



Laboratory Equipment Manufacturer
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Steam Sterilization

STE-HT-60/80

Operation Manual



PLEASE READ THIS MANUAL CAREFULLY BEFORE OPERATION
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MRC.7.19

Welcome to use Steam Sterilizer. To bring the maximum performance into full play and ensure that the product operate safely, please read the manual carefully first and strictly comply with the requirements of installation, operation and maintenance mentioned in this manual.

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Preface

The following symbols in the manual are used to get highly attention and caution:



NOTICE Highly attention should be paid.



NOTICE The cases possibly cause equipment damage.



NOTICE The cases possibly endanger personal safety.

Please read each chapter carefully and fully understand it before any operation, maintenance on the product especially the contents with the above symbols.

Please properly keep this manual away from loss and damage.

The operator has responsibility to renovate the manual and complete the lost, damaged or unsuitable contents.



NOTICE Anyone in any situation cannot tear off any page from the manual. During the usage of the product, please do not hesitate to contact us if there is any inconsistent explanation or unmentioned cases. We will timely solve the problems and update or renew the manual for free.

1. Overview

1.1. Product information

- Product function structure and components:

This product includes body, door, pipeline system and control system. It works under high temperature and takes saturated steam as medium to achieve disinfection and sterilization purpose. The pulse time can be set according to user's requirement.

- Scope of application:

It is used for sterilization of medical instrument, laboratory ware, culture medium, unsealed liquid and any material that may contact blood or body fluid.

- Supplementary instructions:

All information mentioned in this manual is only applicable for standard product. If you have any special requirements in product order please read the manual selectively according to the sales agreement of custom product.

1.2. The sterilization factor and characteristics

The product adopts damp and hot steam as sterilization factor.

According to the specified sterilization process, the product, in the environment of high temperature, high pressure and high humidity with certain pressure and time, adopts saturated damp and hot steam as factor to sterilize the items which can be penetrated by steam. Under the load situation described by the program, all the default technology parameters of this equipment are tested and determined taking the thermophilic fatty liver bacterium sporangium under special resistance or the equivalent performance microorganisms as the representative microbes that can be sterilized.

Note 1: When the infected microbe resistance of sterilization load is higher than the standard stipulated resistance (such as pathogen microorganism of mad cow disease, AIDS), according to the characteristics of specific microbes, adjust the sterilization pressure , sterilization time and other relative technology parameters, and after the relative technology confirmed, the sterilizer can be used.

Note 2: The killing ability of sterilization factor on agreed microorganism can be guaranteed effectively only when the equipment and related facilities are in normal working condition. For example: the equipment fault, external connection system fault, sterilization items loading and layout and so on are likely to interfere the bacteria killing effect of sterilization factor.

Note 3: due to the continuous update on the sterilization load, the operator should check whether sterilization load can be applied in this equipment for sterilization, then can do the operation, otherwise it may cause unpredictable damage on the equipment or the load!

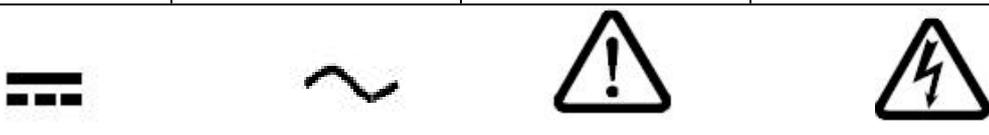
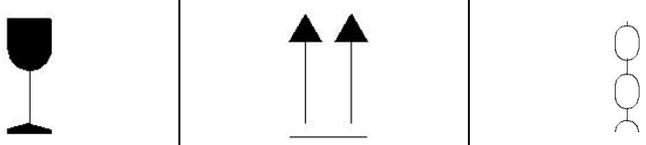
1.3. Parameters

Use rang of this manual:

Equipment Model	Volume	Chamber dimension/mm (usable)	Power supply	Power/ kVA
SHE-HT-60	60L	φ385×595	AC 220V/230V 50/60Hz	7.4
SHE-HT-80	80L	φ385×717	AC 220V/230V 50/60Hz	7.4

- Design pressure: -0.1/0.30Mpa
- Design temperature: 144℃
- Vacuum low limit: -0.08MPa (Type B)
- Temperature selection range: 105~138℃
- Temperature display precision: 0.1℃
- Pressure display precision: 1KPa

1.4. Mark instruction

			
On (power on) IEC417, No.5007	Off (power off) IEC417, No.5008	Ground IEC417, No.5017	Protected Ground IEC417, No.5019
			
D.C. IEC417, No.5031	A.C. IEC417, No.5032	Refer to the attached materials ISO3864, No.B.3.1	Electric Shock Danger ISO3864, No.B.3.6
			
Prevent Surface Overheating IEC417, No.5041	Refer to User Manual	Keep Dry	Temperature Limitations
			
Avoid Direct Sunlight	Avoid High Voltage IEC417, No.5036	Fuse IEC417, No.5016	
Safety symbol			
			
Fragile	Keep in Upright Position	Lift here	
Packaging symbol			

Instructions



DANGER

1. User should make the constantly daily maintenance during this product using process, and inspect it itself regularly.
2. User should make once self-inspection each month on the product under using, and take a record. If user finds abnormal situation while doing self-inspection and daily maintenance, should treat it in time.
3. User should make periodical calibration, maintenance on the safety accessories(safety valve, pressure gauge etc.) , safety protective device, measuring control device and relative auxiliary device of the products under using, and take a record.
4. The operator or relative administrator for this product should be tested qualified by the department of special vessel safety supervision and management accord to national relevant regulation, and obtain special operation certificate with national unified format, then can do the relative operation or management wok.

User unit should make special vessel safety, energy-saving education and training on the operators, ensure them master necessary safety and energy saving knowledge on the special equipment. This product operator should strictly execute the special vessel operation rules and relative safety regulations during operation.



NOTICE Please keep this manual completely during the equipment service life and ensure that all the updated information is included in this manual. In the case of that the equipment must be transferred to a new site, please make sure that the manual should be transferred as a part of the equipment.

The following symbols in the manual are used to get highly attention and caution;



NOTICE The product is not applicable for unsealed bottled liquid. Please contact us to order special liquid sterilizer.



NOTICE The bottle explosion that could endanger the personal and product safety may happen, if bottled liquid with tight seal is sterilized by this product.



NOTICE Since the chloridion is the important factor of corroding stainless steel, if the items that contain chloridion are sterilized by this product please wash the chamber everyday by clean water to increase the product service life. Otherwise, the chloridion may corrode the chamber.



NOTICE The improper operation (i.e. sterilize the items that contain chloridion without washing the chamber everyday) that decreases the product service life is not included into our warranty.



NOTICE In order to adopt proper measures when you see the  sign in any place please consult the manual or other relevant document to clarify the potential danger.



NOTICE  Indicates high temperature, please protect yourself from scald when you see this sign.

2. Installation

2.1. Unpacking

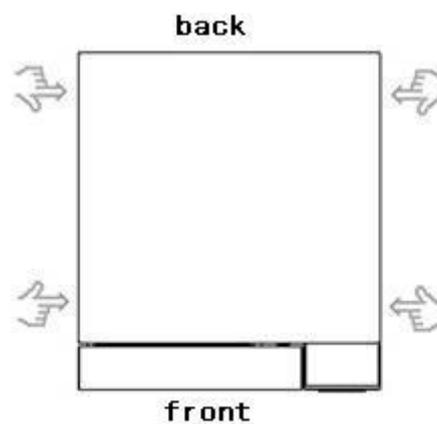
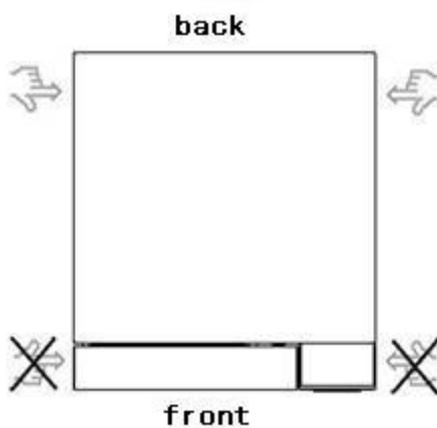
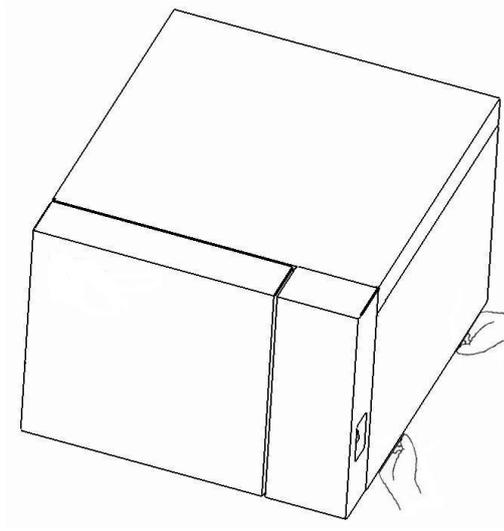
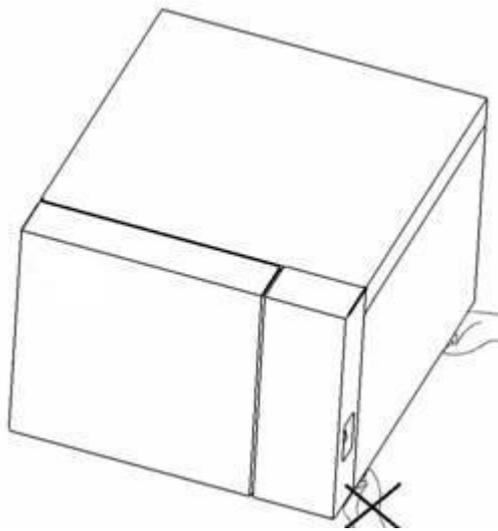
➤ Unpacking

Open the top lid of the packing case first then remove the four flaps successively. Finally, remove the plastic film from the equipment.



NOTICE Caution on carrying:

- Do not lift the door when handing the equipment.
- Do not lift the supporting feet when handing the equipment.
- Do not place the equipment on the side or invert it.
- Please refer to the following diagram for handing the equipment.

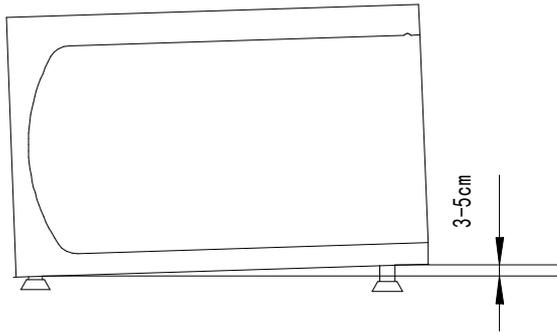


- Equipment inspection
 - After unpacking the equipment, please check the consistency of equipment model and name between nameplate and the order form. (The nameplate is on the back outer cover of the equipment.)
 - Please make a record and contact us or the transport company if there is any damage.
- 2.2. Equipment normal work condition
 - Environment temperature 5°C---40°C
 - Relative humidity ≤85%
 - Atmospheric pressure 70kPa---- 106kPa

Instruction: when the equipment is used in environmental where temperature is lower than the normal working conditions, need to pay attention to drain all the water in the water tank and steam generator after the program running is finished, it is suggested to open the equipment preheat mode, switch on the electricity for preheating before use.

