FULLY AUTOMATIC

Ethylene Oxide Sterilizer

USER'S MANUAL

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Name of registrant (manufacturer): Hefei Sada Medical Equipment Co., Ltd

Registration Certificate (Manufacturer) Address: No. 12629, Jingdian Plaza, Fanhua Avenue, Economic Development Zone, Hefei, Anhui, China

Hefei SADA Medical Equipment Co.,Ltd. is a professional high-tech enterprise, incorporating research, manufacturing, distribution of sterilization equipment and laboratory equipment, located in Hefei City, Anhui Province, China.

At present, SADA has two producing zones, covering the area of 40 acres and the building area of 30000 m2. The main products: portable steam autoclave, table top pressure steam autoclave, vertical pressure steam autoclave, horizontal pressure steam autoclave, pulse vacuum autoclave, super water autoclave, ampoule leak autoclave. H2O2 low temperature plasma sterilizer, gas ethylene oxide sterilizer and other related medical disposables. It can meet the needs of pharmaceutical, lab, hospital, food, biotechnology for different products. All the products from SADA, are strictly treated according to quality control system, such as CE, ISO9001, ISO13485. To supply the"zero-defect"units with comprehensive, thoughtful and sincere service is our final target goal.

For the honor and commitment, we strive to do better.

Instructions revision date: January 1, 2024

2. Main Structural Components or Ingredients

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

3. Scope of application

 It is suitable for sterilizing medical devices that are afraid of moisture and heat and can withstand ethylene oxide.

4. Contraindications

 It is prohibited to use unpackaged liquids and powders for sterilization. For liquids, ethylene oxide may dissolve in the liquid, and for powders, the powder may fly around and be sucked into the vacuum pump during vacuuming.

V. Precautions and contents requiring warning or reminder

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1. Operators should read the instructions carefully and operate only after mastering the methods.

2. Before powering on, check whether water has been added to the overflow port (except for automatic water addition).

3. The operation must be carried out in the order listed in the manual. It cannot be reversed. If the keyboard is touched accidentally during operation, turn off the power switch and restart

the power to operate again.

4. Each time you turn off the power and then restart it, there must be an interval of more than ten seconds, otherwise it will easily cause confusion in the display.

5. Add medicine according to the procedures specified in the operation process. When opening and closing the gas cylinder, do not use excessive force. Open the valve slowly to prevent waste caused by excessive addition of gas.

6. Ethylene oxide mixed gas cylinders are used exclusively. It is strictly forbidden to bump or turn them upside down during transportation. It is strictly forbidden to use ethylene oxide sterilization gas that is not configured by our company. Otherwise, we will not be responsible for any consequences.

7. The storage place of ethylene oxide mixed gas cylinders should be free of fire, heat, sunlight, good ventilation, and the temperature should be below 40 ℃, but it should not be placed in a refrigerator. If the temperature of the cylinder is below zero, it should be allowed to reach room temperature before use.

8. After using the ethylene oxide cylinder, use a wrench to remove the dosing tube on the cylinder, and connect the new

cylinder to the dosing tube. If you find that there is a leak in the drug inlet pipeline on the cylinder, you should close the cylinder valve and replace the drug tube before using it.

9. The product is provided with packing list, certificate of conformity and warranty card.

10. The packaged ethylene oxide sterilization box should be stored in a well-ventilated room with a relative humidity not exceeding 80% and no corrosive gas. It is strictly prohibited to disassemble or twist it at will. During transportation and handling, it should be handled with care and should not be tilted, squared or inverted.

11. Operators must be trained by our company and fully master the knowledge of safe use of ethylene oxide gas before using this equipment.

12. Personnel who come into contact with ethylene oxide must be familiar with GB50493-2009 "Petrochemical Combustible Gas and Toxic Gas Detection Alarm Design Specifications" and install an ethylene oxide leak detector next to the equipment.

13. Conduct maintenance training for operators every year and keep records of each person's learning and performance.

14. How to remove the load in case of a fault: Manually depressurize the system and observe the pressure gauge display. When the pressure in the cavity reaches between -10KPa and +10KPa, you can open the equipment door and remove the items.

15. If the equipment is used in a manner not specified by the company, the protection provided by the equipment may be impaired.

16. If the sterilizer container leaks and causes a fire or comes into contact with glasses or skin, please refer to GB50493-2009 "Petrochemical Combustible Gas and Toxic Gas Detection Alarm Design Specification" for handling.

17. The maximum leakage rate of ethylene oxide is 10ppm, which will trigger the leak detector to alarm. If the room detection alarm occurs, all ventilation facilities must be opened immediately. All electrical equipment must be turned off and leave the room.

