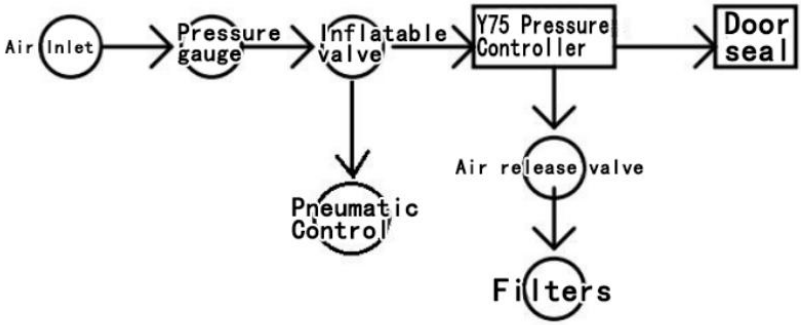


Figure 18 Pipeline flow

Safety Management System

1.Disinfectants must strictly follow safety operating procedures.

2.A dedicated person is responsible for the operation and maintenance of the ethylene oxide sterilizer and shall check whether all pipelines are leaking before use.

3.When taking objects at the end of the sterilization cycle, you should wear a mask and protective gloves, and move the objects in a way that people are in front and objects are in the back.

4.During the use and maintenance of the sterilizer, workers should be prevented from poisoning. If they experience symptoms such as dizziness, nausea, vomiting, etc., they should leave the site immediately and rest in a well-ventilated place. Those with severe symptoms should seek medical attention in a timely manner.

5.The ethylene oxide gas discharged from the ethylene oxide sterilizer during the analysis process should be discharged through a dedicated exhaust pipe system and in accordance with the relevant management regulations of the relevant departments on the emission system.

6.Ethylene oxide gas cylinders should be stored in a well-ventilated, sun-proof environment with a temperature of 30 degrees Celsius or less, but not in a refrigerator. A fixed bracket should be installed.

7.Open flame operations are strictly prohibited in the sterilization room, and ventilation facilities and fire-fighting equipment are available.

Safety Operating Procedures

General

Ethylene oxide is a flammable, explosive, and moderately toxic hazardous chemical. If the concentration in the air exceeds 3%, it may cause an explosion when exposed to open flames. The ethylene oxide sterilizer is a mechatronic device with a high degree of automation and a certain pressure resistance. Therefore, the use and operation of the ethylene oxide sterilizer must strictly comply with this safety regulation .

1. 6. Sterilizer Installation

1 . Site

The ethylene oxide sterilizer should be placed in an independent workshop, away from the crowd. There should be no open flame operation or other

situations that produce open flame within 30-50 meters of the site.

2 . Isolation

The workshop for the security of ethylene oxide sterilizer must have isolation measures, that is, the ethylene oxide cabinet, ethylene oxide cylinder, etc. should be installed in separate rooms.

3 . Ventilation

The workshop where the ethylene oxide sterilizer is installed must have good ventilation. If the ventilation conditions are poor, forced ventilation should be carried out. It is strictly forbidden to seal the sterilization workshop from the outdoors. The installed ventilation equipment should be explosion-proof.

4 . Illumination

The lighting and electrical switches used in the ethylene oxide sterilization workshop should be explosion-proof

5．Fire-fighting ethylene oxide sterilization workshops and sterilization areas should have obvious fire prevention and no smoking signs. The sterilization workshop should be a key fire protection area and have sufficient fire fighting and fire extinguishing equipment.

1. 7. Sterilizer Operation

1．personnel

Personnel engaged in sterilization work must be trained by the factory staff and hold a work permit issued by the factory before they can work. Any unlicensed operation will be regarded as a violation of regulations, and the consequences will be borne by the operator. Non-operating personnel are prohibited from entering the sterilization workshop.

2．Operating procedures

The operation of the sterilizer should be carried

out strictly in accordance with the operating (use) instructions. It is strictly prohibited to change the operating procedures without authorization or operate in violation of the operating regulations.

3 . Operator Guidelines

Operators should have a strong sense of responsibility. They should not leave their workstations without reason during sterilization. It is strictly forbidden to operate the sterilizer without anyone. It is not allowed to change the circuit of the electrical control cabinet or add or reduce electrical equipment without permission.

1. 8. Storage of Ethylene Oxide

1 . Ethylene oxide is stored in a separate room. The room should have ventilation, explosion-proof and fire-fighting facilities.

2 . Ethylene oxide cylinders should be stored in a cool place away from heat sources. The storage

temperature of ethylene oxide should be below 30° C.

3 . Ethylene oxide cylinders should have fixed brackets.

1. 9. Ethylene Oxide Sterilizer Safety Inspection

1 . Equipment in good condition

The sterilizer must be kept in good condition, especially the air tightness of the box. If there is a malfunction during the use of the equipment, the sterilization should be stopped immediately and the ethylene oxide in the box should be evacuated. Every time the sterilization is done, observe whether the pipeline is leaking or the interface is not tightened. If any problems are found, stop adding medicine and sterilization immediately, evacuate the site, and keep the ventilation system open for a while before entering to deal with the leaking area.

2 . Leakage Check

When sterilizing with ethylene oxide, the sterilizer should be regularly tested for leaks. You can also install an ethylene oxide leak detector for testing. The system also comes with a liner leak test program. The equipment will be automatically tested at the beginning of each work. (You can also use a test paper soaked in sodium thiosulfate solution containing 1% phenolphthalein and stick it on the suspected leaking pipe. If the test paper turns red, it proves that ethylene oxide is leaking).

3 . troubleshooting

Troubleshooting should be performed by operators and equipment professional technicians, referring to the maintenance and servicing manual and common troubleshooting list provided by the factory. If the fault cannot be eliminated, the manufacturer should be contacted in time.

1. 10. Operator Safety Protection

1 . Dress

Operators should be neatly dressed, wear protective gloves, and not wear shoes with spikes.

2 . First Aid

If the operator finds symptoms of poisoning such as dizziness, nausea, vomiting, etc., he should immediately leave the scene and rest in a ventilated place. If the condition is serious, he should be sent to the hospital for diagnosis and treatment in time.

3 . Health Care

Personnel engaged in ethylene oxide sterilization should undergo regular physical examinations.

Product Maintenance & Care Methods

To ensure that the sterilizer can maintain good working condition and reduce the number of failures as much as possible, please strictly follow the maintenance and care measures introduced in this chapter.

Note: Before performing maintenance on the equipment, please make sure that the power supply has been cut off and that there is no pressure inside the sterilization chamber.

1 . After sterilization every day, please wipe the door seal with a soft cloth. Then apply a little lubricant.

2 . After sterilization each day, please wipe the inner wall of the sterilization chamber with a soft cloth.

3 . Please wipe the sterilizer cover with a soft cloth every week.

4 . The lower switch of the air inlet pressure regulating valve should be opened regularly to release the water in the regulating valve.

5 . The air intake filter should be replaced regularly.

6 . If the decomposition box is not used for a long time, open the switch at the bottom to release the water inside the decomposition box. There is some ethylene glycol in the water.

7 . Regularly check the line fixation

8 . Regularly check components and screw fastening

9 . Regularly treat steam generator blowdown

10 . If the sterilizer is not used for a long time, please turn off the main power switch, drain the water in the vaporization water tank and steam generator, and keep the storage environment clean and dry .

Instructions Preparation Date: September 22, 2024