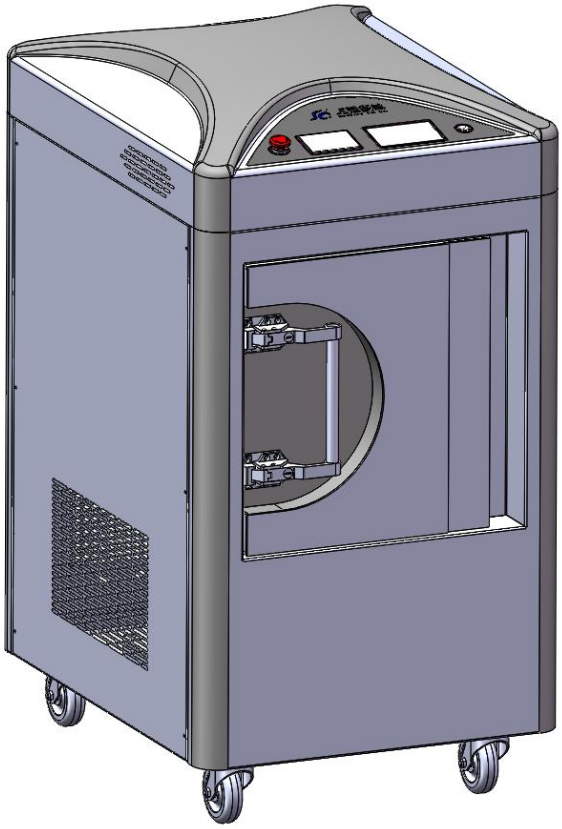
SQ-H series

Ethylene Oxide Sterilizer

User's Manual



Contents

1. Product Introduction

1.1、Overview

Product name: ethylene oxide sterilizer

Company Name: Henan Sanqiang Medical Equipment Co., Ltd.

Management category: Class II

1.2、working principle

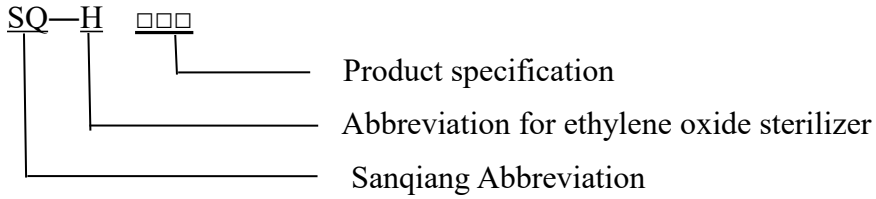
The ethylene oxide sterilizer uses an automatic controller to control each component so that the sterilization box reaches the preset temperature, humidity and vacuum to preprocess the sterilization load in the sterilization box, and then use ethylene oxide The penetration and alkylation properties of the alkane sterilant sterilize the sterilized load. After the sterilization is completed, the vacuum system and the residual gas processing system are used to replace and process the gas in the sterilization box to achieve the forced analysis of the sterilization load.

1.3、Working mechanism

The mechanism of action refers to the physiological reaction that occurs throughout the body or part of the body when the medical device acts on the human body. Ethylene oxide sterilizers are non-therapeutic medical devices and do not act on the human body, so they are not applicable.

1.4、Product model/specification and division description

1.4.1、 Product model naming



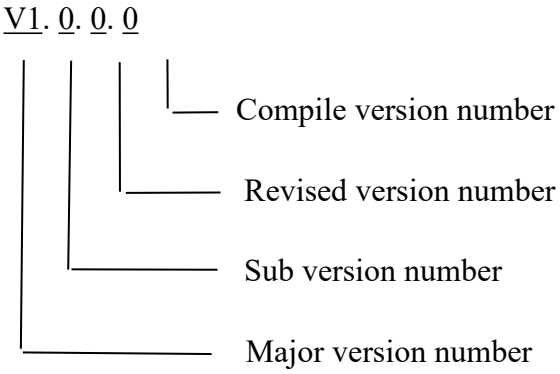
1.4.2、Software component name, model/specification and description of division

A. Software name: EO sterilizer program software

B. Software model: SQ-H

C. Software release version number: V1

D. Software version naming rules



1.5、Product specifications and basic parameters

Table 1 Basic parameters of each model specification

Model	Sterilization chamber size（mm）	Rated power	Work pressure	Operating temperature	Working humidity	Sterilization time
SQ-H40	diameter：Φ246，deep：450	3.3 kVA	-75kPa～0	30℃～60℃	Relative humidity 40％～85％	0～999h
SQ-H80	L：585，W：275，H：422	2.6 kVA				
SQ-H120	L：585，W：375，H：472	3.0 kVA				
SQ-H220	L：705，W：505，H：552	3.3 kVA				
SQ-H330	L：760，W：575，H：682	3.6 kVA				
SQ-H460	L：935，W：600，H：820	4.2 kVA				
SQ-H600	L：965，W：680，H：910	4.8 kVA				
SQ-H800	L：1085，W：730，H：1000	5.4 kVA				
SQ-H1000	L：1155，W：815，H：1045	6.0 kVA				

1.6 、Product working conditions

a) Ambient temperature: +5℃～+40℃;

b) Ambient humidity: no more than 85%;

c) Atmospheric pressure (absolute pressure): 70kPa～106kPa;

e) Power supply: ac.220V±22V, frequency 50Hz±1Hz

1.7、Product category

The product belongs to Class II active medical devices in accordance with the "Medical Device Classification Rules" of the State Food and Drug Administration Order No. 15. Project number is 1103-03

According to the classification rules in GB4824-2013 "Industrial, Scientific and Medical (ISM) Radio Frequency Equipment Disturbance Characteristics Limits and Measurement Methods", the equipment belongs to Group 1 Class A, medical appliances, electrical equipment, non-domestic and

not directly connected to residential low-voltage power supply Equipment used in the facility. It is mainly used in hospitals, medical device manufacturers, scientific research units, etc. in industrial production environments.

2. Structure composition, scope of application and main product performance

2.1、Structure and composition

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

2.2、Scope of application

The ethylene oxide sterilizer is used for the sterilization of medical devices that can withstand ethylene oxide. EO has a wide range of clinical uses. The equipment and instruments commonly used for EO sterilization include:

(1) Rigid and flexible endoscopes: arthroscopy, bronchoscope, cystoscope, gastroscope, colonoscopy, mediastinoscopy, ophthalmoscope, otoscope, pharyngoscope-rectoscopy, prostatectomy device, thoracoscopy, urethroscopy.

(2) Medical equipment: anesthesia equipment, artificial kidneys, diathermy equipment, wires, meters, heart-lung machines, breathing, treatment equipment, hemodialysis.

(3) Instruments: electric drills, electric burners, electric knife pens, dental drills, microsurgical instruments, nerve stimulators, pressure gauges, surgical instruments, bone drills, needles, artificial joints.