18. Equipment intermittent operation times: A half-hour interval is required before the equipment is operated again.

19. Any parts that can only be inspected or provided by our company or agents.

20. The product is valid for eight years. Our company is

responsible for the free installation and commissioning of the product. Please contact our company after the goods arrive. If there is any fault, free repair will be made during the warranty period (the warranty period is one year), except for abnormal damage caused by human factors and damage caused by force majeure. For products that exceed the warranty period, repair fees will be charged.

6. Technical parameters

Table 1

model	Sterilization chamber size Length: Width: Height: (mm) Tolerance ±1 %	Rated Power Tolerance ±20%	Work Pressure	Operating temperature	Operating humidity	Sterilization time
SD-EO60L	Length: 620mm , Width: 350mm , Height: 280mm	1.7 kVA	0 kPa ~ − 60 kPa	30 ℃ ~ 60 ℃	Relative humidity 40% ~ 80%	3h ~ 9 9h
SD-EO90L	Length: 6 10mm, Width: 4 80mm, Height: 3 80mm	2. 3 kVA				
SD-EO120L	Length: 710 mm, Width: 480 mm, Height: 380 mm	2.7 kVA				
SD-EO160L	Length: 7 70mm, Width: 46 0mm, Height: 46 0mm	3.5 kVA				
SD-EO180L	Length: 8 60mm, Width: 46 0mm, Height: 46 0mm	3.7 kVA				
SD-EO200L	Length: 9 60mm, Width: 46 0mm, Height: 46 0mm	4.1 kVA				
SD-EO300L	Length: 9 60mm, Width: 56 0mm, Height: 56 0mm	4.3 kVA				
SD-EO400L	Length: 10 10mm, Width: 66 0mm, Height: 60 0mm	4.5 kVA				

SD-EO600L	Length: 12 10mm, Width: 66 0mm, Height: 7 60mm	5.5 kVA	
DOUBLE DOOR (PASS THROUGH TYPE)			
SD-EO60L	Length: 620mm , Width: 350mm , Height: 280mm	1.7 kVA	0 kPa ~ – 60 kPa 30 ℃ ~ 60 ℃ Relative humidity 40% ~ 80% 3h ~ 9 9h
SD-EO90L	Length: 6 10mm, Width: 4 80mm, Height: 3 80mm	2. 3 kVA	
SD-EO120L	Length: 710 mm, Width: 480 mm, Height: 380 mm	2.7 kVA	
SD-EO160L	Length: 7 70mm, Width: 46 0mm, Height: 46 0mm	3.5 kVA	
SD-EO180L	Length: 8 60mm, Width: 46 0mm, Height: 46 0mm	3.7 kVA	
SD-EO200L	Length: 9 60mm, Width: 46 0mm, Height: 46 0mm	4.1 kVA	
SD-EO300L	Length: 9 60mm, Width: 56 0mm, Height: 56 0mm	4.3 kVA	
SD-EO400L	Length: 10 10mm, Width: 66 0mm, Height: 60 0mm	4.5 kVA	
SD-EO600L	Length: 12 10mm, Width: 66 0mm, Height: 7 60mm	5.5 kVA	

VII. Installation and Usage Instructions

Equipment installation should be carried out under the guidance of professionals and by professional construction personnel.

⚠ **Notice The equipment must be installed and used in accordance with the company's requirements, otherwise the company will not be responsible for the consequences caused by incorrect installation .**

7.1 Working environment conditions

a) Ambient temperature : 5℃ ~ 40℃;

b) Relative humidity : 30% ~ 84 %;

c) Atmospheric pressure : 70 kPa ~ 106 kPa .

d) Power supply : ac 220V±22V; 50Hz±1Hz

e) Rated input power: see Table 1.

7.2 Equipment space and installation requirements (place the equipment according to regulations, otherwise it will be difficult to disconnect the device)

- For the convenience of operation and maintenance, the distance between the left and right sides of the sterilizer and the wall should be no less than 1m, otherwise it will be difficult to disconnect.
- Floor: The surface should be flat. If it is installed upstairs, consider whether the floor needs to be reinforced based on the load-bearing condition of the floor. The load-bearing requirement is 500Kg/㎡.
- Room ventilation and heat dissipation: To control the temperature of the working environment, a set of ventilation devices should be installed in the workroom and above the equipment. The room ventilation requires 8 cycles per hour. If the ventilation measures fail, all ventilated facilities and doors and windows in the room must be opened.

- Equipment drainage: The equipment drainage pipe should be led to a separate ditch and discharged outdoors. The ditch should be at least 200mm wide and 200mm deep.

7.3 Equipment Components Description

- Air compressor: The maximum pressure of the external air compressor is not less than 0.8 Mpa . The minimum volume is 80L. Use Φ8mm air pipe for connection.