2.3. Horizontal debugging

Once the equipment is placed on the table-board please adjust the equipment height according to the following drawing to prevent too much water accumulated in the equipment. (The air and water outlet are in the back end of equipment.)



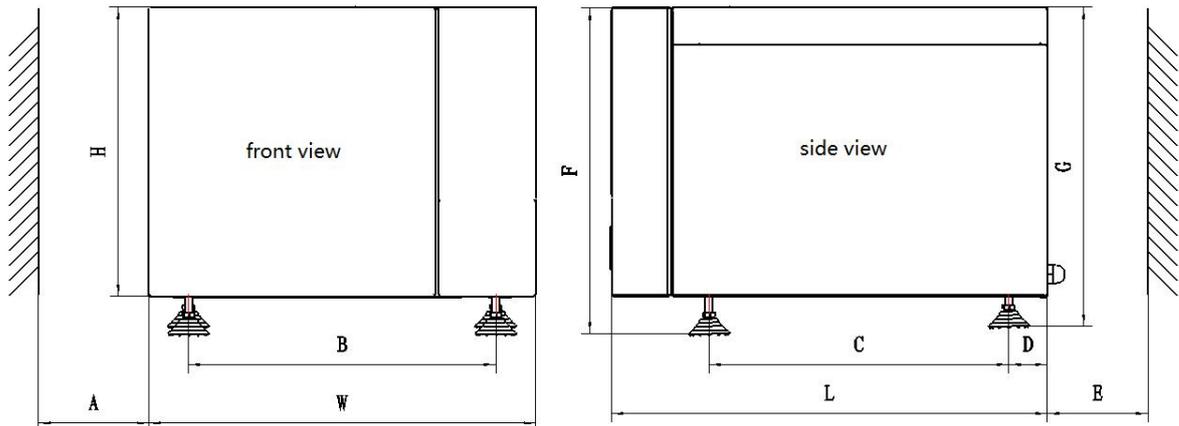
2.4. Equipment installation

2.4.1. Requirements of installation space

During the installation, qualified staff should record the equipment name and model with the guidance of professionals in order to contact us for technology consulting. Requirements of installation space:



NOTICE When install the equipment, do not install it in the place where the equipment or its power switch is difficult to operate.



content	size	
	volume: 60L	volume: 80L
L(mm)	1002	1002
W(mm)	730	730
H(mm)	560	560
A(mm)	500	500
B(mm)	644	644
C(mm)	728.5	728.5
D(mm)	86.5	86.5
E(mm)	500	500
F(mm)	635-655	635-655
G(mm)	605	605

2.4.2. Requirement on power supply, water supply

- After the equipment is in place, check whether the power supply meets the requirements: AC 220V/230V 50/60Hz single-phase power, fluctuations range $\pm 10\%$, power supply

power is $\geq 7.4\text{kVA}$.



NOTICE About the circuit breaker on-off, "ON" is connected, on "OFF" is disconnected

- Water supply: There is no need to connect the equipment with external water supply. Please inject water manually into the equipment clean water tank and circulating water tank.

Only pure water can be used and the water quality must meet the following requirements:

- Electrical conductivity: $\leq 15\mu\text{S/cm}$
- Bleach concentration: $\leq 2\text{mg/L}$
- PH value: 5-7
- Hardness: $\leq 0.02\text{mmol/L}$



NOTICE If there is a poor water quality prompt after adding water in the tank t, means that water is unqualified, please replace the good quality water.



NOTICE When install the equipment, please install the leakage protection device in to prevent security problems caused by parts damage

For safety purpose, an earth wire must be set. The earth wires of equipment outer cover and control cable must be connected with the exterior earth wire.



NOTICE The equipment must be reliably grounded!

2.5. Check accessories with machine

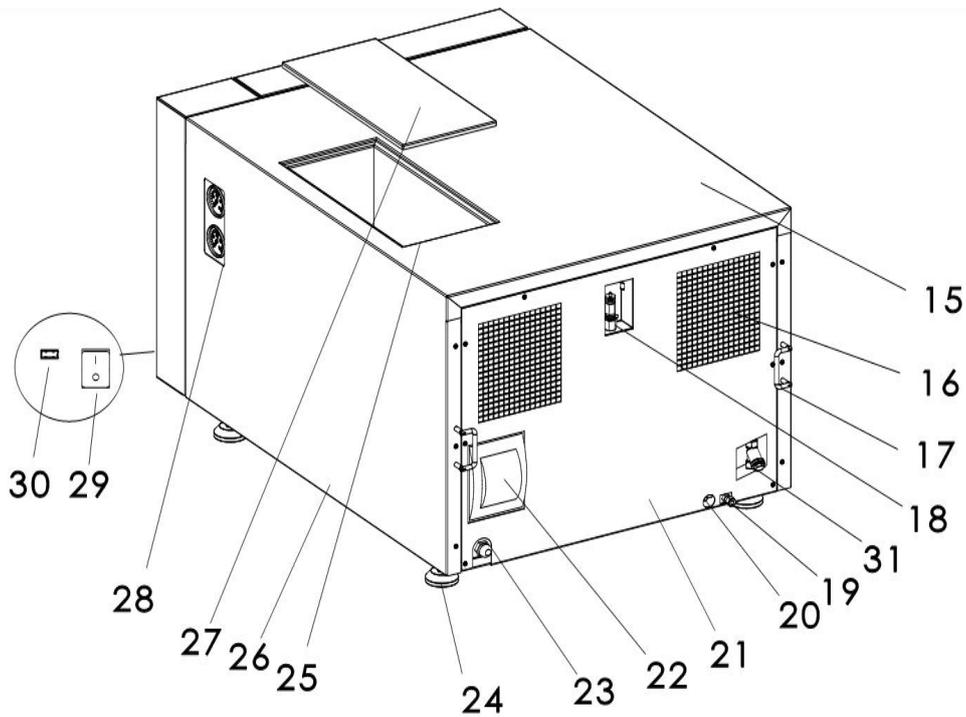
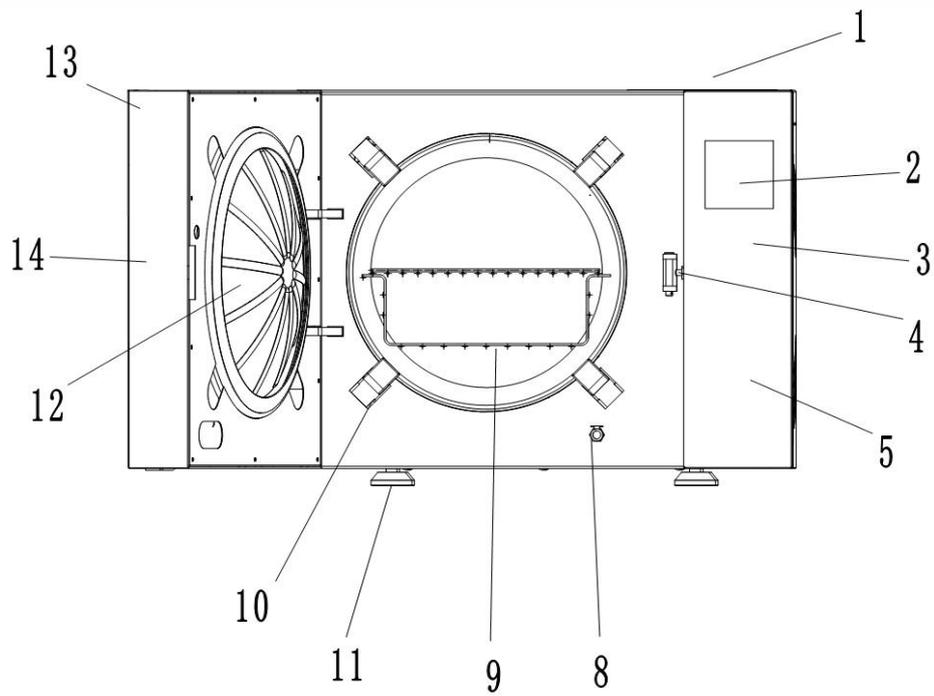
- Please check the intactness of the equipment components according to the packing list. If any damage or loss is found please make a record and contact us in time.
- Check the fastness of all connectors and fasteners. Please refasten them if there is any looseness.
- Check and record all attached accessories.



NOTICE Please power on the equipment before open the door. Door switch operations see the detailed door operation in 3.4

3. Equipment debugging

3.1. Equipment visible components introduction



S/N	Component name	S/N	Component name
1	Water cap handle	17	Side cover handle
2	Display screen	18	Safety valve
3	Operation button	19	Drain joint
4	Door switch WD4	20	Steam generator drain ball-valve FC3
5	Printer(Optional)	21	Equipment back cover
6	Circulating water drain port(retained part of the water, used for double water tank, conventional equipment is not configured)	22	Breaker

7	Circulating water drain port (completely drain the water, used for double water tank, the conventional equipment is not configured)	23	Power line
8	Drain port for clear water tank	24	Equipment feet
9	Equipment racks and trays	25	Water tank
10	Door lock hook	26	Equipment right cover
11	Equipment feet (supporting function)	27	Water tank cover
12	Sealing door	28	Pressure gauge for chamber and steam generator
13	Door cover	29	Power switch
14	Door handle	30	USB connect port
15	Equipment top cover	31	chamber filter
16	Cooling hole	32	

3.2. Operation of keys and screen

3.2.1. The buzzer will sound and the interface will work normally when the keys are pushed.

Operation of keys:

SN	Icon	Function	Remark
1	ESC	Return	
			
2	OK	OK	
3		Open	
4		Up	
5		Down	

➤ Return Key

Press this key so as to return to the previous page.

➤ OK Key

- Press this key so as to select the icon where the cursor remains.
- When setting the parameters, this key can be used to move the cursor

➤ Up Key

- Press this key so as to move the cursor upwards or rightwards

- When setting the parameters, this key can be used to increase the value. (press and hold the button to add repeatedly)

- This key can be used to change the page.

➤ Down Key

- Press this key, so as to move the cursor downwards or leftwards
- When setting the parameters, this key can be used to decrease the value. (press and hold the button to subtract repeatedly)

- This key can be used to change the page.

➤ Open Key

When the motor is jammed, please press the Open Key to open the door. Under normal conditions, just turn the door handle, and then the door will be opened automatically.