(4) Rubber products: catheters, dilators, drainage tubes, endotracheal tubes, surgical gloves, sheets.

(5) Plastic products: airway intubation, dilator, endotracheal intubation gloves, pacemaker, heart valve, nebulizer, petri dish, syringe.

(6) Other books, toys, linear probes, thermometers, sutures.

2.3、Main product performance

- 2.3.1 Materials

The sterilization chamber is welded by 304 stainless steel.

- 2.3.2 Sterilization time

According to the different sterilization objects, the user can adjust the sterilization time, and the adjustment range is: 0-999h.

- 2.3.3 Sterilization cycle

Preheating→vacuum→humidification→injection→sterilization→ventilation cleaning

- 2.3.4 Control system

The embedded circuit board is used for orderly control, and the relevant analog and digital quantities are processed more accurately to ensure the effectiveness and scientificity of the sterilization process.

- 2.3.5 Electrical selection

Using domestic and foreign well-known brand electrical components to reduce product failure rate and ensure product service life.

- 2.3.6 Protection function

The system is set with protective alarm functions such as abnormal temperature, ultra-high temperature, abnormal pressure, low vacuum rate, and cleaning failure in the sterilization chamber to avoid the expansion of secondary failures.

- 2.3.7 Record function

▪ Use high-performance thermal printer.

▪ Various parameters in the sterilization process, including temperature, time, pressure, and sterilization times, can be printed for easy viewing and analysis.

▪ When a failure alarm occurs in the sterilizer, the equipment will print out the corresponding failures by itself.

- 2.3.8 Sterilization effect

Carry out the sterilization test according to the method in Appendix E of YY0503-2016 "Ethylene Oxide Sterilizer". After the sterilization cycle is over, the biological indicator has no biological activity.

- 2.3.9 Electrical safety requirements

The electrical safety of the sterilizer meets the requirements of GB4793.1-2007 and GB4793.8-2008.

3. Contraindications and precautions

3.1、Contraindications

Ethylene oxide is toxic to the human body. Excessive inhalation can cause dizziness, headache, nausea, and vomiting; Ethylene oxide gas is flammable and explosive. When the concentration in the air exceeds 3%, it will burn and explode when exposed to open flames and static electricity. Therefore, when the sterilizer is operated, it must be airtight and airtight. Ventilation devices should be installed in the room where the sterilizer is installed.

3.2、Precautions

- The sterilizer should be installed in a well-ventilated special room with a room temperature of 10°C or higher, with water source, power supply, and sewer; smoking and open flames are strictly prohibited, and the mixed gas should not be installed and stored in the basement. Once the ethylene oxide gas leaks, it is not easy Diffusion and drainage.

- The room where the ethylene oxide sterilant gas tank is placed should be equipped with corresponding safety protection equipment and fire extinguishing agents (such as: water mist, alcohol-resistant foam, dry powder, carbon dioxide).
- The power supply is a dedicated circuit and has a reliable ground wire.
- The sterilization box should be placed steadily, and the water injection port should be connected to the water source, and the exhaust steam should be connected to the discharge equipment. Pay attention to sealing.
- Connect the mixed gas cylinder to the medicine inlet with the equipped special medicine inlet pipe to ensure no leakage.

3.3、Emergency handling

3.3.1Handling in case of fire

➢ When the sterilant container leaks and causes a fire

Evacuate people quickly, wear protective equipment, use water spray, alcohol-resistant foam, dry powder, and carbon dioxide fire extinguishers to extinguish open flames. If the leak cannot be stopped in time, it can be left to burn, and the ethylene oxide sterilant container should be moved from the fire scene to an open place if possible.

➢ When the sterilizer catches fire

If the fire point is on the sterilizer equipment, immediately cut off the power supply of the sterilizer before extinguishing the fire to avoid greater losses.

➢ When a serious fire occurs and the scene cannot be controlled, the crowd should be evacuated and evacuated immediately. Call the fire number to avoid greater losses.

3.3.2 Handling of human body contact with ethylene oxide

➢ Acute inhalation

Symptoms of poisoning: respiratory tract irritation, dizziness, weakness, dizziness, vomiting and symptoms of nerve poisoning.

First aid method: quickly leave the scene to a place with fresh air, keep the respiratory tract unobstructed, and then seek medical attention immediately.

➢ Eye contact

Symptoms of poisoning: severe eye irritation and damage.

First aid method: immediately lift the eyelids, rinse thoroughly with a large amount of running water or normal saline for at least 15 minutes, and then seek medical attention immediately.

➢ Skin contact

Symptoms of poisoning: Liquid ethylene oxide causes skin irritation, dermatitis and blisters.

First aid method: Take off contaminated clothing immediately, rinse with plenty of running water

for at least 20 minutes, and then seek medical attention immediately.

- Ingestion

Symptoms of poisoning: cause severe irritation and burns to the mucous membrane of the digestive tract.

First aid method: immediately notify the doctor or poison control center, take the initiative to vomit after drinking water, but for unconscious people, can not induce vomiting or feed anything.

4. Item handling before sterilization

4.1、Preparation before sterilization

Items that need to be sterilized must be thoroughly cleaned. Note that they cannot be cleaned with saline. There should be no water droplets or too much moisture on the sterilized items to avoid dilution and hydrolysis of ethylene oxide. Packaging materials suitable for ethylene oxide sterilization include paper, composite dialysis paper, cloth, non-woven fabrics, ventilated rigid containers, polyethylene, etc.; packaging materials that cannot be used for ethylene oxide sterilization include metal foil, Polyvinyl chloride, cellophane, nylon, polyester, polyvinylidene chloride, impermeable polypropylene. Changes to packaging materials should be verified to ensure the reliability of the sterilization of the sterilized items.

4.2、Packaging requirements for sterilized items

4.2.1、Packaging material

The packaging material must be made of materials that can permeate air, steam and ethylene oxide gas, can withstand a certain temperature, and can easily remove ethylene oxide residues. Paper-plastic packaging, medical crepe paper, polyethylene plastic bags, cloth, non-woven fabrics are commonly used, but nylon, various metal foils, sealed glass and cellophane cannot be used as materials.