7.4 Equipment Installation and Connection

- Move the equipment to the selected location. Place the front door of the equipment facing outwards for easy operation and installation.
- Connect one end of the included water pipe to the external faucet and the other end to the water inlet port at the bottom of the device, forming a quick connector.
- Connect the air compressor port to the equipment air inlet.
- Connect the residual gas outlet to the outside of the sterilization room and the highest point of the building, and take measures to prevent rainwater. There are two ways to discharge residual gas. One is to have a water supply and drainage device, and use the gas decomposition box in the equipment to decompose the gas into water and discharge it

into the floor drain. The second is to discharge the residual gas directly to the atmosphere. Connect the humidification water outlet with a pipe and insert it into a bucket (suitable for electric heating). Be careful not to lack water. The residual gas outlet is firmly connected to the PU pipe and pay attention to sealing. The other end is introduced outside the room directly to the atmosphere. There should be no fire source and good ventilation within 7 meters of the outlet. Note that the anti-rain outlet has an elbow facing downward.

- Ethylene oxide aluminum alloy gas cylinders should be placed in yellow garbage bags and treated as medical waste.
- Adjust the level

The device can be placed directly on level ground.

- Power requirements

1) The power cord uses a 5-core sheathed cable, and the live wire, neutral wire, and ground wire are clearly marked.

2) The power supply adopts a three-phase four-wire connection method. The power cord should be directly crimped to the dedicated circuit breaker of the distribution box and must be reliably grounded.

⚠ the phase sequence light comes on after the power is

connected and turned on, please turn off the power and adjust any two of the three-phase power before turning it on again.

⚠ **Note : The power ground wire must be reliably grounded! !**

7.5 Equipment Debugging

This series of ethylene oxide sterilizers have pre-set general parameters. During the debugging process, users can modify the program parameters according to the use requirements. For specific parameter settings, please read Chapter 4 "Equipment Instructions".

- Before debugging, check whether the wiring and sockets of the electrical parts are detached or loose.
- Check whether the water supply switch is turned on and whether there is water.
- Check whether the ventilation equipment is working properly.

1) Sterilizer No-load Test

- Before running the program, you should first perform a vacuum test according to the instructions in the " Instructions for Use ". If the test fails, it means that there is a leak in the pipeline

connected to the inner chamber. At this time, you must carefully check, eliminate the leak, and retest until the test passes, otherwise it will affect the sterilization effect of the equipment.

- Parameter setting: Refer to the method of presetting the basic parameters of the equipment and the working parameters of each program in " Instructions for Use " .
- After the parameters are set, normal no-load operation can be performed. For the specific procedure, please read 7.6 " Instructions for Use ".

2) Load Test

The above procedures are all carried out under no-load conditions. After the no-load test is passed, a load test should be carried out.

During the load test, the loading volume of sterilized items such as instruments and fabrics should not exceed 80% of the inner chamber volume. The load should be placed 3-5CM away from the top, side walls and back walls. The load test must test the sterilization effect of the center point inside the package according to standard requirements.

Conduct biological detection tests on the sterilizer and observe whether the test results meet the requirements.

7.6 How to use:

Operation Process

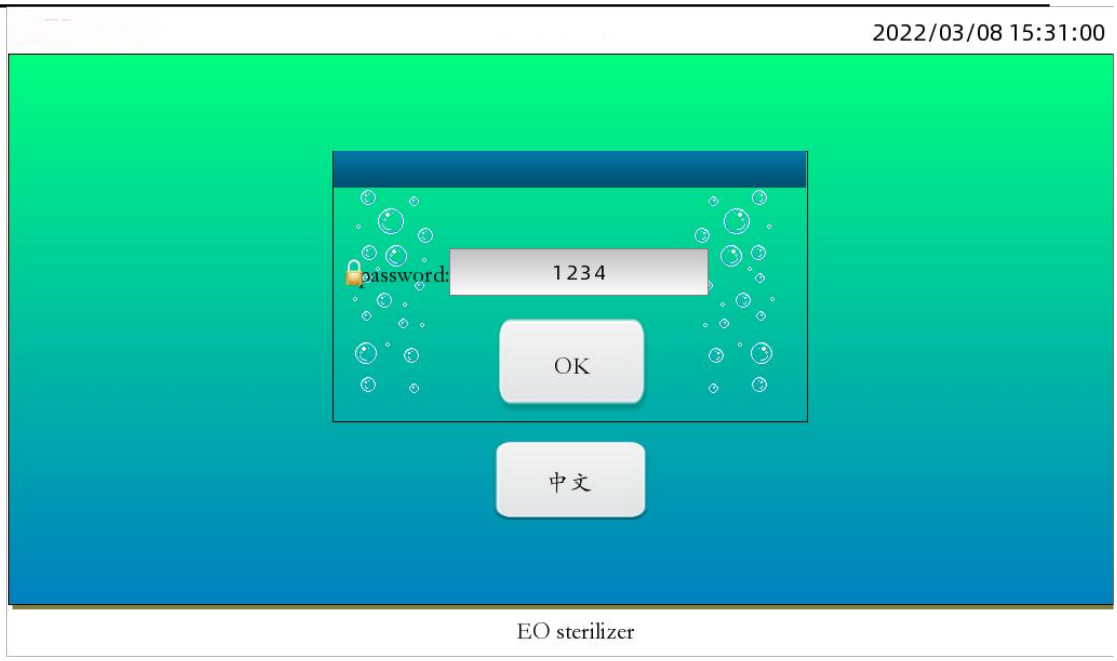
1 . Insert the special gas tank into the barrel with the mouth facing inwards (some equipment facing downwards) .