➤ Cursor

When the cursor is moved to the icon or parameter selected, the color of such icon or parameter will change:

Example: The cursor is not moved to icon



The cursor is moved to the icon



In the table below explains the meaning of the icons:

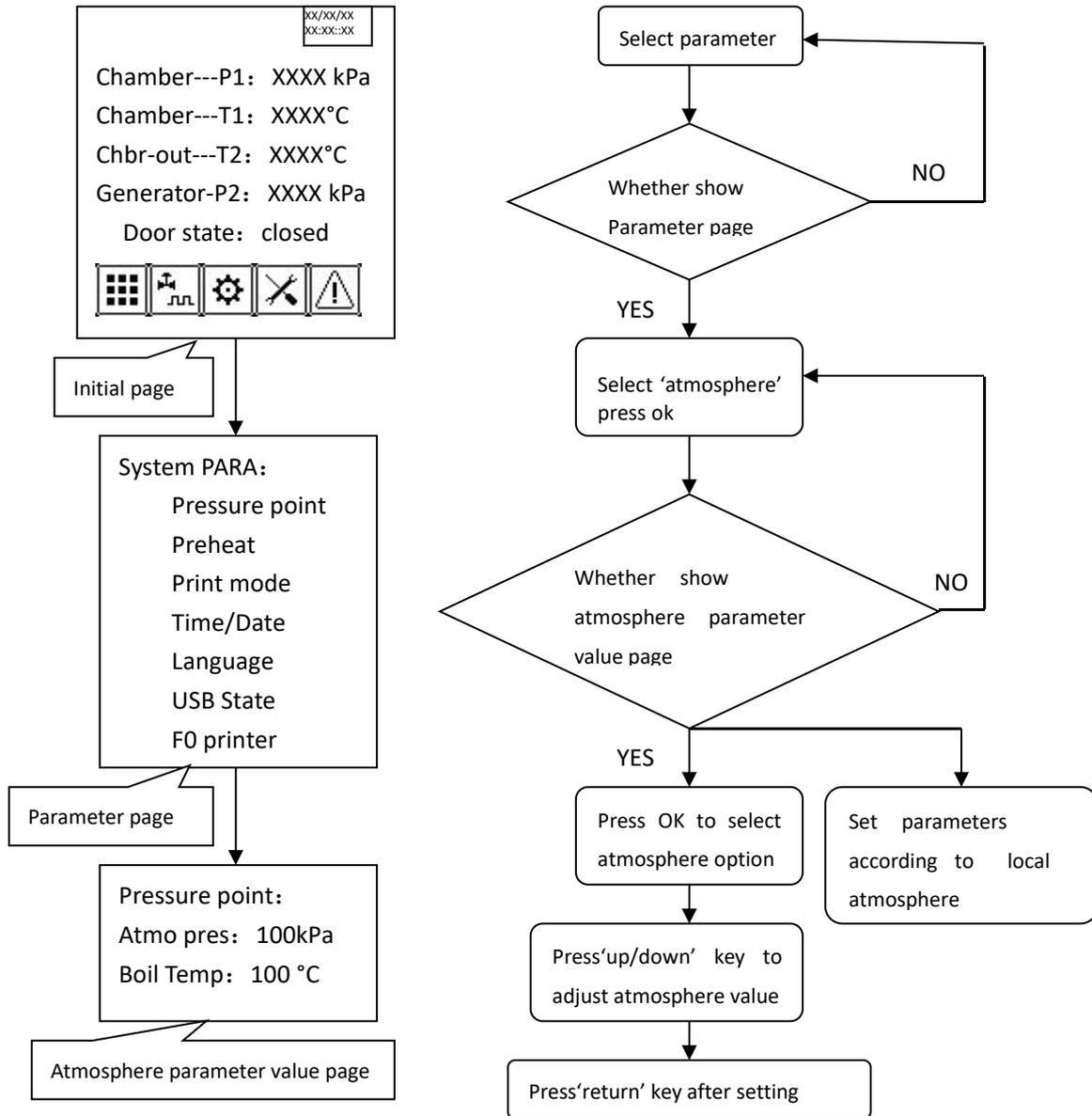
SN	Icon	Function	Remark
1		When cursor selects this, after OK is pressed the menu changed to program kind selection	
2		When cursor selects this, after OK is pressed the menu changed to parameter setting	
3		When cursor selects this, after OK is pressed the menu changed to parameter setting in system maintenance	
4		When cursor selects this, after OK is pressed the menu changed to alarming information	
5		When cursor selects this, after OK is pressed, the program starts and the menu changed to program running	
6		When cursor selects this, after OK is pressed the menu changed to program parameter viewing	
7		When cursor selects this, after OK is pressed the menu changed to parameter setting viewing in the program setting.	
8		When cursor selects this, after OK is pressed the menu changed to output messages for all outputs	
9		When cursor selects this, after OK is pressed the menu changed to processing data viewing	

10		When cursor selects this, after OK is pressed the menu changed to cycle exit confirm	
----	---	--	--

3.3. Parameter setting

Turn the power switch to 'I' position after get the power supply ready. Turn on the preheating mode (Please refer for the preheating mode setting.) and the heating film and steam generator will be preheated. Turn on the printer if any. (Please refer to the printer setting.)

3.3.1. Atmospheric pressure parameter setting



NOTICE :

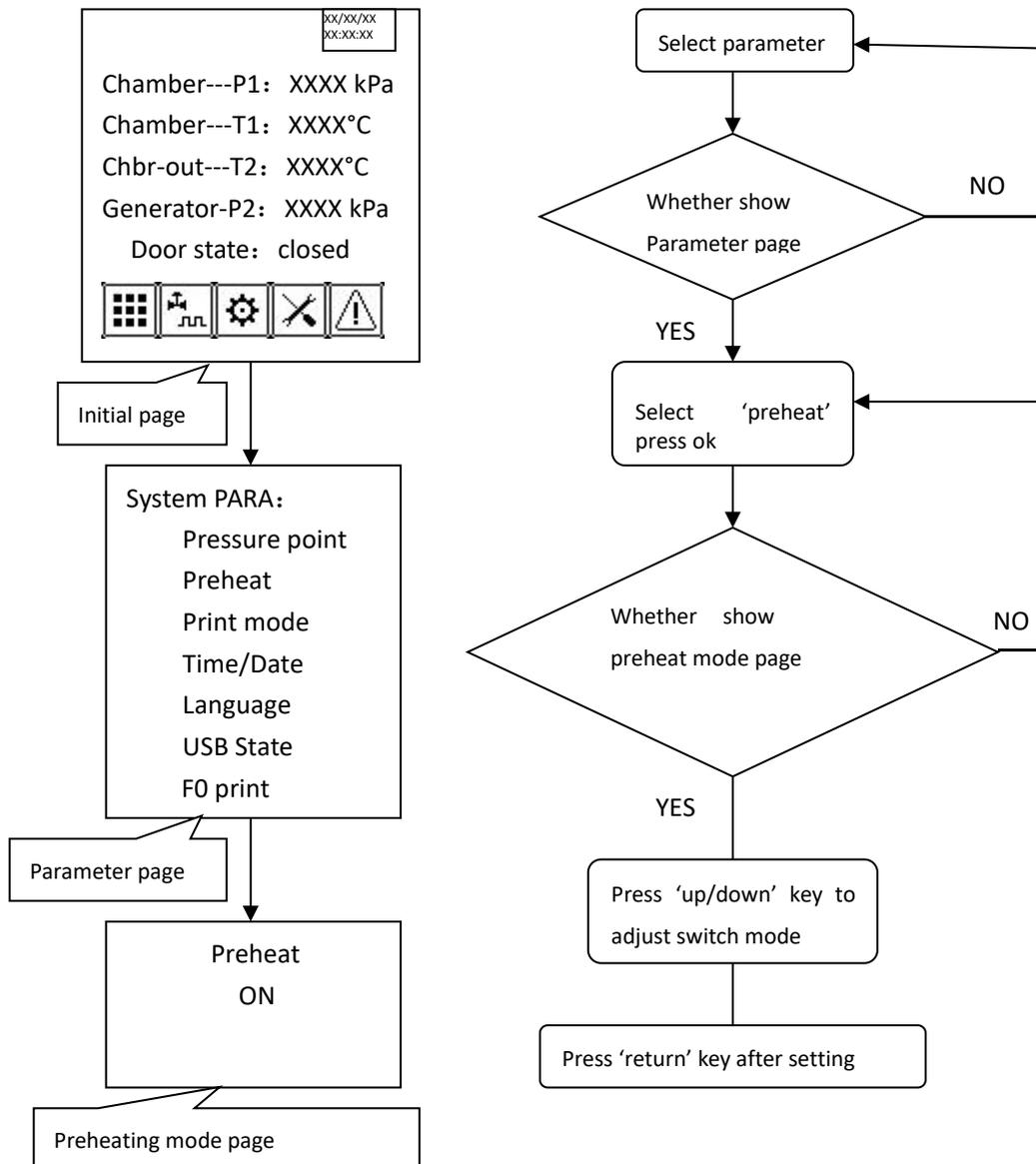
Adjust the atmospheric pressure value according to the local atmospheric pressure and the boiling temperature will be calculated automatically.

Standard atmospheric pressure is a unit of pressure equal to 101KPa. (i.e. 0.1Mpa=101KPa) It decreases with the increase of altitude. Under 3km, every 1km increase of altitude the atmospheric pressure will decrease about 10KPa.

If you have no idea about the local atmospheric pressure: when the atmospheric pressure is

101KPa, the displayed chamber pressure P1 will be 0KPa under the door opening status; the door can be opened/closed under the pressure of ± 5 KPa; user could get to know the local pressure according to the door status. For example: the chamber pressure is -6KPa under the door opening status, the local atmospheric pressure will be 95KPa.

3.3.2. Preheating mode setting



3.3.3. Other system parameters

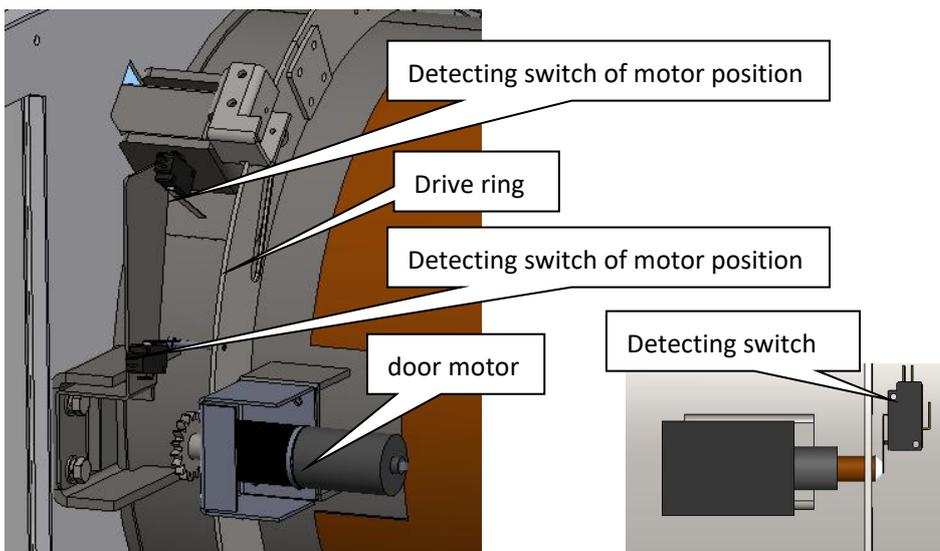
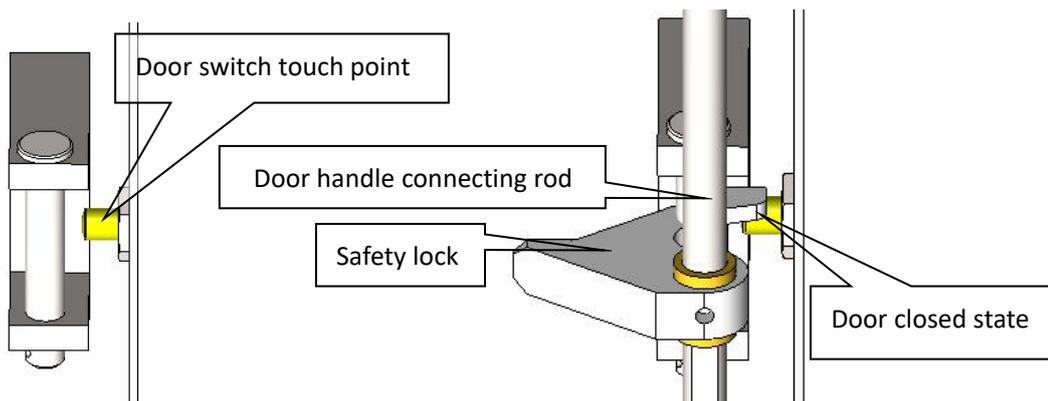
In powered-on initial screen, select the system parameters setting icon , enter the system parameters screen