4.2.2、Packaging requirements for sterilized items

a、Preparation of items:

Depending on the size and shape of the sterilized items, choose a medical sterilization bag with a suitable length, width, and width. If it is too large, it will easily cause folding, breakage, and affect the use. Because ethylene oxide sterilization is susceptible to various contaminants, the items to be sterilized must be cleaned and dried at room temperature. There should be no water droplets or too much moisture on the sterilized items, so as not to cause dilution and hydrolysis of ethylene oxide and affect the sterilization effect. The clean items to be sterilized and the packaging materials used are stored in a storage room with a relative humidity of 40% to 60%.

b、Packaging of sterilized items

Articles to be sterilized are usually packaged with paper and plastic, generally single-layer packaging. If double-layer packaging is required, the paper and plastic are in the same direction, and the inner layer must not be folded. The sealing width of the paper-plastic packaging bag is not less than 6mm, and the width of the blanking outside the seal is not less than 1.5cm. The equipment items are placed in the paper-plastic packaging, leaving a space of about 2cm around; sharp equipment should have a protective cover (such as scissors); Remove air as much as possible inside, and place a chemical indicator card, indicate the name of the item, sterilization date, expiration date and sign on the outside of the package.

c、Placement of sterilized items

The packaged items to be consumed shall be checked again to see if the package is up to standard. The items to be eliminated should be placed on the loading basket. The items should have gaps up and down, left and right, and should not touch the cabinet wall. The sterilization chamber should not exceed 80% of the total volume. The sterilized items should occupy the ethylene oxide sterilizer. 3/4 of the inner space is appropriate. At the same time, follow the principle of heavy objects, light objects should be separated, heavy objects on the bottom layer, and light objects on the upper layer. Do not press and do not fold, and the loaded objects should be placed vertically and not flat.

4.3、Item sterilization and analysis time

Sterilization time refers to the time that the temperature, humidity, pressure and ethylene oxide sterilant concentration in the sterilization chamber reach the preset conditions during the sterilization operation. The analysis time refers to the time required for the removal of ethylene oxide residues from the sterilized items to reach the safety standard under certain conditions after the sterilization process is over. Analysis is divided into natural analysis and mandatory analysis.

ITEM	STERILIZATION TIME	RESOLUTION TIME
Metal product	3 hours	3 hours
Metal silicone products	6 hours	4 hours
Silicone products	4 hours	3 hours
rubber products	4 hours	4 hours
Cotton fabric	3 hours	5 hours
plastic products	4 hours	3 hours

Glass product	5 hours	4 hours
Paper products	3 hours	3 hours
Endoscope	4 hours	3 hours
Human body bracket	9 hours	24 hours

5. Appearance and installation

5.1、Overview of the appearance of ethylene oxide sterilizer

The appearance of the sterilizer is shown in Figures 1 and 2, and the main component names and functions are shown in Table 3

Figure 1

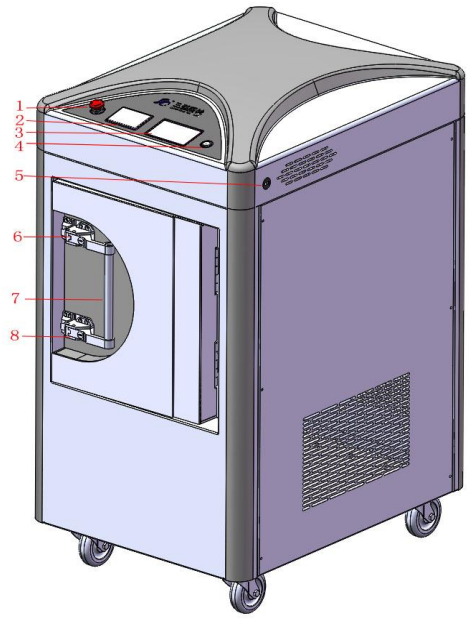


Figure 2

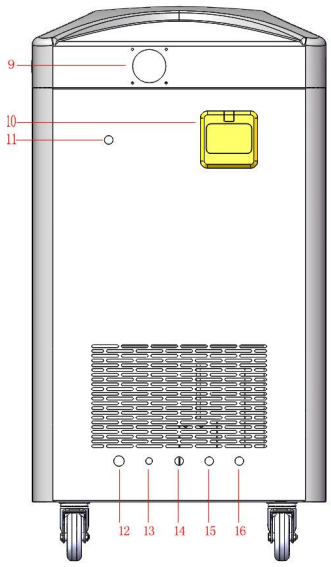


Table 3

Item	name	function
1	scram button	Press the button quickly to turn off the sterilizer in the event of an emergency
2	printer	Print key process data information in the sterilization process
3	touch screen	Display and control the sterilization process of the sterilizer
4	Switch button	Control the startup and shutdown of the sterilizer
5	USB port	Upgrade the system program, read the historical data during the sterilization process
6	Key socket	Key socket, used to open and lock the switch door handle
7	Switch door	Open or close the door of the sterilization chamber

	handle	
8	Key socket	Key socket, used to open and lock the switch door handle
9	Cooling fan	Heat dissipation of sterilizer components
10	Add distilled water	Provide an interface for humidifying water source to the sterilizer
11	power cable	Want to provide power to the sterilizer
12	Water filler	Add water to the decomposition tank
13	Drainage port	Decomposition tank drain
14	Drainage port	Distilled water tank drain
15	Exhaust port	Exhaust the overflow water in the decomposition tank and the exhaust gas generated during the sterilization process
16	Exhaust port	Distilled water tank overflow

5.2、Device identification description

Table 4

Logo	Description	Logo	Description
	Warnings and cautions		Alternating current
	High voltage danger		Risk of burns due to high temperature
	Ground wire		Direct current

5.3、installation

The installation of the sterilizer is generally carried out by the after-sales technicians of Sanqiang Medical Equipment, who have received professional and rigorous training. Therefore, installation by professional after-sales technicians is the best guarantee for the quality of your equipment during the warranty period.

warning: When the sterilizer needs to be adjusted or repaired, please contact our company's after-sales service department. Maintenance personnel who have not been certified by our company may put you or the sterilizer in a very dangerous state.

Note！！ The ethylene oxide sterilizer meets the electromagnetic radiation and immunity standards of GB/T 18268.1-2010. Although this machine has no radiation effect, it may be affected by radiation from other equipment. It is recommended to install this machine away from potential sources of interference.

5.3.1 Installation requirements

(1) Energy demand

All input and output connections are fixed connections:

Power supply: 220V/50HZ, 20A (reliable grounding is required)

(2) Environmental requirements

Ambient temperature: +5℃～+40℃

Relative humidity: no more than 85%

Atmospheric pressure: 70kPa～105kPa

(3)Installation space requirements

- Should be placed in a separate sterilization room to ensure safe operation.
- The distance between the left and right sides and the back end of the sterilizer should not be less than 0.5m from the wall for later maintenance. The distance between the front end of the sterilizer and the wall is not less than 1.5 times the total length of the equipment.
- Foundation: The surface should be solid and smooth, and the load-bearing capacity should meet the requirements of the corresponding equipment. If the installation is above the second floor, the user should consider whether it is necessary to strengthen the corresponding part of the floor according to the specific situation.

(4)Room ventilation requirements

The room where the ethylene oxide sterilizer is installed should be well ventilated and equipped with a suitable exhaust fan and ventilation system to ensure 10 air exchanges per hour.

The equipment is reserved with terminals connected to the sensor device used to monitor the ventilation system failure in the workplace. The user's sensor to monitor the ventilation system failure should be connected to it under the guidance of our technicians.