2 . Place the sterilized items in a special sterilization bag (which can keep the sterilized items for 3 months), seal it, put the EO indicator card in the sterilization room, and then place them loosely on the shelf. It is best if the sterilized items occupy 80% of the space in the sterilization room.

3 . After all work is completed, turn off the power to complete the entire sterilization process.

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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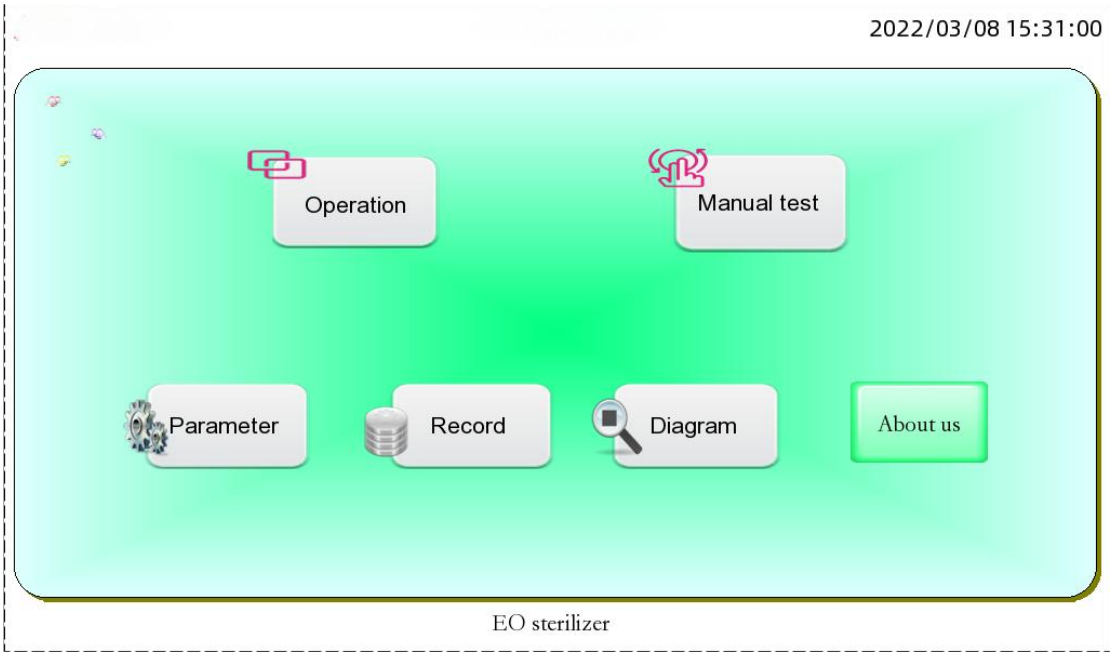
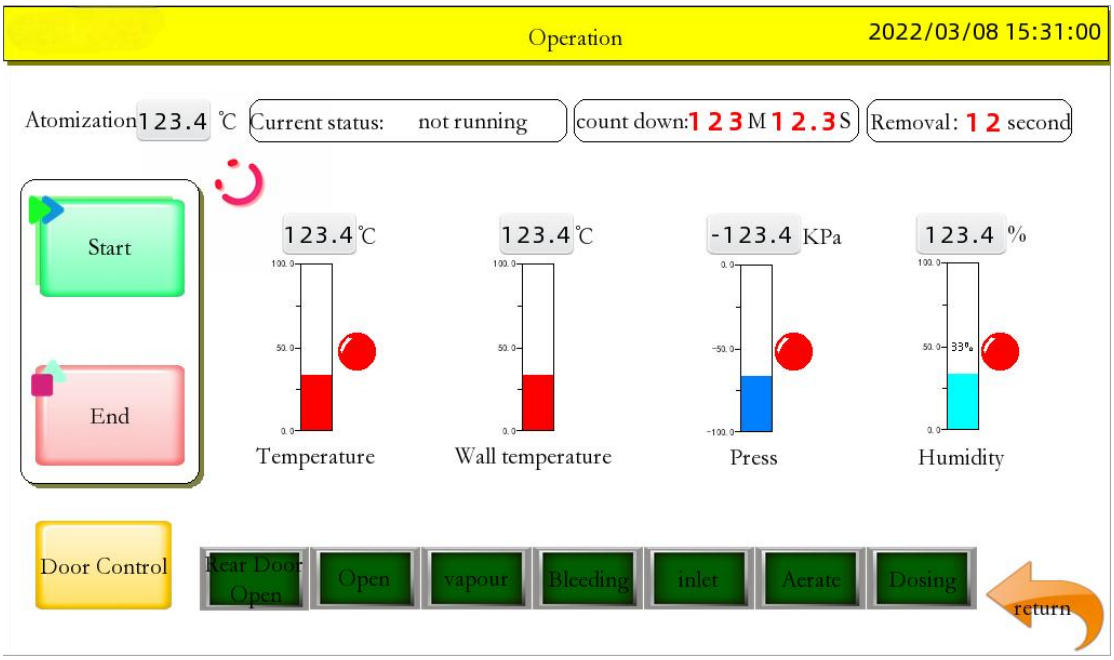
2. Select the interface. You can choose "Parameter Setting", "Manual Test", "History Record", "Graph", or " Run Interface"!