System PARA:

Pressure Point
Preheat
Print mode
Time/Date
Language
USB State
F0 printer

- Pressure point: adjust the atmosphere value according to local atmosphere. The boiling point will be automatically calculated according to the atmosphere value.
- Preheat: turn on the preheat mode, the steam generator and chamber in wall will be preheated automatically in the stand-by status.
- Print mode: select print or do not print.
- Time/Date: set present time and date.
- Language: select language.
- USB state: view USB connection. (Optional USB flash disk)
- F0 printer: Select whether to print the F0 value, the default does not print.

3.4. Operation of opening/closing door



Door closing operation:

- The door handle is connected with the safety lock through the door lock axis, and when the door handle is turned, the lock axis is also simultaneously;

- When the door motor is working, it will drive the four door lock jaws to act, so as to complete the opening/closing of door;
- When the door is closed and the door handle is turned, the safety lock will press the door lock touch point and then the motor works to drive the door closed.
- When the door handle is turned, the door lock touch point is released. The motor will work, so as to complete the opening of door (It will take some time for motor to run).

Door opening operation:

Pull the door handle and rotate it to make the door safety lock depart from the micro-motion switch WD4, after motor action is completed pull the door handle, open the sealing door. Or directly press the door-open key, it will indicate the door is opening, after motor action is completed please open the door, now rotate and pull the door handle to open the door.



NOTICE When the local atmospheric pressure is 101KPa (i.e. the displayed chamber pressure is 0KPa under door opening status), the pressure condition of opening/closing door is ± 5 KPa. The door opening pressure will be lower in high altitude.



NOTICE The system will prompt “out condition, Can’t open door”, if the detected chamber pressure beyond the certain range. Now you need check the chamber, atmospheric pressure and running condition.

3.5. Operation of adding water into water tank

- Prepare the pure water, and Water container, convenient to add water into water tank.
- Remove the tank cap; note that if the program is already running, when you open the tank cap, there will be condensed water that flows down.
- Add pure water into the water tank, till water reaches the position between the lowest water level and the highest water level, cover the tank cap, prevent some debris from falling into the water



NOTICE The water that used in sterilizer must be pure water. The water volume of high level is about 14L.

Advice: The temperature of water in tank will increase after 4 operation cycles. Please change the water if the vacuum performance decreased.

3.6. Operation of program

- Carry out the preparation work according to the relevant information in this manual. The equipment should be operated with no load for first usage.
- Select a sterilizing program, for example instrument program, and observe whether the program runs normally. Check whether there is any leakage in pipeline and water tank.

Please repair it in time if any. Selecting a program as follows: select the  icon on initial

page and push ok key \Rightarrow select a program on the program selecting page (sterilizing program or testing program) and push ok key \Rightarrow select the  icon on program running page and push ok key \Rightarrow the selected program starts running.



NOTICE If there is a poor water quality prompt after adding water into the tank, it means that water is unqualified, please replace with good quality water.



NOTICE If the equipment water tank has no water and there is no water alarm, please contact the company engineering.



NOTICE The power switch is powered on, parameters display is normal and no alarm, the sterilizer can be used normally.

3.7. Operation of sterilization program

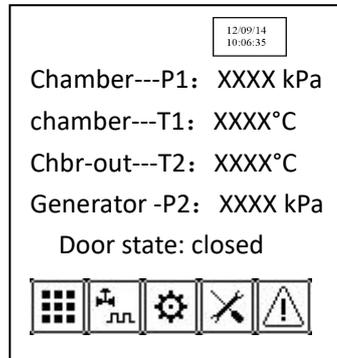
If there is any leakage after running a sterilizing program, please repair it according to relevant information in this manual.

3.8. End of installation and commissioning

4. Display screen instructions

4.1. Initial page

If there is no alarming once the sterilizer is turned on, the interface will remain on the initial page.



Chamber-P1: Indicates the chamber pressure

Chamber-T1: Indicates the chamber temperature

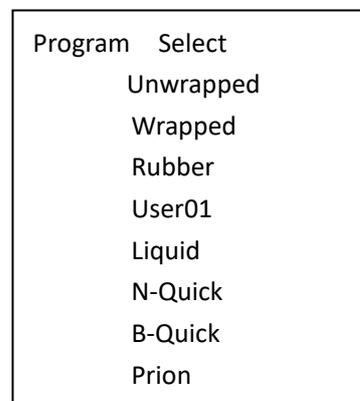
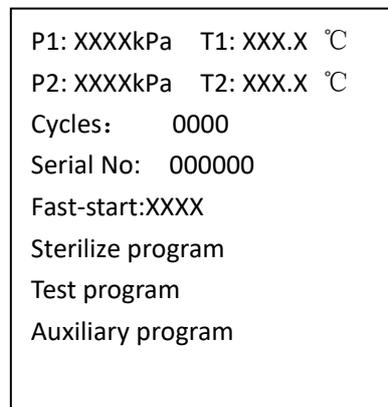
Chbr-out-T2: Indicates the chamber wall temperature

Generator -P2: Indicates the steam generator pressure

4.2. Program selection & start page

4.2.1. Program selection page

Select the program selection icon  on the initial page to enter into the program selection page (see the left picture showed below). After selecting the sterilization program the right picture showed below will appear.

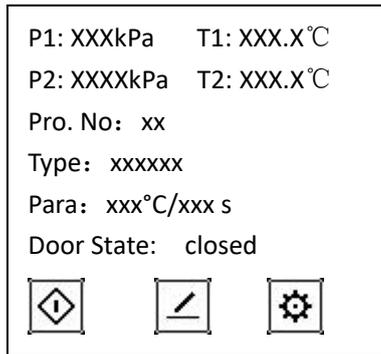


"Fast-start:XXXX": Fast start program, here "XXXX" is the memory of last program select.

Push the up/down key to move the cursor and push ok key to enter into a selected program.

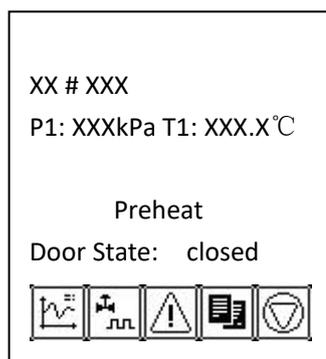
4.2.2. Program start page

Select a program and push ok key to enter into the following page.



4.3. Program running page

Select the  icon to start a program and enter into the following page



4.3.1. Main process page

Once a program starts, the system will firstly enter into the preparation phase. System will prompt 'Please open door' on the program end phase.

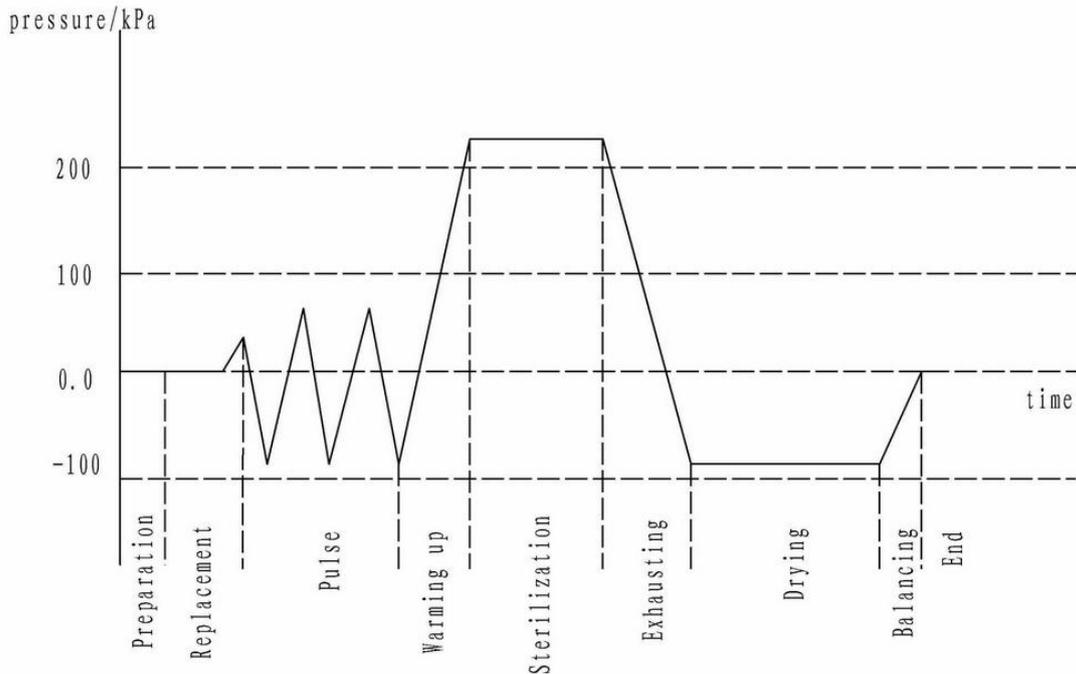


The interface displays the name of each phase, chamber temperature and pressure value. A sterilizing cycle includes the following phases:

- Preparation phase: the steam generator and chamber wall will be heated to certain temperature in this phase. The report title will also be printed at the same time if the printer was switched on.
- Replacement phase: the cold air will be replaced out of chamber by steam.
- Pulse phase: the cold air will be discharged by repeatedly vacuuming between the pulse upper and lower limit.
- Warming up phase: chamber temperature and pressure will increase in this phase.
- Sterilization phase: chamber temperature and pressure will be held in certain range till the end of sterilization.
- Exhausting phase: steam will be exhausted in this phase and chamber pressure reduces.

- Drying phase: dry the items in chamber.
- Balancing phase: the chamber pressure will be automatically adjusted to ensure the door can be opened or closed.
- End phase: the buzzer sounds and screen prompts 'End'.

The corresponding relationship between pressure and time during work cycle, set the "unpacked program" of type B in ex- factory settings as an example, as the following diagram:



Instruction: When the product is not equipped with the vacuum function, the process is the positive pressure pulse

4.3.2. Parameter view

Select the data review icon  in process page to enter into the parameter view page.