A local ventilation system should be configured at the door of the sterilizer to be connected to a dedicated ventilation terminal inside the equipment, so that it runs before the door is opened after the sterilizer is sterilized.

(5) Sterilization gas storage requirements

1. It should be stored in a cool, well-ventilated warehouse away from fire and light.

2. The temperature of the warehouse should be between 10℃～40℃.

3. The warehouse ventilation and lighting facilities should be explosion-proof.

4. Strictly manage in accordance with the storage requirements for inflammable and explosive materials formulated by the state.

note:

1. Another local exhaust ventilation system may be needed in the sterilization gas storage warehouse;

2. Emissions from the local exhaust ventilation system should be discharged to a place that does not cause danger.

(6) The schematic diagram of the installation environment is shown in Figure 3

1. EO gas sterilizer
2. power supply
3. Water source
4. Sewer
5. Vent

Figure 3

5.3.2 install equipment

- The size and weight of the sterilizer

Table 5

Model	Sterilization chamber size L*W*H（mm）	Dimensions L*W*H（mm）	Weight kg
SQ-H40	Φ246×450	730×510×410	56
SQ-H80	585×275×422	795×615×1140	124
SQ-H120	585×375×472	795×615×1140	147
SQ-H220	705×505×552	968×800×1240	207
SQ-H330	760×545×712	968×800×1380	227
SQ-H460	935×600×820	1143×825×1488	277
SQ-H600	965×680×910	1173×905×1578	340
SQ-H800	1085×730×1000	1293×955×1668	410
SQ-H1000	1155×815×1045	1363×1040×1713	505

- Unpacking

1) Before unpacking, check whether the outer packing box is intact and undamaged.

2) Open the outer packing box in a flat open area

3) Check whether the equipment, accessories and accompanying documents are complete according to the packing list.

4) Remove the connection between the equipment and the base of the packing box

5) Move the equipment from the base of the packing box to a level ground.

- Fixed equipment

1) Move the equipment to the installation position, move the equipment to make the equipment stable, and the four casters of the equipment should be evenly struggling to land.

2) Lock the locking structure of the front casters of the equipment.

- Pipeline connection

Connection of water source and water inlet of sterilizer

An overhaul valve and water filter should be installed between the water source and the equipment to facilitate future overhaul of the sterilizer. The steam exhaust port and the exhaust pipeline are connected firmly and reliably, and the exhaust pipeline should discharge the drained water and gas to a safe place. The installation diagram is shown in Figure 4

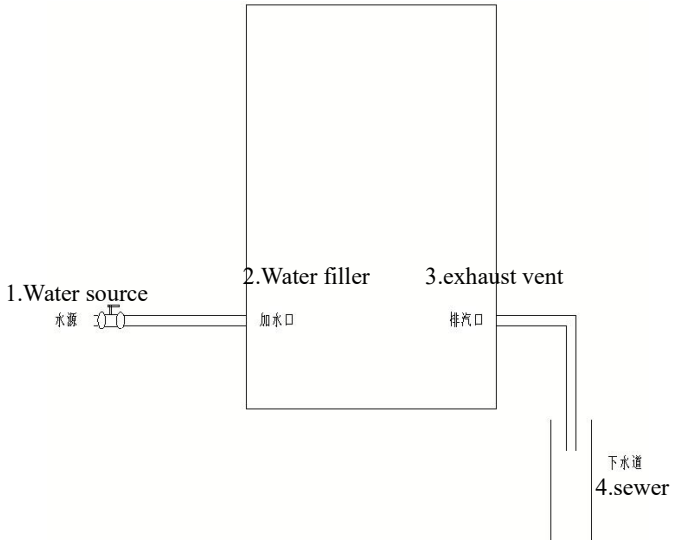


Figure 4

- Electrical installation

Install a power switch box on the wall behind or on both sides of the device. A main air switch circuit breaker must be installed in the power switch box, and an over-current protection device must be installed to realize the on-off and over-current protection functions of the equipment power supply. The installation location of the power switch box should be close to the equipment and the place that is easy for the operator to reach. This switch power box should be dedicated to the

ethylene oxide sterilizer. To ensure the safety of personnel and equipment, the equipment ground wire must be reliably connected to the ground wire in the power switch box.

Connect the equipment wire to the 220V power supply, and carefully check the reliability of the power supply wiring.

Note： The ground wire of the equipment must be reliably grounded.

- Power-on debugging

The debugging of the equipment must be carried out by professional after-sales service technicians.

5.4、Training

- Ethylene Oxide

Ethylene Oxide (EO), also known as ethylene oxide, has a small molecule and a 3-membered ring with unstable structure, strong penetrability and chemical activity. Ethylene oxide is a colorless and transparent liquid at 4°C, with a density of 0.884g/mL, a boiling point of 10.8°C, and an aromatic ether smell. Ethylene oxide can be miscible with water in any proportion, and can also be soluble in organic solvents or grease. Ethylene oxide is flammable and explosive. When the content in the air is 3%-80%, it will form an explosive mixture, which will burn or explode when it encounters an open flame.

Ethylene oxide is chemically active, and contact with catalysts can cause chemical reactions. This reaction accelerates with the increase of temperature, pressure and water volume, producing yellow viscous substances, which can easily block pipelines and affect sterilization.

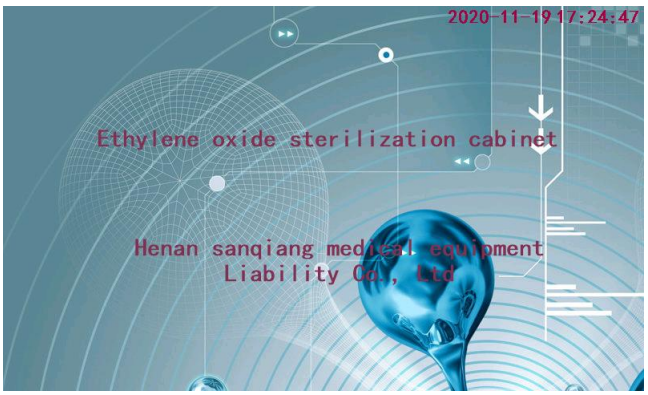
The toxic effect of ethylene oxide on the human body is mainly direct contact or inhalation. Ethylene oxide gas can irritate the respiratory tract. Protective measures should be taken during the sterilization operation. If you accidentally spill ethylene oxide liquid on your skin or eyes, you should immediately rinse with running water and seek medical attention.

6. Operation screen introduction

The sterilizer uses a resistive touch screen that is more resistant to electromagnetic interference, and the keys and buttons are input by pressing the screen.

6.1、Startup screen

Before starting the machine, check whether the power cord is connected. If the connection is correct, press the switch button (No. 4 in the appearance drawing). When the sterilizer is turned on, the touch screen will light up and the welcome interface will appear. See picture 5



Picture 5

6.2、Equipment self-check

After booting up, the device will perform a self-check to check whether the various parameters of the sterilization process are normal, as shown in Figure 6, click the "skip" button to enter the main page of the system.