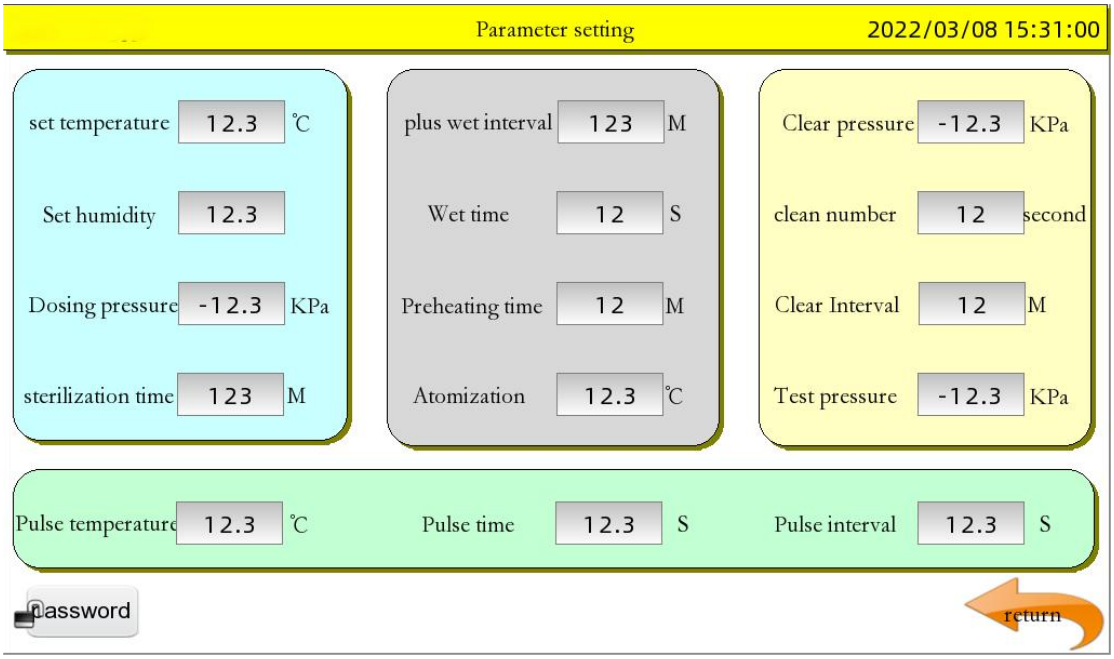
1 . The "Automatic Interface" equipment is loaded with sterilized items and sterilization consumables are placed. Click the start

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.