PARA:
 xx # xx xx xx
 Ster.time: xxx min
 Ster.tem: xxx °C
 Dry.time: xxmin
 Plus.time: x
 H.Pluse: xxxkPa
 L.Pluse: xxx kPa
 Purg.time: xxx s

This page displays the code, name and parameters of selected program.

4.4. Output information

Select the output information icon  in main process page to enter into the output information page.

P1: XXXkPa	T1: XXX.X°C		
P2: XXXXkPa	T2: XXX.X°C		
F2	off	H2	off
F3	off	I0	off
F4	off	I1	off
F5	off	I2	off
F6	off	I3	off
B1	off	I4	off
B2	off	I5	off
H1	off	I6	off

Refer to the following table for the code description. (a few code hasn't been used which is reserved)

F2	Steam entry valve	For steam feed into the chamber after the door is closed
F3	Vacuum valve	For chamber air discharge and vacuuming
F4	Air readmission valve	For chamber vacuum break to normal pressure
F5	Release valve	For chamber drainage
F6	Water feed valve	reserved
B1	Circulation pump	For vacuuming the chamber
B2	Water feed pump	For feed water into the steam generator
H1	Main heater	Steam generator heating
H2	Chamber wall heater	Chamber wall heating
LK	Solenoid lock	Door interlock device
I0	Door close signal	door-trip WD4 off-position detection
I1	motor off-position signal	Motor door on position detection
I2	Motor turn on signal	Motor door off position detection
I4	steam generator high water level	steam generator high water level signal detection
I5	steam generator low water level	steam generator low water level signal detection
I6	Door lock strict position	Door lock strict position signal detection

Remark: In this table some codes are not used in this equipment, as the equipment reserved.

4.5. Process data



Select the process data icon in main process page to enter into the process data page.

Phase Info	
Pur: 0:00	Ste: 0:00
Pv1: 0:00	Max: 0:00
Pp1: 0:00	Min: 0:00
Pv2: 0:00	
Pp2: 0:00	
Pv3: 0:00	
Pp3: 0:00	

Pv1: Actual running time from pulse upper limit to low limit during the first pulse vacuum

P p1: Actual running time from pulse low limit to upper limit during the first pulse

vacuum

Pv2: Actual running time from pulse upper limit to low limit during the second pulse vacuum

P p2: Actual running time from pulse low limit to upper limit during the second pulse vacuum

Pv3: Actual running time from pulse upper limit to low limit during the third pulse vacuum

P p3: Actual running time from pulse low limit to upper limit during the third pulse vacuum

Ste: Sterilization time

Max: Maximum temperature in sterilization phase (The possible highest temperature during sterilization cycle is pre-set temperature +4 °C, under normal circumstances it will not happen)

Min: Minimum temperature in sterilization phase

4.6. Alarm information

Select the alarm information icon  in main process page to enter into the alarm information page (see the left picture below). The right picture showed below is an illustration of alarming page.

P1: XXXXkPa T1: XXX.X°C
P2: XXXXkPa T2: XXX.X°C
Program No.: XX Stage: XX
Alarm code: XX
 XXXXXX
Trigger: XX-XX-XX XX:XX:XX
Clear: XX-XX-XX XX:XX:XX


E16! Water lack in water tank

Please refer to the equipment maintenance information for the alarm description table.

4.7. Program stop

Select the Stop icon  in main process page to enter the stop confirmation page.

Are you sure to stop?

Please push the return key when the screen prompts to do so. Now you can open the door or keep running the program.

5. Equipment program introduction

Select the parameter setting icon  on the program start page to set the program parameters.

- Select parameter setting icon to enter into the password page. Type in the password to enter into the parameter setting page.



NOTICE This must be carried out by qualified staff.

- Select the name of the parameter that to be edited by pressing the Ok key to move the cursor on parameter setting page.
- Leave the cursor on the parameter that to be changed and edit the value by pressing the Up/Down key.
- Press the Return key to return after setting.

PARA:
 xx # xx xx xx
 Ster.time: xxx min
 Ster.tem: xxx °C
 Dry.time: xxmin
 Plus.time: x
 H.Pluse: xxxkPa
 L.Pluse: xxx kPa
 Purg.time: xxx s

Program Type	Sterilization Temperature /°C	Sterilization Time/S	Drying Time/S	Max running time	Application scope
Unwrapped	134	240	300	55min	Type B: Unpacked items with heat resistance. Type S : high temperature resistance, unwrapped and solid items.
Wrapped	134	360	600	60min	Type B: Packed or unpacked items and fabrics with heat resistance. Type S : high temperature resistance and wrapped or unwrapped solid instruments, fabric
Rubber	121	1200	600	75min	Rubber and fabric items without heat resistance.

User01	134	360	300	60min	Can be ordered according to the custom parameters
Liquid	121	1800	----	90min	Liquid items put in the cap-opened container
N-Quick	134	240	30	15min	Unpacked solid items.
B-Quick	134	240	30	20min	A small amount of bare cavity class objects (Type B)
Prion	134	1080	600	90min	Containing a load are harder to kill bacteria
BD&Helix	134	210	600	30min	To detect the performance of steam penetration and cold air discharging. (Type B)
Leak Test	40min	To detect leakage. (Type B)			
Preheat	134	240	30	30min	To fully preheating equipment
Drying	----	-----	600	15min	For drying

Note: The longest running time is in the circumstance of the standard loading.

Ster.P: Operation time of sterilization phase, of which the range is [0,99] min

Ster.temp: Temperature to be maintained in sterilization phase, of which the range is [105 138]°C

Drytime: Operation time of drying phase, of which the range is [0,99] min

Plus.time: Times of pulsation vacuum, of which the range is [0,6]

H.Plus: Upper limit of pressure in pulsation phase, of which the range is [0,150] kPa

L.Plus: Lower limit of pressure in pulsation phase, of which the range is [-99,50] kPa (Type S: [0,50] kPa)

Prug.time: Operation time of exchange phase.



NOTICE *Liquid program applies only to non-sealed liquid sterilization." B-Quick "/>

*"BD&Helix"/" B-Quick " is applicable for B type products only and is not applicable for S type.**

Type B: The sterilization of all wrapped or non-wrapped, solid, hollow load products type A and porous products as represented by the test loads in this standard.

Type S : The sterilization of products as specified by the manufacturer of the sterilizer including non wrapped solid products and at least one of the following: porous products, small porous items, hollow load products type A, hollow load products B, single wrapped products, multiple-layer wrapped products.

Instructions on program:

Under default state, this equipment is equipped with a total of 12 programs, among which the Programs Unwrapped, Wrapped, Rubber, User01, Liquid, N-Quick, B-Quick and Prion are sterilization programs, and the Programs BD&Helix, Leak Test are test programs, and the Preheat, Drying are auxiliary programs.

When the products can run vacuum program (BD&Helix、vacuum test), the product is B type product. If not, it is S type. S type products can not sterilize the lumen instruments. Please refer to the nameplate for the details.

The default value of every technological parameter of this equipment is the default value set through testing under the standard loading conditions as specified in the product standard. If the load or the loading mode adopted by the user changes, the relevant value may be used only after the relevant technological verification has been carried out (The user shall firstly make sure that the article to be sterilized may be operated in the technological process corresponding to the program selected).

- Programs Unwrapped, Wrapped, Rubber, User01, B-Quick and Prion are B-class based sterilization program, and their technological process is the same, with the only difference that the value of relevant parameters is adjusted on the basis of the characteristics of various loads.
 - Program Unwrapped is mainly used to sterilize the exposed metal articles which are unwrapped and can resist high temperature. The standard simulated load is solid metal screw.
 - Program Wrapped is mainly used to sterilize the wrapped articles which can resist high temperature. The standard simulated load is metal screw wrapped with paper or plastics and the fabric article wrapped with cloth.
 - Program Rubber is mainly used to sterilize the rubber articles of which the heat resistance is relatively low.
 - Program User01 Under this program, the operator who after operation training and have permissions of the operator can be process parameter Settings.
 - Program B-Quick is only used to sterilize single B-class cavity device under emergency circumstance. The device so sterilized shall be used within 4 hours after the completion of sterilization, and shall be protected against secondary contamination caused by environmental factors during the transportation to using place.

Note: As to program N-Quick and 7 B-Quick, if you want to reach the shortest running time please take out the redundant racks and trays.

- Program Prion Applicable to common sterilization procedures are harder to kill bacteria and viruses such as sterilization, this program is mainly manifested in the sterilization time is long.
- Program N-Quick is only used to sterilize single exposed device under emergency circumstance. The device so sterilized shall be used within 4 hours after the completion of sterilization, and shall be protected against secondary contamination caused by environmental factors during the transportation to using place.
- Program BD&Helix is used to, in conjunction with special materials, test the discharging effect of cold air and the penetration effect of steam for items such as standard BD kit and disposable BD kit. As for this program, the parameters should be set on the basis of the value required by manufacturer of most widely used BD testing paper (sterilization for 3.5mins at 134℃). If it is different from the material or testing paper adopted by hospital, the specific parameters should be changed by referring to the hospital requirements of the material or testing paper adopted by hospital. It is also used to, in conjunction with special tube/cavity PCD, test the discharging effect of cold air and the penetration effect of steam for tube/cavity instruments of certain length. As for this program, the parameters should be set on the basis of the value required by manufacturer of most widely used PCD instruments (sterilization for 3.5mins at 134℃). If it is different from the parameters that the hospital

requires please edit those parameters according to specific requirements of instruments.

- Program Leak Test is used to test the sealing performance of pipe or device connected to chamber under the negative pressure state. In the course of adjustment or routine inspection/testing of this equipment, especially after long-distance transportation, it is very likely that some pipes are loosened (or when the B-D testing is disqualified). In such case, you may select this program to carry out testing. It is mainly used to inspect the vacuum leakage of this sterilizer, so as to inspect the sealing performance of pipe. This testing shall be carried out under the precondition that the sterilizing chamber is unloaded. After the operation enters into the testing phase, if the change in pressure during 600 seconds does not exceed 1.3kPa, the vacuum leakage testing shall be deemed as qualified. If the testing fails, then inspection and repair shall be carried out. Please inspect the sealing of door and the connection between pipe system and chamber, identify and eliminate the leakage point, and carry out the testing again until the testing is qualified. This program is only used for testing rather than verifying whether the sterilization is qualified and reliable.
- As auxiliary programs, program Preheat and Drying must be operated according to the applicable conditions.
 - program Preheat, every day equipment to run the program for the first time, can do no load running for this program, to preheating equipment, in order to achieve better and faster sterilization effect and drying effect.
 - program Drying, Can be separate to dry, according to the requirements of don't need to set up the corresponding drying time, meet the needs of dry goods.

6. Sterilization procedure

6.1. Washing before sterilization

- 6.1.1. Wash the surgical instrument thoroughly after using.
- 6.1.2. We recommend that wash the instrument by ultrasonic washer, cleaning detergent or water that does not contain mineral substance.
- 6.1.3. Rinse the instrument after washing it. It is better to pack it or place on the tray.

6.2. Packing

- 6.2.1. Pack the instrument according to specific requirement by different packing material.