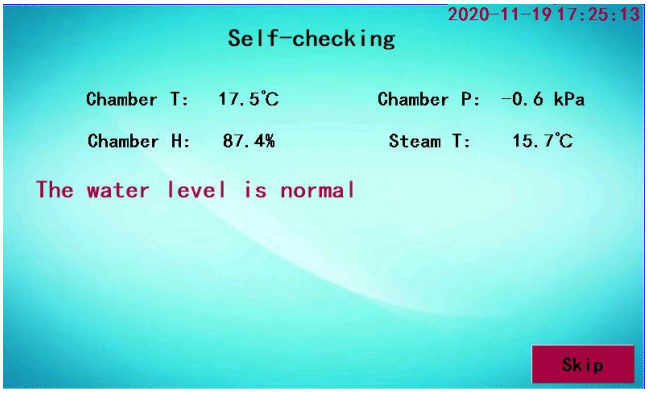


Figure 6

6.3、main page

The main page displays some main information and operation buttons of the system. You can click the button to enter the corresponding operation page. The main page is shown in Figure 7

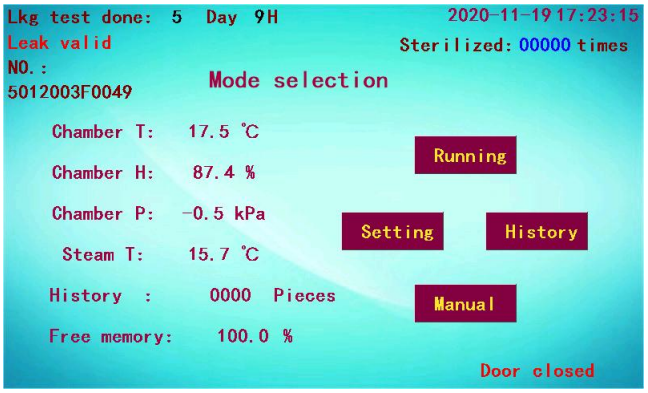


Figure 7

6.4、Sterilization operation

After clicking the "Sterilization Run" button, the system will enter the working screen of the sterilization operation. Click the "Start" button to start the sterilization program. At this time, the

"Start" button becomes the "Stop" button; after clicking the "Stop" button The sterilization program stops running. Click the "Back" button, the system returns to the main page. The working screen of sterilization operation is as shown in Figure 8

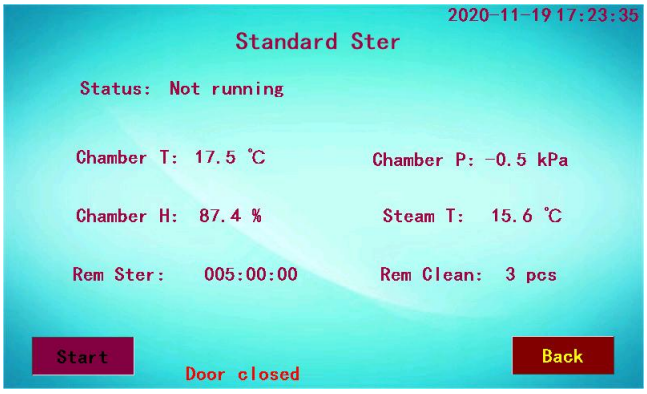


Figure 8

6.5、Password input

Click the "Parameter Setting" button, and a digital keyboard screen asking for a password will appear. Enter the correct password to enter the parameter setting interface. In addition, this digital keyboard is also used to modify other data. "DEL" key means delete, "OK" key means confirm, the numeric keyboard is shown in Figure 9

Figure 9

6.6 、Parameter setting interface

The parameter setting screen is shown in Figure 10. These operations need to be performed by professional technicians. This is also a menu specially created for the convenience of technicians to modify some process parameters of the equipment. Non-professionals need to operate under the guidance of professional technicians. I won't go into details here.

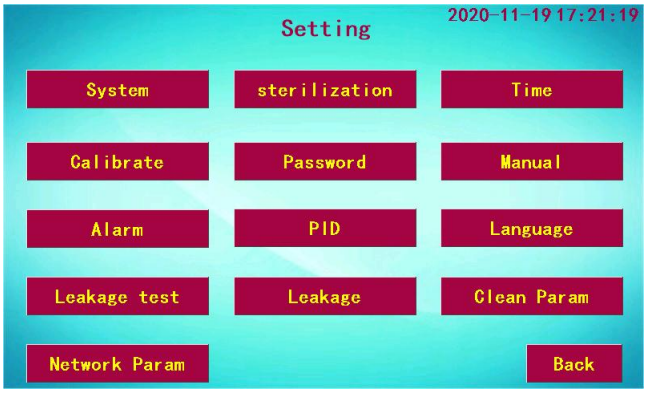


Figure 10

6.7、Sterilization parameters

Different sterilization items need to be set with different sterilization times. The sterilization time parameters are set in the "sterilization parameters" menu. Except for the sterilization time that can be set, other parameters are the best parameters for factory debugging. modify. The company is not responsible for all adverse consequences caused by tampering of parameters. The parameter setting screen is shown in Figure 11

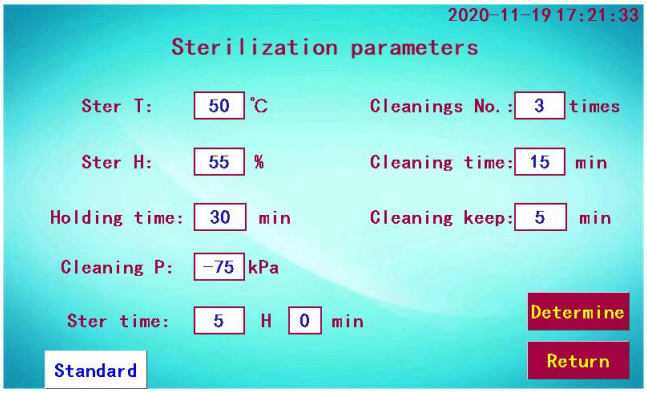


Figure 11

6.8、time setting

The display time of the sterilizer is controlled by the internal clock chip of the controller. The internal clock chip will inevitably deviate from the standard time when it runs for a long time. For occasions that require high time accuracy, the time needs to be manually checked through the "time setting". Click the modified time option to modify it on the numeric keyboard, the time setting screen is shown in Figure 12

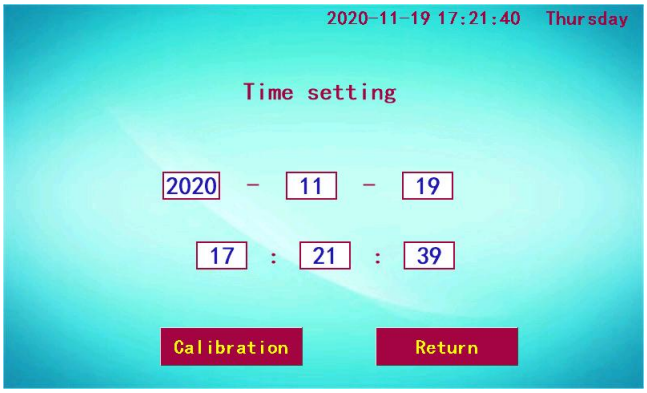


Figure 12

6.9、Manual cleaning

In "Manual Cleaning Mode", click the "Start" button at this time, and the equipment will automatically run cleaning. If you click the "Return" button, the system directly returns to the main interface. The manual cleaning interface is shown in Figure 13.