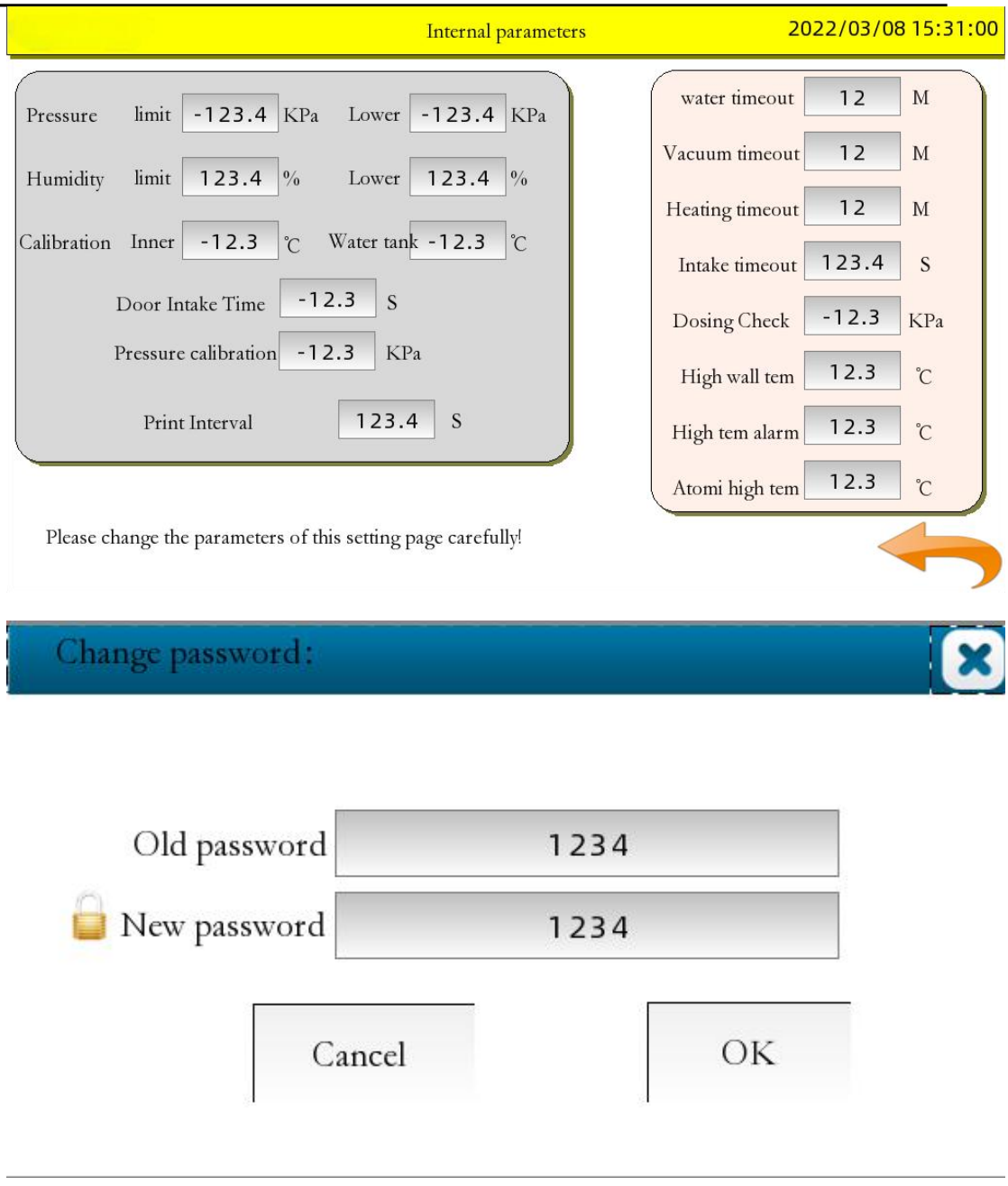


4. Parameter setting interface. The main parameters of the

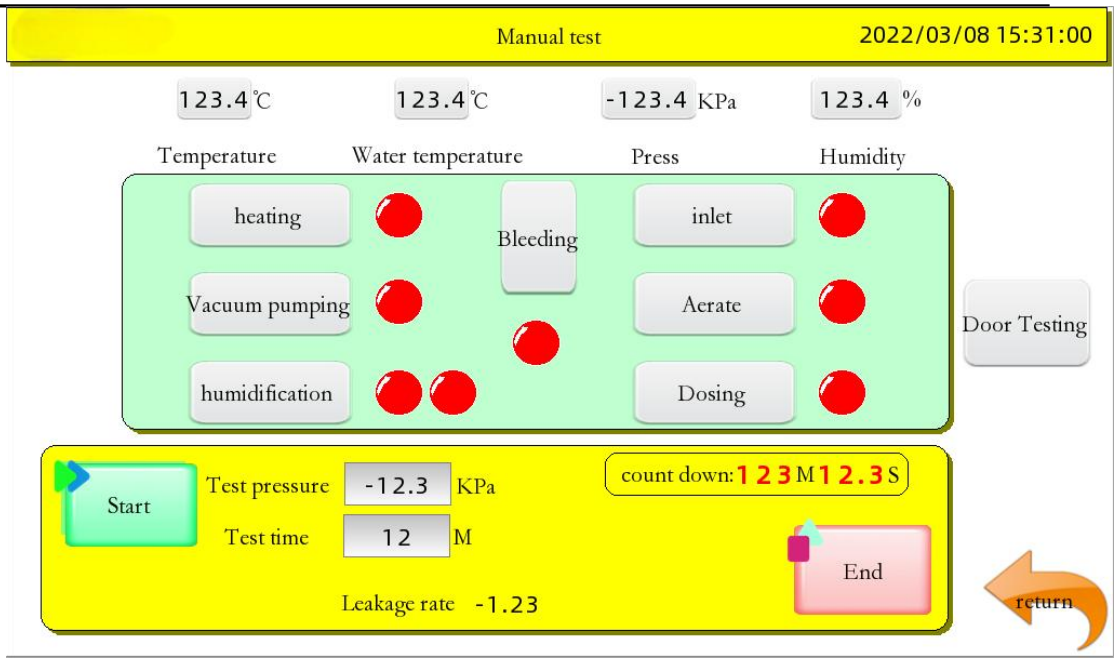
equipment are set. This interface is generally not recommended for customers to modify. If you need to modify it, you can only modify the "set temperature", "set pressure" and "sterilization time" on the first page. If you modify other parameters by yourself, it will affect the operation of the equipment.