NOTICE Packaging materials including rigid containers, disposable medical crepe paper, plastic bags, paper bags, non-woven textiles, etc. shall be in accordance with the relevant requirements. Textile shall also meet the following requirements: non bleached fabric; fabric except should not have suture except four sides, should not be mended; prior to initial use should be washed at high temperature, remove its skim the slurry, colors; should has record of use times.

- 6.2.2. Pack the dressing and instrument separately. It is better to put medical dishes upside down. Put gauze in between the dishes.
- 6.2.3. All the instruments must be tightly packed on same direction.

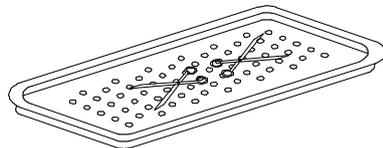
Sterilizer capacity:

Equipment volume	Maximum load for instrument kind	Maximum load for fabric	Maximum load for single package
60L	14 kg	6kg	3kg
80L	18kg	8kg	4kg

The maximum weight that net cover, grid of 60L equipment can bear is half of maximum load for instruments kind, and of 80L equipment the same as the maximum load for instrument kind.

6.3. Placement

- 6.3.1. Keep the instrument away from chamber wall.
- 6.3.2. Make sure both ends of catheter are open without sharp bend.
- 6.3.3. Instruments should be put upside down to avoid accumulating water.
- 6.3.4. Instruments should be put uniformly without overlap to avoid poor sterilization.



- 6.3.5. Classify the instruments and rightly place them in trays.
- 6.3.6. Do not put any trays on fabrics or soft items to avoid condensate water wetting the items in below.

6.4. Program selecting and start

- 6.4.1. Check power and water supply (make sure the water in tank reaches required level.).



NOTICE Please add water if the water level below the low level mark. The buzzer will sound when the water level exceeds the probe of water quality monitoring (about 4L water) . Keep adding water till the level in between the low and high level mark(about 14L water) .The steam generator water injection need about 5L!

- 6.4.2. Turn on the power and twist the switch to ‘|’ position. Close the door (Refer to the introduction of "Door switch operation")
- 6.4.3. Select a program needed(The detailed please refer to the specific program introduction) .
- 6.4.4. Operate as screen operation.

6.5. Running

The sterilizer should be supervised by operator during its running process to ensure that the sterilizer can be immediately turned off in emergent case.

6.6. Taking out the instrument from chamber

- 6.6.1. Push the open key to open the chamber door after sterilization. Wait 2mins to let the heat dissipates.



NOTICE There will be condensate water generated if the item was taken out immediately.

- 6.6.2. The operator must wear gloves or other protective tool to remove the sterilized articles, preventing from scald.



NOTICE To avoid scald, operator must wear protective gloves to take out the items from chamber after sterilization.

6.7. Storing of sterilized items

6.7.1. The sterilized items should be stored in dust-free, sealed and dry place with stable temperature.

6.7.2. Storage valid time: It depends on the packing material and type; un-packed goods should be used immediately after sterilization.

Packing material	Storage valid time	Note
Fabric material	14 days	The valid time is only 7 days if the storage requirement (requirement: environment temperature < 24°C, environment humidity < 70%) has not been matched.
Medical disposable paper bag	1 month	
Medical disposable crepe paper	6 months	
Medical non-woven fabrics	6 months	
Medical disposable paper-plastic packing bag	6 months	
Hard container	6 months	

7. Maintenance and servicing

Frequency of maintenance and cleaning:

No.	Component	Maintenance Interval	Maintenance Requirements	Remarks
1	Chamber	Once a day	Clean and free of water and dirt	
2	Chamber strainer	Once a month	Clean and free of water and dirt	Located in the exhausted port
3	Tray	Once a day	Clean and free of dirt	
4	Clean water tank	Once every two weeks	The wall of water tank shall be free of dirt	
5	Water replacement for steam generator	Once a month	Attention shall be paid to steam generator pressure	
6	Rubber door strip	Once a week	The surface of rubber door strip shall be free of dirt	
7	Clean water tank filter	Once a month		

Note: The above maintenance interval shall be adjusted flexibly in light of the actual use of this equipment by the user, so as to ensure that the performance of this equipment will be brought into

No.	Component	Maintenance Interval	Maintenance Requirements	Remarks
full play and your needs will be met better.				

7.1. Cleaning

7.1.1. Tank clean

Discharge the water from tank and wipe the tank inner wall with a clean and dry cloth.



NOTICE In the process of cleaning dirt, it had better best not remove the water tank filter firstly to prevent dirt from entering into the drainage pipeline and the circulating water pipes.



NOTICE If sterilize the dental handsets, and if there is much dirt oil in water tank, the water should be replaced after 5 times of program running, at the same time use cloth and cleaning agent to clean the water tank. If it is the other common load, and use many times every day, water can be replaced for each 3 days, and use use cloth and clear water to wipe the water tank.

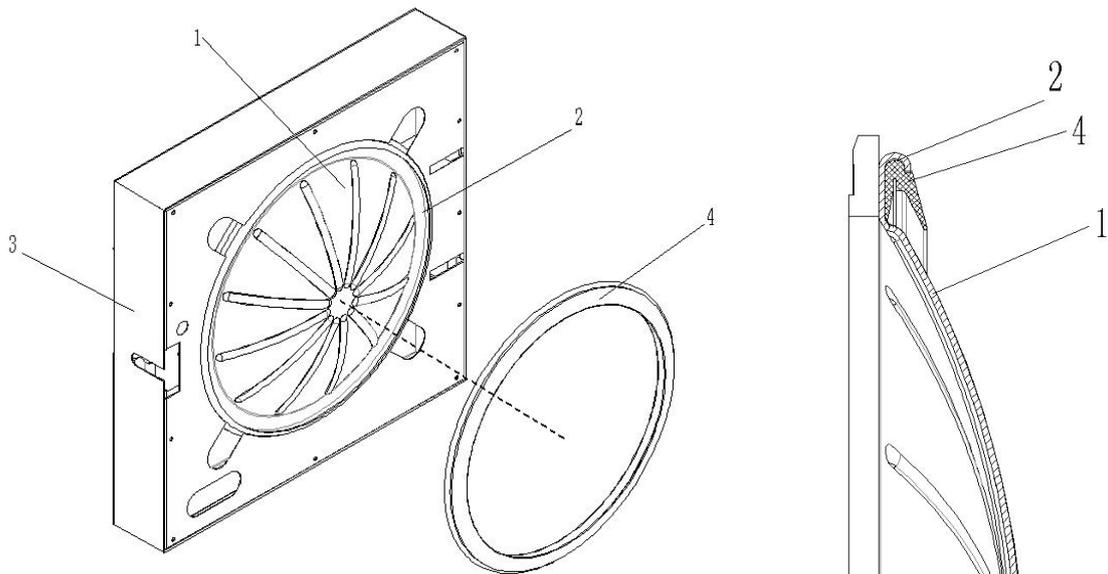
7.1.2. Cleaning of door gasket

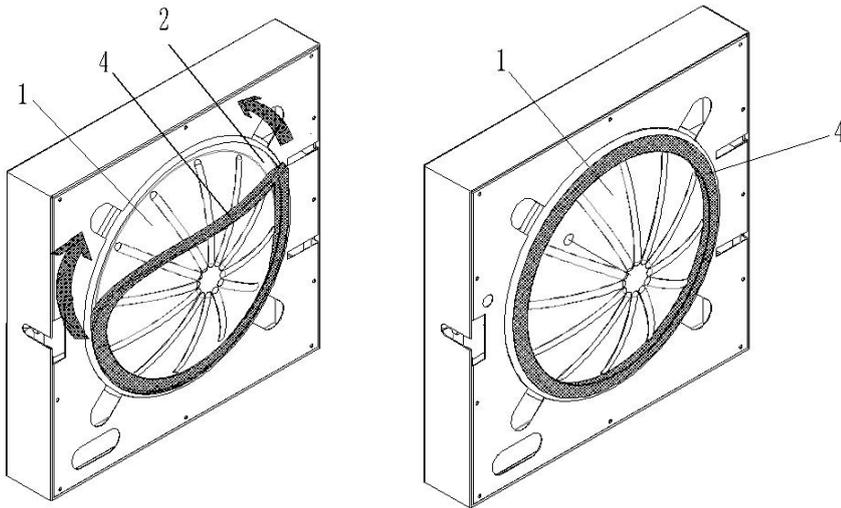
Remove the door gasket and wipe it by a clean and wet cloth with cleaning detergent. Rinse the gasket after wiping it. Wipe the gasket groove by a clean and wet cloth.

7.1.3. Cleaning of tray rack

Wipe the tray rack by a clean and wet cloth and rinse it after that.

7.2. Replacement of door gasket





S/N	Component Name	S/N	Component Name
1	Sealing door	3	Door cover
2	Sealing groove	4	Sealing ring

While install the sealing door, install the sealing gasket into the sealing groove accord to method of diagram, and in the installation process can install according to the installation diagram:

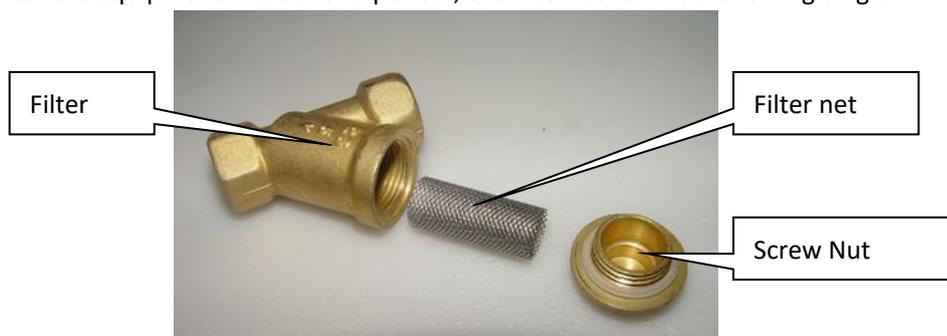
Firstly install door sealing gasket into the bottom of the sealing groove, and then along the direction of the arrow push the door sealing gasket into the sealing groove step by step, finally smooth the whole door sealing gasket.

Instruction: The door sealing gasket must be installed correctly according to the diagram, can not be installed in wrong direction, otherwise it will appear the problems of air leakage, water leakage, difficult vacuum.

7.3. Cleaning and replacement of filter

7.3.1. Cleaning of chamber filter

Chamber filter is Y type filter (located on the external cover of equipment back), it is need for cleaning after the equipment is used for a period , the filter is shown as following diagram:



After removed the nuts, remove the filter net, clean the filter impurities by clear water. After leaning re-install it. Cleaning of solenoid valve

7.3.2. Water tank filter



Water tank filter

Tank with threaded filter, clean or replace when first will filter counterclockwise from the water tank filter, to remove it. According to the above filters for decomposition, decomposition and brush with water after cleaning filter. After completion of cleaning will filter recovery and will reinstall the water tank.

7.4. Cleaning of solenoid valve



Remove the 4 screws of the solenoid valve.



Lift the valve head vertically. Keep the spring stays on it.