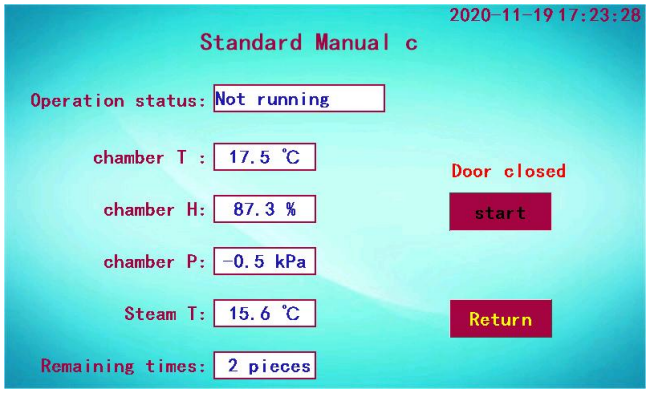


Figure 13

6.10、historical data

The historical data menu records and saves some important data at each stage of each operation of the sterilizer, including key data such as sterilization time, sterilization pot times, temperature, pressure, and humidity. These data facilitate the research on the sterilization performance of the sterilizer in the later stage. The historical data page is shown in Figure 14

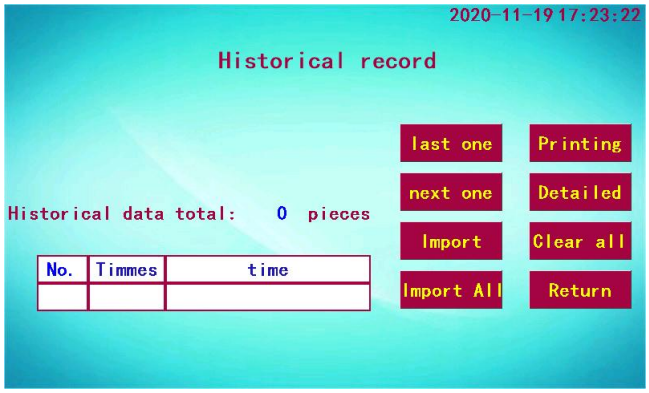


Figure 14

Click the "Detailed " button to view the detailed historical data of the current pot times, click

the "Printing" button, the printer will print the detailed data of the current pot times, click "Import", the historical data of the current pot times will be in csv file format Save to U disk. Click all to import the U disk, and all the historical data information of running pots will be saved to the U disk in csv file format. The detailed view page is shown in Figure 15

Figure 15

7. How to use

7.1. Check whether the pipe connections of the water filling and draining hoses are firmly installed.

7.2. Check if there is distilled water in the clean water tank. How to add water: flip up the switch of the water box for adding distilled water, pour in distilled water, and the opened state of the water box is as shown in Figure 16

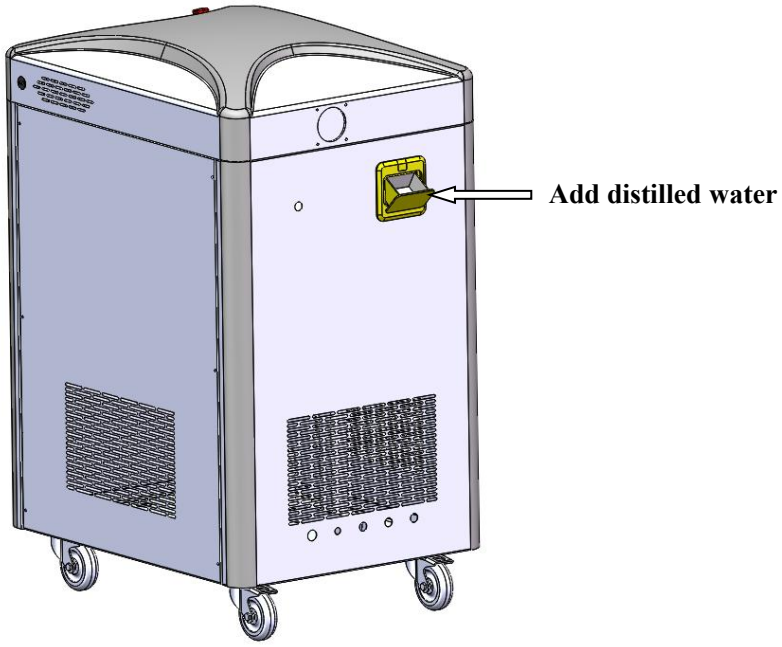


Figure 16

7.3. Open the sterilizer door and observe whether the sterilization chamber is clean. It is forbidden to carry foreign objects for sterilization. The fully opened state of the door is about 85 degrees. When there is obvious resistance in the process of opening the door, do not continue to open it with

force to avoid damage to the decorative cover of the door. The fully open state of the door is shown in Figure 17

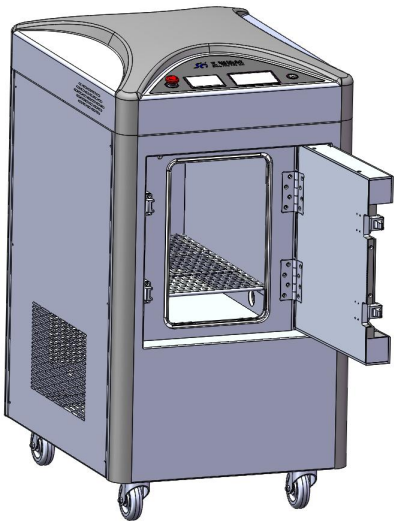


Figure 17

7.4、Put the ethylene oxide aerosol canister into the storage position of the dosing can in the sterilization room, and place the dosing can according to the instructions of the aerosol can. The location of the dosing tank is shown in Figure 18