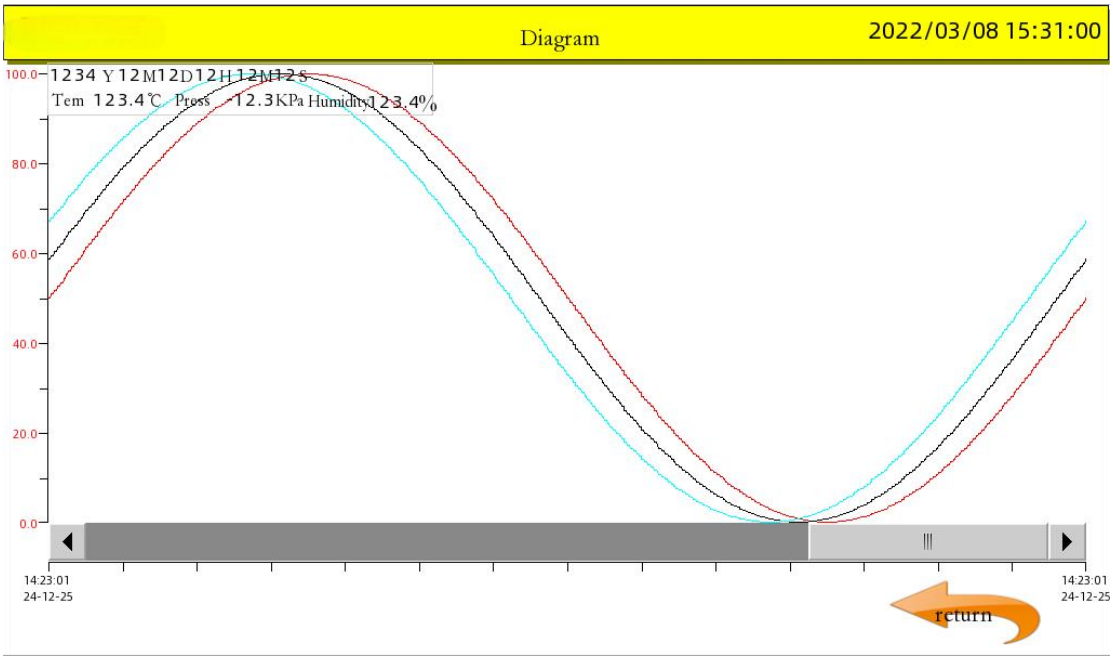
5. Password setting, enter the parameter setting interface in the sub-interface background parameter interface. Click password modification, enter the second password to enter the password and time setting interface. The power-on password is the password to be entered when the device is turned on! The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

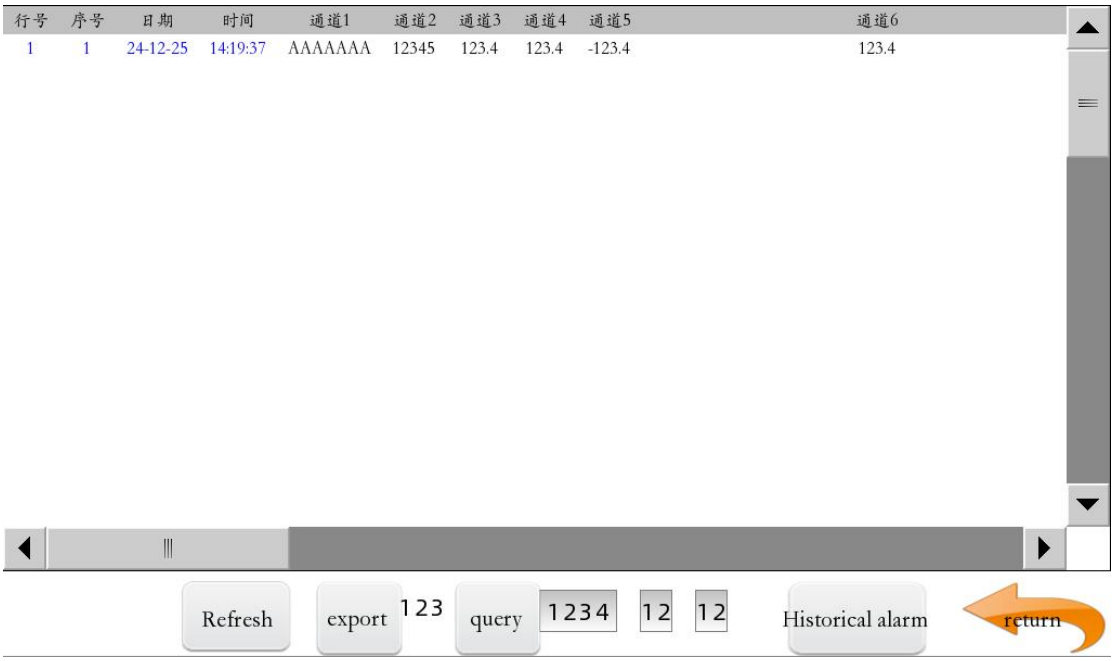


7. Curve graph interface. Displays the parameter curve of this pot operation. Blue is pressure. Red is temperature and black is humidity.



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

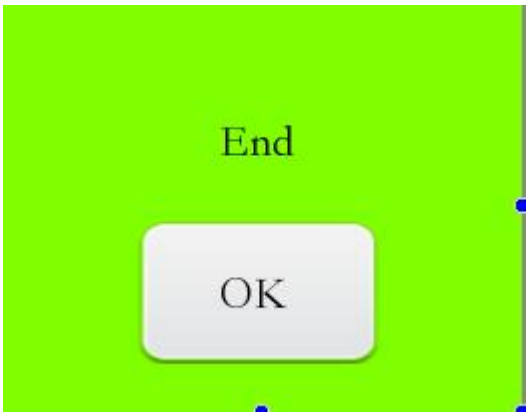
9. The history record interface displays historical operation data, which can be exported to a USB flash drive. After export, the data will be automatically cleared. The history record is basically synchronized with the printed receipt record.



7.7 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.



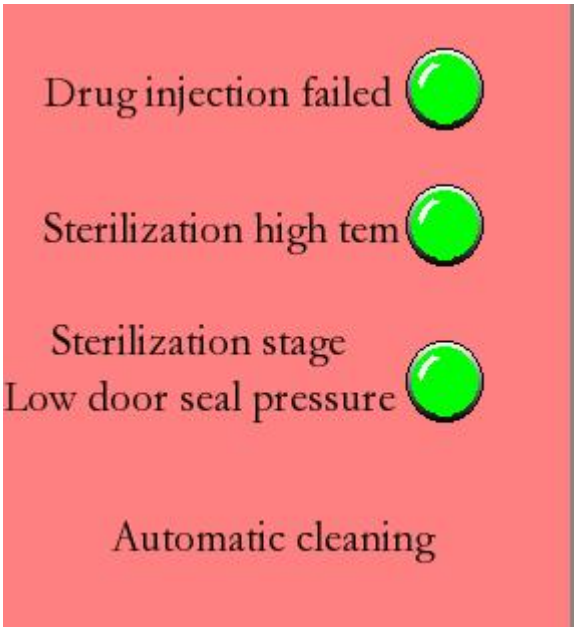
2. Water filling timeout display. It indicates that the water filling time is too long and the water level in the water tank has not been reached when the equipment is running. It is necessary to check the water source, water inlet valve and water tank float.

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!

8. Product Maintenance and Care Methods, Special Storage and Transportation Conditions and Methods

8.1. Product Maintenance and 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 each day, please wipe the door rubber ring with a soft cloth.

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

8.2 Storage Conditions and Methods

①This product should be loaded and transported in a covered carriage or cabin, and kept clean and protected from the sun and rain.

②This product should be stored in a well-ventilated and clean room with a relative humidity not exceeding 80% and no corrosive gas.

IX. Validity Period or Expiration Date

Validity period: 8 years

10. Accessories List

name	Origin	model
Vacuum Pump	Shandong	2BV-5110T
Relay	Shanghai	H380ZF
Empty	Shanghai	DZ47
Magnetic ring	Zhejiang	UF-118

Note: Product accessories are replaced by our company's after-sales personnel.

11. Medical device labels


Fear of sun exposure;


It means fear of rain;


Indicates warning attention;

 Be careful to avoid burns;

 Grounding mark;

For the " " warning mark that appears in the manual and the equipment ⚠, the contents of the manual must be compared with the equipment and their meanings must be understood. Users must be careful during installation and use and **must strictly follow this manual. Otherwise, the insulation and protection of the equipment itself will be damaged, causing the equipment to freeze or be damaged.**

12. Date of preparation/revision of instructions: January 1, 2024

13. Other contents that should be marked

none