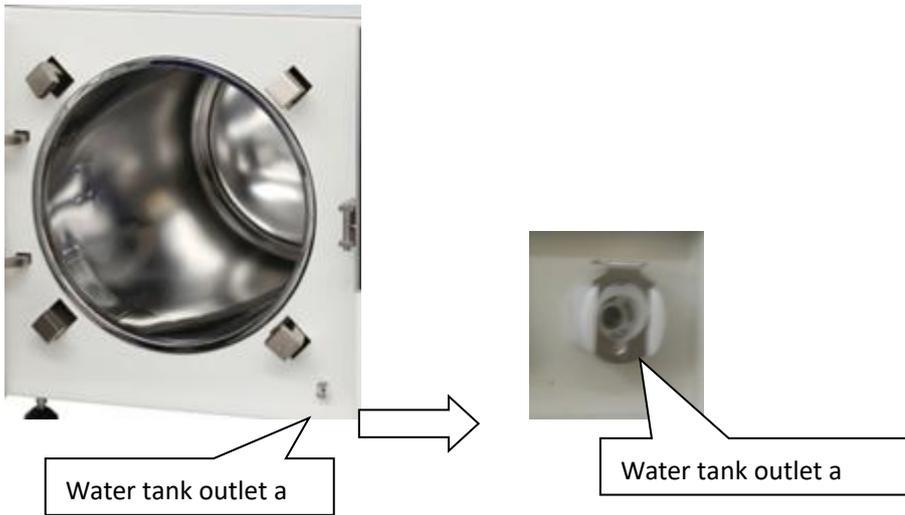
Take out the movable core and seal ring to view the sealing surface of the valve.



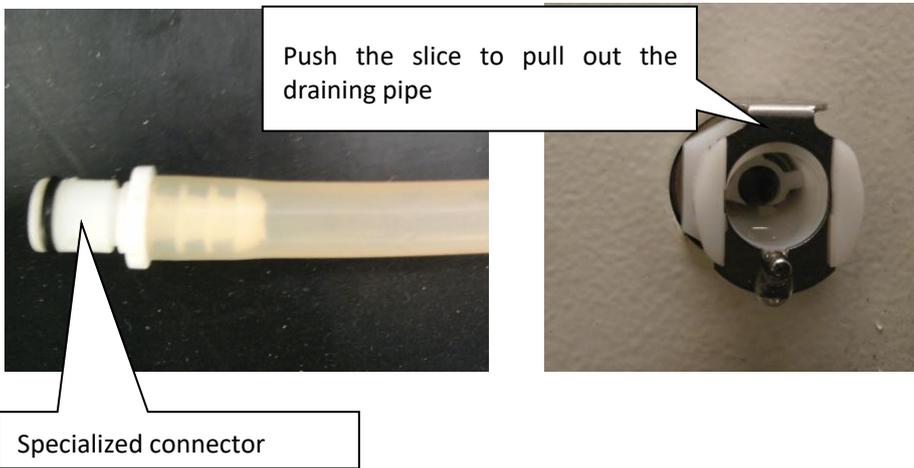
Clean up the sealing surface and re-install the solenoid valve.

Thoroughly clean the parts after removing them. And then have a re-installation.

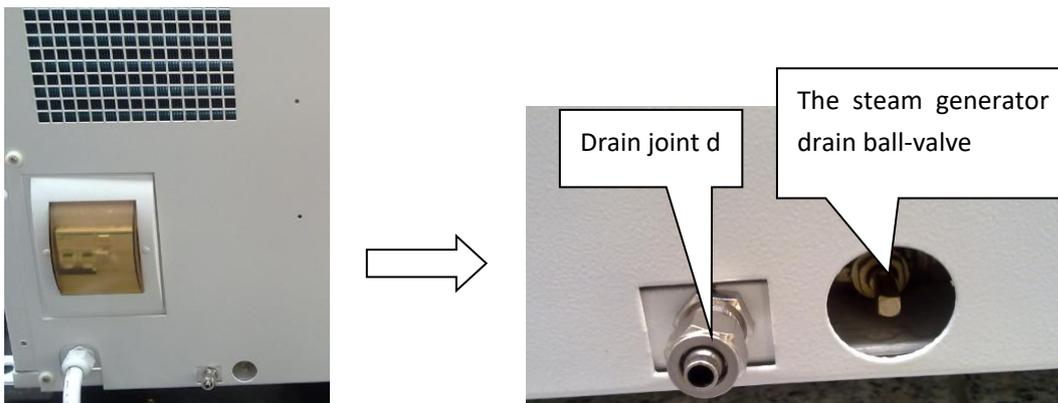
7.5. Tank drainage

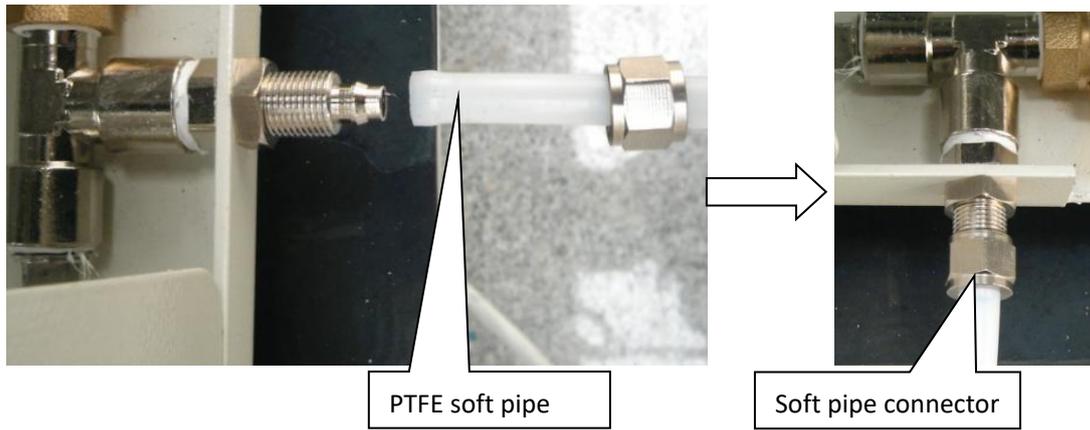


Drain outlet port is used to discharge water from water tank, insert the special interface into the drain outlet port, When need to pull out the drain pipe press the top slice on the joint of the drain outlet port.



7.6. steam generator draw off the water



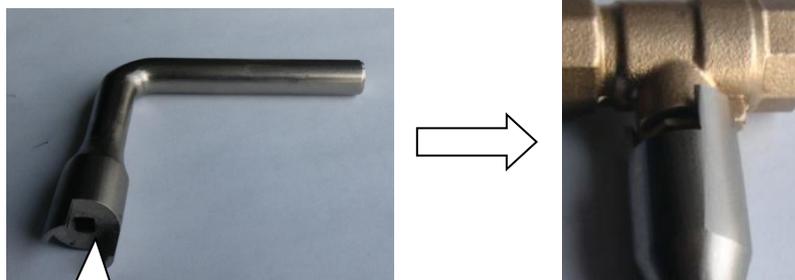


When discharging the residual water in steam generator, please operate in accordance with the following steps:

- Ensure that the drain the steam generator drainage joint.
- Electric steam generator after preheating on equipment (equipment debugging is completed set the preheating mode open) to 30 kPa to 50 kPa.
(If the pressure in steam generator is higher than 30 kPa, it is unnecessary to re-start the program, because the water in steam generator can't be fully discharged when there is no pressure in steam generator.)
- Insert the drain valve handle into the steam generator drainage ball valve, slowly rotating handle, until the steam generator in the inland waters continuous smooth flow.
- When the pressure in steam generator is relatively high, the opening angle of water-discharging ball valve of steam generator may not be adjusted too large, so as to prevent the leakage of steam and scalding.

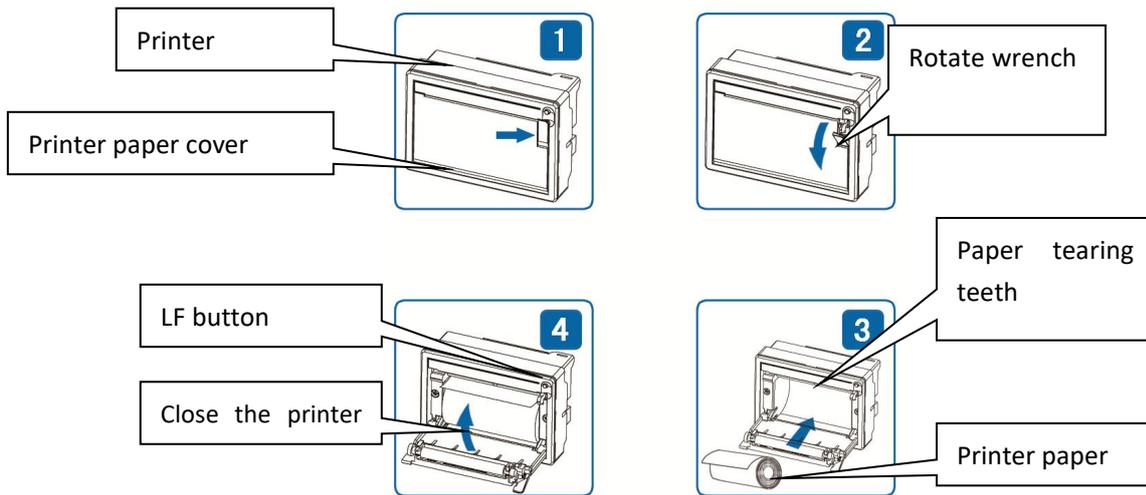


NOTICE Steam generator pressure , when the steam generator pressure is higher to pay attention for safety, to ensure the safety of operating personnel to manually controlled drainage ball valve opening Angle, prevent because opening Angle is too large and cause leakage of steam.



Handle rabbit

7.7. Replace printer paper



NOTICE When you see the red print on the printing paper roll, please replace the roll with a new one. Unsheathe the circumrotated wrench from the position the arrow point to as shown in Fig.1 and circum-rotate it until the paper cover opened as shown in Fig 2.

- Undrawn the paper cover, and insert the paper into the printer, then pull out a small amount of paper. Notice the direction of the paper according to Fig.4.
- Close the paper cover. Press the platen roller back to the printer head, then push the circumrotated wrench to the original position.
- Power the printer on, then press LF button, make the print head to run, and the paper will come out. Turn off the power.

7.8. Check and replace safety valve

- check safety valve

In order to prevent the safety valve in the blocking state, under normal use, each month allow the steam pressure release through it .

- Run sterilization program
- when the sterilization container pressure P1 reaches 100 kPa, pull TAB on the relief valve, it is open, waiting two seconds, a steam erupt, steam generator relief valve working properly, otherwise you need to check or replace the relief valve.



NOTICE Pull TAB on the relief valve will have the steam erupt, to pull TAB which it is best to use screwdriver tools, don't directly use the finger to pull, operators also need stay as far as possible , to prevent burns.