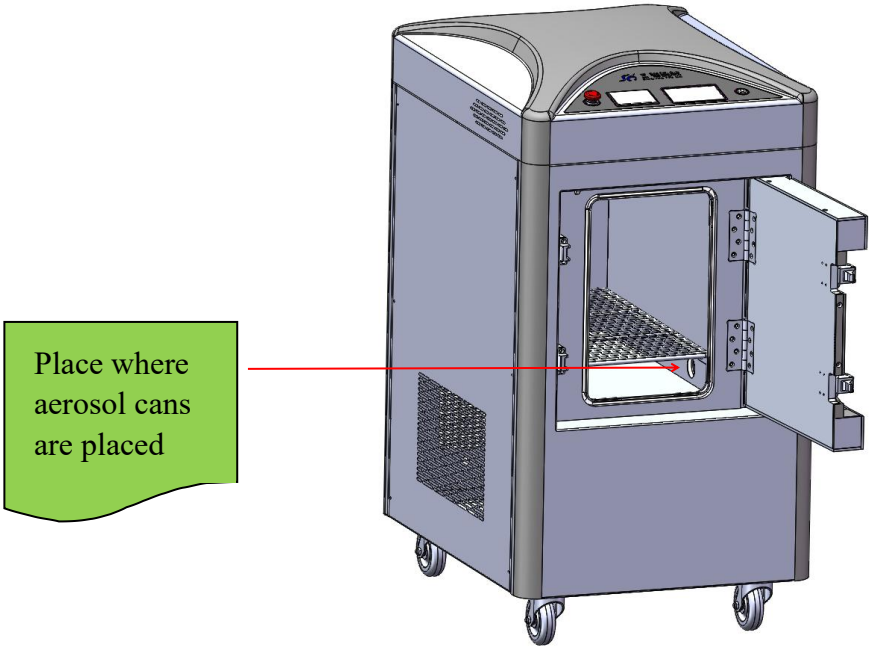


Figure 18

7.5. Open the water source valve.

7.6. Pack the sterilized items in a medical packaging bag (guaranteed the sterilized items shelf life is 2 years), and put the EO indicator card in the bag, and place it loosely on the carrier after sealing. The sterilized items will be sterilized 80% of the room space is the best.

7.7. Check whether there are any omissions in the above operations, lock the door after confirming that it is correct, and then use the key to lock the door lock. See picture 19

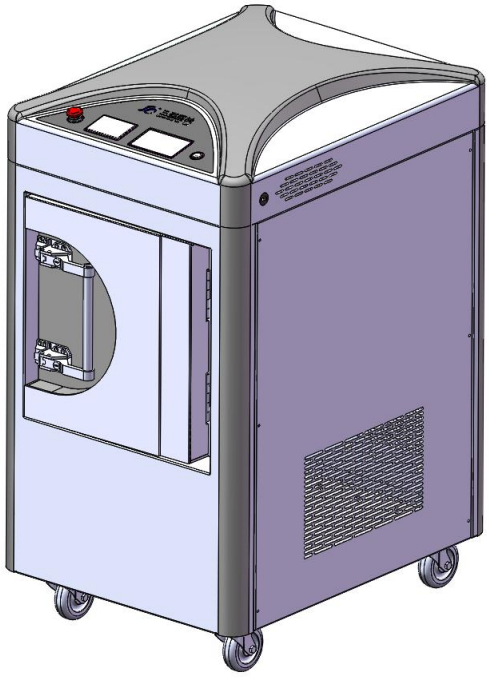


Figure 19

7.8. Turn on the power supply and turn on the power switch, enter the operation interface and click the "Sterilization operation" button.

7.9. Click the "Start" button, and the machine can enter the working state of the sterilization program.

7.10. When the temperature of the sterilization chamber reaches a certain value, the machine automatically enters the vacuum state. After the vacuum pressure reaches the set pressure(-60kpa), it enters the vacuum leakage test, humidification and humidity retention stage. After the test is passed, the system will automatically inject medicine and the equipment will continue to heat up.

7.11. The temperature rises to the set value, and the sterilizer starts timing. When running from the set sterilization time to the set time, the machine automatically enters the residual cleaning state. After the set number of residual discharges is completed, the equipment alarms to indicate that the sterilization is complete. At this time, the printer prints the data of each stage in the entire sterilization process, and all the sterilization process ends after the printing is completed.

7.12. Open the sterilizer door, take out the sterilized items for natural analysis; take out the aerosol cans in the sterilization chamber, check whether the aerosol cans are effectively punctured, and put the discarded aerosol cans for proper disposal.

7.13. Turn off the power and water source after all the work is completed to complete the entire sterilization process.

7.14. In addition, according to the special needs of the items to be disinfected, the machine can set

the corresponding parameters arbitrarily, but this setting needs to be approved by professional and technical personnel before it can be set.

Note: If there is no one to operate after 20 minutes of sterilization, the equipment will automatically vacuum to -20kPa. At this time, when opening the door of the sterilization chamber, you need to enter the manual operation interface, find the "intake valve" and click the start button behind the "intake valve", the device will automatically enter the air, and wait until the pressure on the display is -0.1kPa. Open the sterilization chamber door.

8. Power-off memory function

This machine has a power-off memory function. When the sterilizer is unexpectedly shut down due to power outage or other conditions during the sterilization process, the equipment will automatically remember the operating state of the machine when it is shut down. When the equipment is called or turned on, the sterilizer will prompt you whether to continue the last run, click the "Yes" button to continue the last run of the program; click the "No" button, the system enters the main page, and the power-off continued screen is shown in Figure 20

Note: If the device is re-called, if there is no operation for ten minutes, the system will default to "Yes" and continue to run in the working state when the power is off.

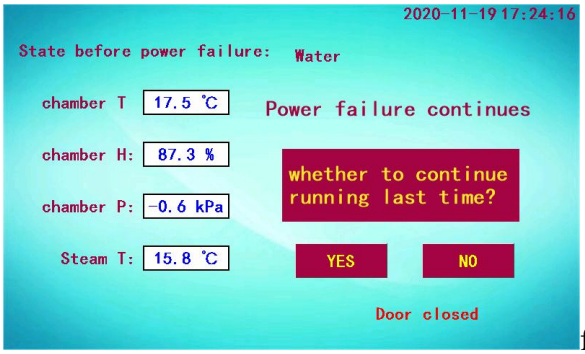


figure 20

9. Sterilization effect detection

Part of this chapter refers to "WS 310.3-2016 Hospital Disinfection Supply Center Part III: Cleaning and Disinfection and Sterilization Effect Monitoring Standards".

9.1、Physical monitoring method

In the standard "WS 310.3-2016 Hospital Disinfection Supply Center Part III: Cleaning and Disinfection and Sterilization Effect Monitoring Standards", it is required to continuously monitor and record the critical parameters of each sterilization cycle, such as the pressure in the sterilization chamber, for each sterilization. Parameters such as temperature, humidity and sterilization time. The sterilization parameters are in accordance with the instructions or technical requirements of the sterilizer.

The device is equipped with a thermal printer, which can print out the sterilization data. The recording paper can be archived for future reference. The recording paper can record the relevant parameters such as pressure, temperature and humidity time in each sterilization stage during sterilization. By observing these values Whether it is consistent with the requirements, can initially determine whether the sterilization effect is good or bad.

Note: Physical monitoring can not truly reflect the sterilization process and microbial killing of each package in the sterilizer. It should be combined with chemical monitoring and biological monitoring to comprehensively reflect the quality of sterilization.

9.2、Chemical detection method

In the standard "WS310.3-2016 Hospital Disinfection Supply Center Part III: Cleaning and Disinfection and Sterilization Effect Monitoring Standards", it is required that each sterilized item should be packaged with an external chemical indicator, and the color change is observed to determine Whether it meets the sterilization qualification requirements.

Chemical monitoring mainly uses the naked eye to observe the substance (state) change or chemical (color) change to test the parameters of the sterilization process. Chemical monitoring is fast, simple and low-cost, and can be used to detect possible sterilization failures, such as incorrect The packaging or loading of the sterilizer fails, etc.

Chemical testing is mainly used for the outside of each package. It has distinguished sterilized and non-sterilized items. Commonly used chemical indicator cards, chemical indicator tapes, discoloration strips and labels on paper-plastic packaging bags, etc.

9.3、Bioassay

In the standard "WS 310.3-2016 Hospital Disinfection Supply Center Part III: Disinfection and Sterilization", it is required that at least one biological monitoring of the sterilization cycle should be carried out every day, and the testing method should comply with the relevant national regulations. For specific use of biological indicators, please refer to the biological indicator manual.

For bioassay methods for newly installed equipment, see the Biological Indicators Specification. Chemical indicator cards and biological indicators should be used within their validity period.

Ethylene oxide sterilization biological indicator can not be replaced by other sterile biological indicators.

10. Daily maintenance

10.1、Sterilizer cleaning

(1) Please disconnect the power supply of the sterilizer before cleaning.

(2) Use a clean soft cloth to wipe the surface of the equipment, and do not use strengthening agents or detergents.

(3) Do not allow water or cleaning solutions to penetrate the sterilization room and the touch screen.

(4) When cleaning the interior of the sterilization chamber, please do not use abrasive materials or abrasive tools to clean the door of the sterilization chamber. When sealing, the sterilization chamber door is pressed tightly on the sealing ring. The flatness of the sterilization chamber door will affect the sealing effect. Please do not use rough cleaning tools such as wire brushes to clean the sterilization chamber door.

10.2、Replace the printing paper

Follow the steps below to replace the paper

（1）Open the printer lid on the control panel.

（2）Load new paper into the printer case, paying attention to the glossy side of the paper.

（3）Pull the paper end from the printer about 50mm, close the lid of the printer, press the test button on the upper right side of the printer to check whether the paper is smooth. If the paper jam occurs, the paper is not placed correctly. Place the printing paper; if the paper is smooth, the paper is placed in the correct position. The paper is replaced.

10.3、Replace the fuse

(1) Use tools to open the top cover of the equipment;

(2) Find the position of the fuse and use a flat-blade screwdriver to open the cover of the fuse holder;

(3) Take out the fuse and replace the fuse of the same specification (model RT18-32, specification Φ10×38 32A)

11. Fault alarm and troubleshooting

If you can't solve the problem by referring to the methods in the list below, please contact the customer service staff, the company will arrange the professional to online guidance.

11.1、Faults and troubleshooting methods

Table 6

item	Fault phenomenon	Cause	Solution
1	The touch screen is not bright when the power is turned on	1）No power supply on the power line	1）Check if the power supply line has power
		2）Emergency stop button is pressed	2）Rotate the emergency stop button clockwise to normal
		3）Power plug connection is loose	3） Check if the power plug connection is loose
2	No response after clicking the touch screen	1）The touch screen is abnormally connected to the control panel.	Contact customer service staff

		2）Control board failure	
		3）Touch screen failure	
3	The printer does not print	1）No printing paper	1）Install a new roll of paper
		2）Print paper loading reverse	2）Correct installation of printing paper
		3）Printer power is not turned on	3）Contact customer service staff
		4）Printer communication line failure	4）Contact customer service staff
		5）Printer failure	5）Contact after-sales service personnel to change the printer
4	Print overwriting	1）Paper is not in place	1）Remove the paper and reinstall the paper
		2）The printer cover is not snapped into place	2）Refasten the printer cover
		3）Standard paper not installed	3）Replace standard paper
		4）The paper roll is not installed correctly	4）Reinstall the paper
		5）Printer failure	5）Contact customer service to replace the printer
5	After the sterilization is completed, the door cannot be opened	1）Negative pressure inside the door	1）Contact service personnel
		2)The switch door handle is locked by the key	2）Use the key to open the switch door handle lock

11.2、Alarm and troubleshooting method

Table 7

Item	information	Reason description	Method of exclusion
1	Unqualified water quality	The quality of the external distilled water is unqualified	Replace water-qualified external distilled water
		Unqualified distilled water in the pipeline	Rotate the distilled water joint knob to drain the unqualified distilled water in the pipeline.
2	Inner tank temperature is too high	Temperature sensor failure or loose wiring	Contact service personnel
		The temperature of the	Contact the after-sales service personnel to modify

		liner high temperature alarm is set low	the over-temperature alarm value
		Control system failure	Contact service personnel
3	Vacuuming timeout	Vacuum pump failure	Contact service personnel
		Leakage of sterilizer	Contact service personnel
		Sterilizer door is not closed	Close the sterilizer door
4	Inner pressure is too high	Pressure sensor failure	Contact service personnel
		Control system failure	Contact service personnel
		The liner high pressure alarm pressure value is set low	Contact the after-sales service personnel to modify the excessive pressure alarm value
5	Steam generator temperature is too high	Steam generator over temperature alarm value setting is low	Contact the after-sales service personnel to modify the steam generator temperature too high alarm value
		Steam generator heating failure	Contact service personnel
6	Sterilization temperature is too low	Heating failure	Contact service personnel
		Sterilization temperature is too low, the alarm value is set too high	Contact the after-sales service personnel to modify the temperature too low alarm value
7	Sterilization humidity is too low	Humidification failure	Contact service personnel
		Sterilization humidity is too low, the alarm value is set too high	Contact the after-sales service personnel to modify the humidity low alarm value
8	Steam shortage	No distilled water	Check if there is distilled water outside
		Detecting water sensor failure	Contact service personnel
9	Leakage rate is too high	Sterilizer leak	Contact service personnel
		Sterilizer door is not closed	Contact service personnel
10	Door not closed	Detecting door sensor failure	Contact service personnel

If you encounter other problems in daily use, please contact customer service.

Tip: Please use a special ethylene oxide spray tank that meets the size of the machine's dosing hole, otherwise the equipment will not be held responsible.

Note: we reserve the right to print errors, software upgrades, product improvements and modifications and final interpretations that are inconsistent with the latest version of this specification. The changes are subject to change without prior notice and will be directly included in the new version of the specification.