- Change safe valve

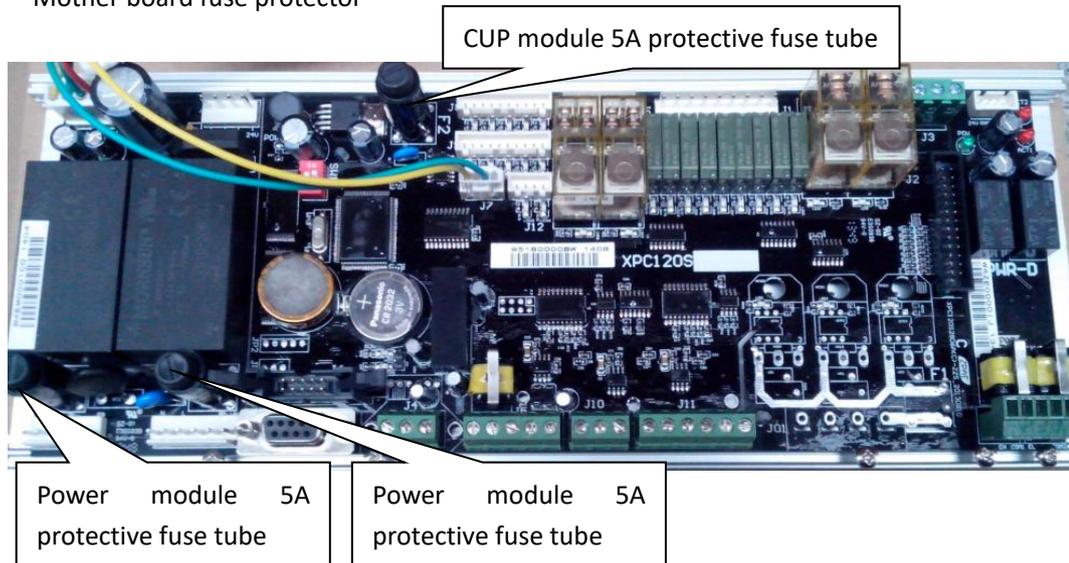
This operation is limited to the professionals

- Loosen the screw holding of the valve; remove the relief valve from the relief valve base.

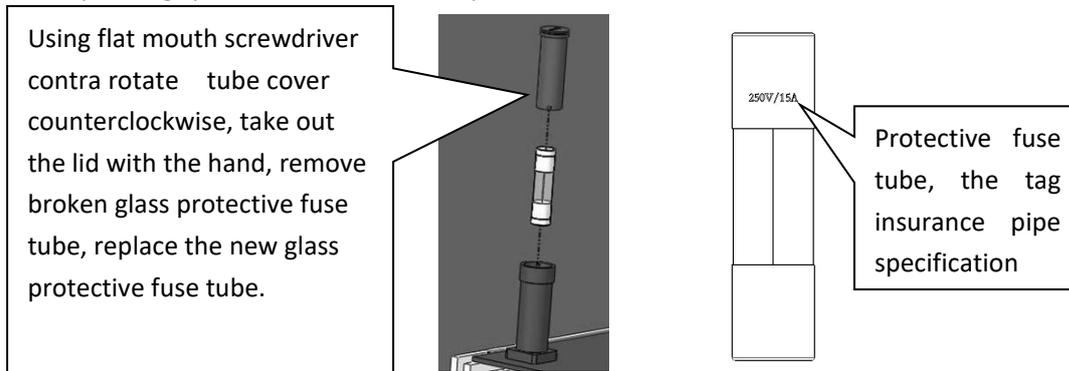
- Use a qualified safety valve to replace it. (Eligibility criteria: ensure between 0.25 MPa to 0.26 MPa pressure relief valve opens).
- Test a sterilization process.

7.9. Fuse protector change

7.9.1. Mother board fuse protector



There are corresponding fuse in the equipment accessories , if there is a fuse burn out, find corresponding specification of fuse to replace it.



Instruction: the number of the actual fuse tube and position are based on real objects, please prevail in kind.



NOTICE All fuse tube need to be changed by professional maintenance personnel, engineering and technical personnel, or permitted operators. Before replacing the fuse tube, power supply must be cut off, and fuse tube parameters must be check!

8. Problems and fault shooting

8.1. Common problems

8.1.1. Bad water quality reminder

When tank water quality below standard requirement, appear poor water quality tips. When a user is eager to use equipment can ignore the prompt, press ok key can continue to normal boot program. If you use the meet the requirements of water quality is still hint water quality is poor, the need to contact problem processing equipment engineering.



NOTICE Use for a long time can lead to pipe of the water quality is unqualified, steam generator blocked!

8.1.2. System prompts the door cannot be opened.

The door opening pressure will be ± 5 KPa if the sterilizer installed in high altitude site (atmospheric pressure= 101 kPa). If the atmospheric pressure is not 101 kPa, please adjust the pressure value in sterilizer. Otherwise, the door will not be opened.

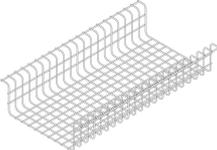
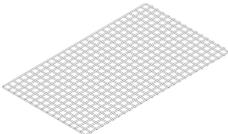
8.2. Alarm code and treatment measures

NO.	Warning Code	Reason	Solutions
1	E00 Interrupted	The program is exited during the operation.	Open the door or restart the sterilizer once it prompts to return.
2	E01 Door SW unclose	The signal of WD4 cannot be detected during the operation. The signal of motor off-position cannot be detected.	Exit the program and check whether the wiring of door switch is normal. Check the wiring of motor off-position switch.
3	E02 Chamber-T1 high	The detected chamber temperature exceeds the sterilizing temperature +4℃.	Check the temperature detecting parts or contact us.
4	E03 Ch-out-T2 high	The detected chamber wall temperature exceeds 160℃.	Check the temperature detecting parts or contact us.
5	E04 Temp. Low	The case of that chamber temperature lower than the sterilizing temperature continues exceeding the preset time.	Check the solenoid valve of exhausting and clean it.
6	E05 Vacuum failed	The vacuum degree did not reach the lower limit during the preset time.	<ul style="list-style-type: none"> ➤ Check the chamber and water tank filter and wash them if there is any blocking. ➤ Check the door gasket and clean it. ➤ There is too much water in tank. Please discharge the redundant water under the high level mark.
7	E06 Heat failed	Heating timeout.	<ul style="list-style-type: none"> ➤ Check whether there is any steam leakage. ➤ Check whether the solenoid valve is well sealed. ➤ Check whether the pressure of steam generator is about 250 kPa ➤ Check whether the equipment drainage is normal or abnormal.
8	E07 water injection over time	Time of injection water into steam generator is over the pre-set time	<ul style="list-style-type: none"> ➤ Check whether the water injection pump and solenoid valve work or not

NO.	Warning Code	Reason	Solutions
			➤ Check whether the water level probe or water level monitoring module is abnormal or not.
9	E09 Motor Overtime	During the process of door closing, the door motor working time exceeds the preset time.	➤ Reinstall the door gasket. ➤ The wire is loose or disconnected. Please rewire.
10	E10 Over Pressure	The chamber pressure exceeds the preset pressure.	Check the pressure sensor.
11	E12 ChamberT1 Error	The detected chamber temperature is 0℃ or 200℃.	Check the chamber temperature sensor.
12	E13 Ch-out-T2 Error	The detected chamber wall temperature is 0℃ or 200℃.	Check the temperature sensor of chamber wall.
13	E14 Generat.P2 high	The detected pressure of steam generator is -100kPa or 300kPa.	Check the pressure sensor of steam generator.
14	E15 Genera.P1 Error	The detected chamber pressure is -100kPa or 300kPa.	Check the chamber pressure sensor.
15	E16 Water1 Lack	The low level signal of clean water tank cannot be detected.	➤ Check whether the tank has been filled with pure water. ➤ Check the water quality detecting device setting of water tank.
16	E23 P1 off	The signal of door locking-position cannot be detected.	Check the electro-magnetic lock and door-locking micro switch.
17	E50 Communication Error	Communication error between screen and maid board.	Check the screen and main board.

9. Appendix

Conventional 60L/80L equipment accessory(Special equipment may different, the take the actual as standard, please prevail in kind)

S/N	Name	Specification	Photo	Usage
1	Sterilization rack	13170-004.07.02.01 (60L)		Lower layer for sterilization items, top for sterilization net cover
		13170-005.07.02.01 (80L)		
2	Sterilization net cover	13170-004.07.02.02 (60L)		For load sterilization items, placed on sterilization rack
		13170-005.07.02.02 (80L)		
3	Water outlet pipe(with connector)	964100349 (6*12)		After open the door ,insert water outlet joint, let the water flows out from water tank

4	Drain pipe (PTFE)	Φ8 (length: 1m)		Insert it into the back of the equipment to drain water from steam generator
5	Corrugated pipe	13002-00301		Door insurance accessory for pressure switch
6	Ball valve handle	13170-005.08.19.00		Exclusively used in drain water from steam generator
7	Glass fuse tube	976210915(5A 5*20)		Fuse tube for power plate of mother board
8	Printing paper(Optional)	901990159 (R57*30)		Equipment printing paper(matched for E62 printer)

Appendix 1 Operation Specification

1. Preparation before Operation:

- ✓ Add pure water into clean water tank and circulating water tank in accordance with the requirements, and connect the power supply for this equipment.
- ✓ Connect the control-purpose power supply, turn the power switch of sterilizer to “|” side, and make proper preparation for operation of the program.
- ✓ According to the specified requirements or load type, select the corresponding BD&Helix and preheating program. For example, the load is cavity load or wrapper kind, you can run the BD&Helix and preheating program; if the load is unpacked solid instrument, can start the preheating program before sterilization. Mark the BD testing paper with the name or code of operator and date, place it into the sterilizer, start the BD testing program, and monitor whether this equipment leaks and whether this equipment works normally.
- ✓ Set in order the parcel to be sterilized, make sure that it is not bound too tightly, paste the chemical indicator tape on it, and place the chemical indicator card in the chamber.

2. Operation of Sterilization:

- ✓ According to the requirement to do the BD test, after the test is qualified or preheating is completed, open the front door, place the article to be sterilized into the sterilizing chamber, and make sure that there is clearance between every two parcels and no parcel contacts with inner wall or door plate.
- ✓ Close the door, select the appropriate sterilization program in light of the article to be sterilized, inspect whether the sterilization parameters are correct, and start the program.
- ✓ In the course of sterilization, the operator may not get far away from this equipment, but shall closely observe the operation of equipment. If any abnormal situation is found, please handle it in time, so as to prevent the occurrence of any accident.
- ✓ Monitor the sterilization effect and properly make and retain the record, so as to ensure the traceability.
- ✓ After the sterilization is completed and the pressure in sterilizing chamber returns to zero, open the rear door and take out the article.
- ✓ After taking out the sterilized article from the sterilizer, put it in an appropriate place, so as to prevent recontamination.

3. Works after Operation:

- ✓ Open the door, turn the power switch to “o” side, and cut off the control-purpose power supply and main power supply.
- ✓ User must change water in reminder of poor water quality or after running of five sterilization programs.
- ✓ After the works are completed every day, please keep the inside and outside of sterilizer clean, clear away all dirt from the chamber, carry out simply maintenance once a week, and carried out thorough maintenance once a month.

4. Notices:

- No article which has been sterilized may be placed together with unsterilized articles.
- The articles which have been successfully sterilized shall be marked with sterilization date and qualified sign.

Name of User:

Date:

