

# User Manual STE-H-SERIES



Thank you very much for purchasing our STE-H-SERIES sterilization.

Please read the "Operating Instructions" and "Warranty" before operating this unit to assure proper operation. After reading these documents, be sure to store them securely together with the "Warranty" within touch for future reference.

Warning: Before operating the unit, be sure to read carefully and fully understand important warnings in the operating instructions.

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Welcome to use STE-H-SERIES 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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# **Cautions and attentions**

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



NOTICE Highly attention should be paid.



The cases possibly cause equipment damage.



The cases possibly endanger personal safety.

Please understand the symbols showed in the following table:

No	Symb	Instruction	
•	ol		
1		It indicates high temperature and be careful of scald.	
2	<u>^</u>	Note, please operate according to the manual.	
3		On earth symbol	
4	4	Here is voltage, please cut power before operation and maintenance	
5	STOP	Emergency stop switch	

Please read each chapter carefully and fully understand it before any operation, maintenance on the product especially the contents with the above symbols. If you use the equipment not by the way offered by my company, the equipment will be damaged.



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.

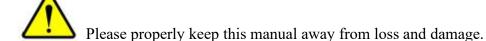


Anyone in any situation cannot tear off any page from the manual. During

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.

This manual booklet should be stored in dry and ventilated place without high temperature.

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



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

The product is not applicable for bottled liquid with tight seal. Please contact us to order special liquid sterilizer.

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 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.

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

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.

This product is only applicable for those instruments that are heat and humidity resisting, but not for the sterilization of oils or powder that contains Vaseline.

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.

On any position on the instrument seeing the symbol , it indicates surrounding temperature is higher; please pay attention to avoid scald.

Recommend continuous operation shall not exceed 8 times a day, otherwise it may cause unpredictable damage.



- 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.
- 5) 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.

#### 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:

Model	Volume	Chamber dimension/mm (usable)	Power supply	Power/kVA
STE-H	18L	Ф250×350	AC 220V 50Hz	2.6
STE-H	24L	Ф250×450	AC 220V 50Hz	2.6
STE-H	45L	Ф316×618	AC 220V 50Hz	5.8

➤ Design pressure: -0.1/0.30Mpa

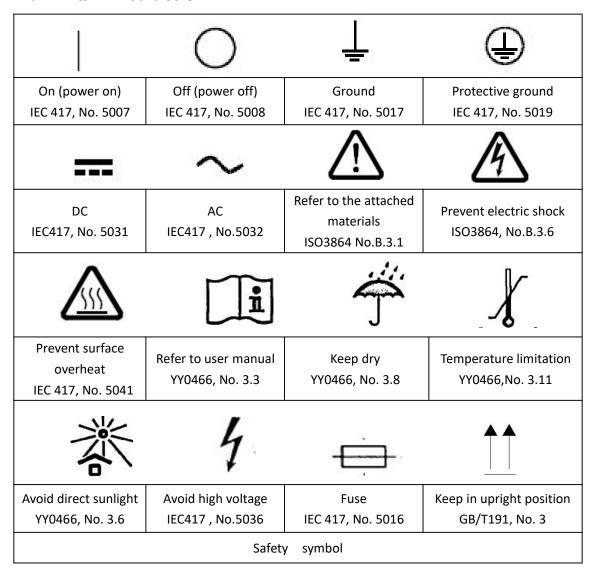
➤ Design temperature: 144°C

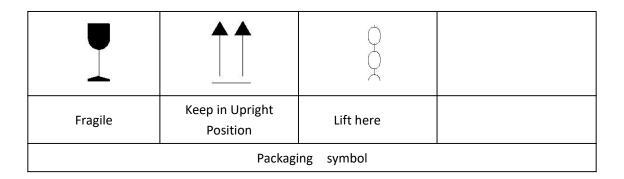
Vacuum low limit: -0.08MPa (Type B)
 Temperature selection range: 105~138°C

➤ Temperature display precision: 0.1°C

Pressure display precision: 1KPa

#### 1.4 Mark instruction





# 2 Installation

# 2.1 Unpacking

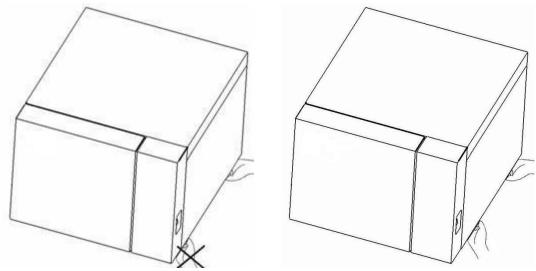
#### Unpacking

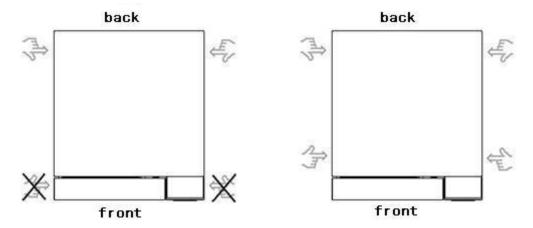
Open the top lid of the packing case first then remove the four flaps successively. Finally, remove the plastic film from the equipment.



## 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.

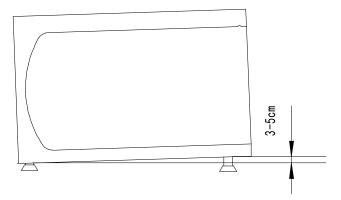
## 2.2 Equipment normal work condition

- > 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.)



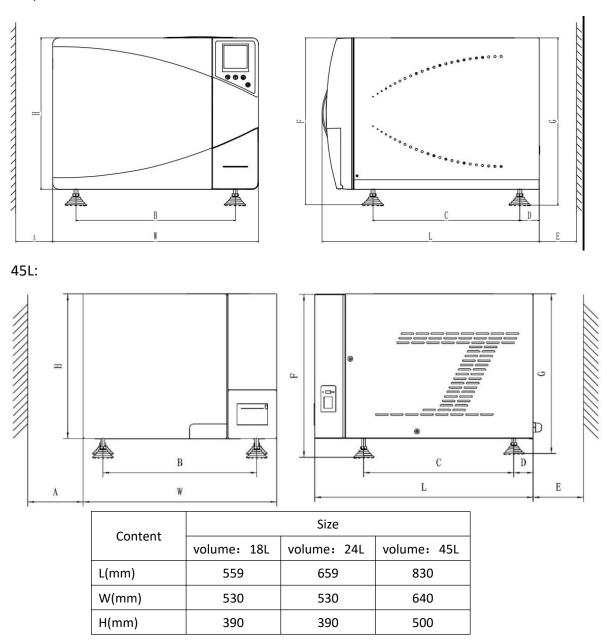
## 2.4 Equipment installation

## 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.

18L/24L:



A(mm)	500	500	500
B(mm)	410	410	554
C(mm)	378	478	648.5
D(mm)	50	50	52
E(mm)	500	500	500
F(mm)	455-465	455-465	595-615
G(mm)	425	425	565

# 2.4.2 Requirement on power supply, water supply

- After the 18/24L equipment is in place, check whether the power supply meets the requirements: AC 220V 50Hz single-phase power, fluctuations range ± 10%, power supply power is ≥2.6kVA.
- $\triangleright$  45L equipment: AC 220V 50Hz single-phase power, fluctuations range ± 10%, power supply power is ≥5.8kVA.



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: ≤2mg/L
  - PH value: 5-7
  - Hardness: ≤0.02mmol/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



NOTICE 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.

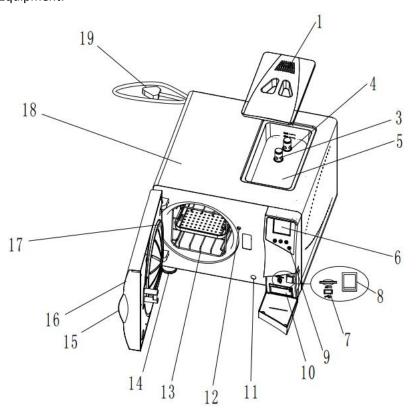


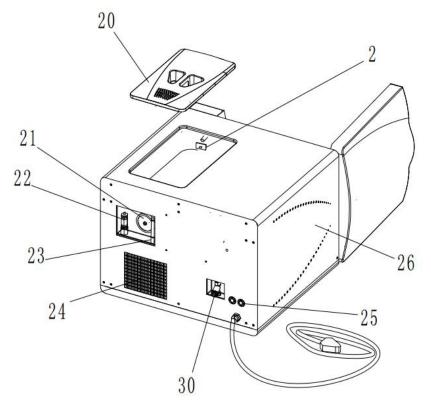
**NOTICE** Please turn on the power before opening the door! Please refer to 3.4 for door operation.

## 3 Equipment debugging

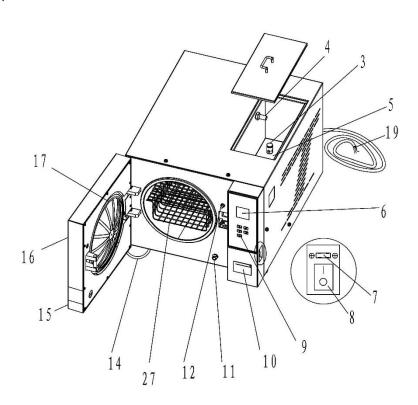
## 3.1 Equipment visible components introduction

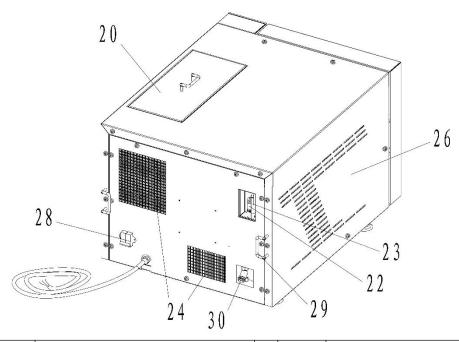
18/24L Equipment:





# 45L Equipment:





S/N	Component name	S/N	Component name
1	Cooling hole	16	Door cover
2	Water quality monitoring probe	17	door gasket
3	Water tank filter	18	Equipment top cover
4	outfall	19	Power line
5	Water tank	20	Water tank cover
6	Display screen	21	Air filte
7	USB connect port(Optional)	22	Safety valve
8	Power switch	23	WIFI antenna(Optional)
9	Operation button	24	Cooling hole
10	Printer(Optional)	25	fuse
11	Drain port for clear water tank	26	Equipment right cover
12	Door switch WD4	27	Equipment racks and trays
13	Equipment racks and trays	28	Breaker
14	Equipment feet	29	Side cover handle
15	Door handle	30	chamber filter

# 3.2 Operation of keys and screen

The buzzer will sound and the interface will work normally when the keys are pushed. Operation of keys:

SN Icon	n Remark
---------	----------

1	ESC	Return	
2	OK		
3		Open	
4	<b>A</b>	Up	
5	<b>V</b>	Down	(45L)

- 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



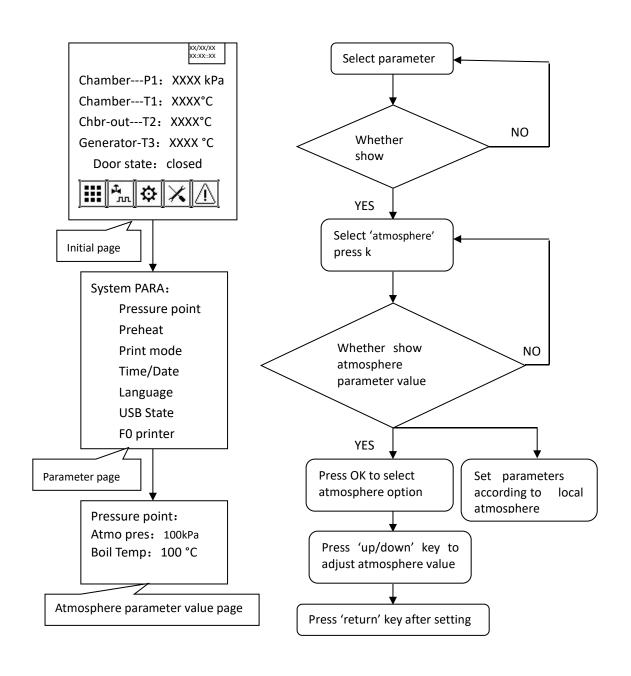
In the table below explains the meaning of the icons:

SN	Icon	Function		
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		
	<u> </u>	parameter setting		
3	X	When cursor selects this, after OK is pressed the menu changed to		
	7 •	parameter setting in system maintenance		
4	$\Lambda$	When cursor selects this, after OK is pressed the menu changed to		
	انت	alarming information		
5	$\bigcirc$	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	[N.]	When cursor selects this, after OK is pressed the menu changed to		
	ı—ı	parameter setting viewing in the program setting.		
8	J.	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 '|' 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



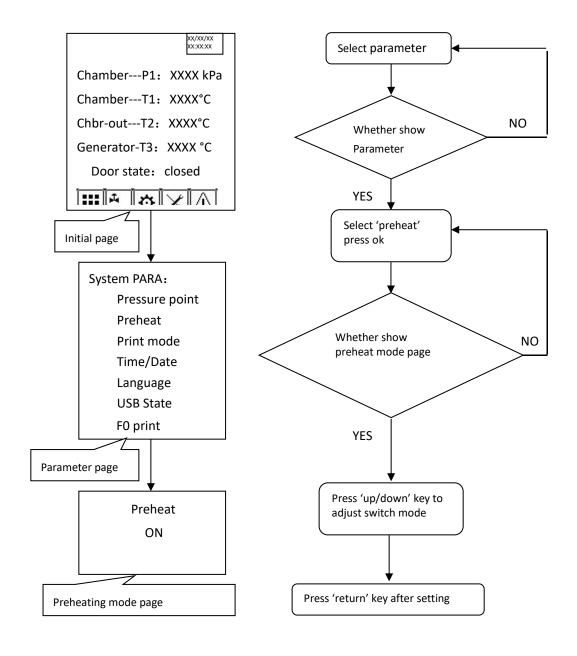
**NOTICE**: Adjust the atmospheric pressure value according to the local atmospheric pressure and the boiling temperature will be calculated automatically.

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  $\pm 5\text{KPa}$ ; 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

To close the door, gently push the right side of the door or the door handle. The system will close the door automatically, and the screen displays 'closing'. Once the door is completely closed, the screen displays 'closed'.

To open the door, push the 'open' button and the screen displays 'opening'. The system will open the door automatically. Once the door is completely opened, the screen displays 'opened', and now, users can pull the handle to open the door. Before pushing the 'open' button please make sure the product temperature and pressure are normal and no program is running.



**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 ±5KPa. 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.

When closing the door of the 45L equipment while its chamber is hot, push the door plate hard, after the door motor works, the chamber pressure may rise, the motor

works for a longer time and the door state displays "error", now just wait a minute, till the chamber pressure drops to be condition that the door can be opened, the motor will rotates to complete the door closing.

## 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 4L(18L/24 L Equipment) and 14L (45L Equipment).

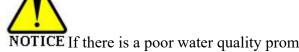
Advice: The temperature of water in tank will increase after 4 operation cycles. Please change the water if the vacuum performance decreased.

## 3.6 Operation of running 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 select a program on the program selecting page (sterilizing program or testing program)

and push ok key select the icon on program running page and push ok key 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.

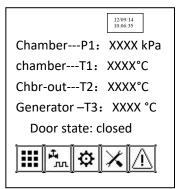
## 3.7 End of installation and commissioning

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

## 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 –T3: Indicates the steam generator temperature

## 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.

P1: XXXX kPa T1: XXX.X °C
T3: XXX.X °C T2: XXX.X °C
Cycles: 0000
Serial No: 000000
Fast-start:XXXX
Sterilize program
Test program
Auxiliary program

Program Select
Unwrapped
Wrapped
Rubber
User01
Liquid
N-Quick
B-Quick
Prion

"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

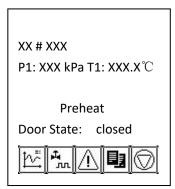
Select a program and push ok key to enter into the following page.

P1: XXX kPa T1: XXX.X℃
T3: XXX.X℃ T2: XXX.X℃
Pro. No: xx
Type: xxxxxx
Para: xxx ℃/xxx s
Door State: closed

☑ ☑ ☑

## 4.3 Program running page

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



## 4.3.1 Main process page

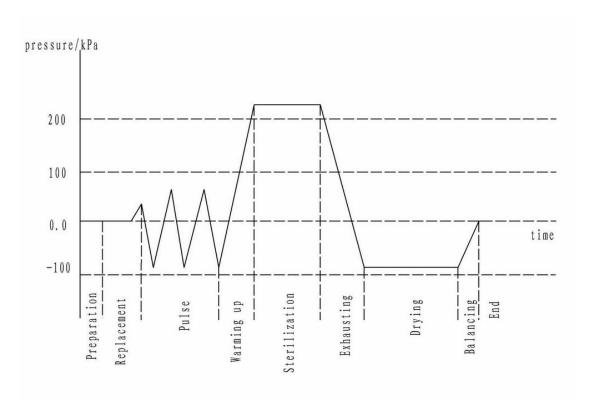
Once a program starts, the system will firstly enter into the preparation phase. System will promt 'Please open door' on the program end phase.



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'.

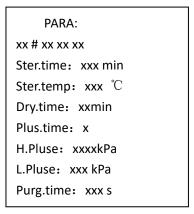
The corresponding relationship between pressure and time during work cycle, set the "unpacked program" of type B in ex- factory settings as an example, as the following diagram:



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.



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: XXX kPa		T1: XXX	
T3: X	xxx°C	T2: XXX	.x℃
F2	off	H2	off
F3	off	10	off
F4	off	11	off
F5	off	12	off
F6	off	13	off
B1	off	14	off
B2	off	15	off
H1	off	16	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	slow draining 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
10	Door close signal	door-trip WD4 off-position detection
I1	motor off-position signal	Motor door on position detection
12	Motor turn on signal	Motor door off position detection
14	steam generator high water level	steam generator high water level signal detection
15	steam generator low water level	steam generator low water level signal detection
16	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	xxx.x $^{\circ}$ C		
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

Pp1: 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

Pp2: 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

Pp3: 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

XXX.X°C: Second steam generator for 45L equipment (further one connecting to body in pipeline connection, i.e. "steam generator II" in 45L equipment PID) temperature

#### 4.6 Alarm information

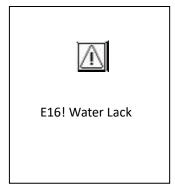
Select the alarm information icon in main process page to enter into the alarm information page (see the left picture below). The right picture showed below is an illustration of alarming page.

P1: XXX kPa T1: XXX.X°C
T3: XXX°C T2: XXX.X°C
NO.: XX Phase: XX
Text: XX

Occur: XX-XX-XXXX:XX

XXXXXX

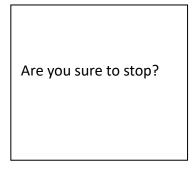
ACK: XX-XX-XXXX:XX:XX



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.



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  $^{\circ}$ C

Dry.time: xxmin

Puls.time: x

H.Pulse: xxxxkPa

L.Pulse: xxx kPa

Table: The default value of each program

Program Type	Ster.temp /°C	Ster.time /S	Dry.time /S	Puls.t ime	Max running time	Application scope
Unwrapped	134	240	300	3	55min	Type B: Unpacked items with heat resistance.  Type S: high temperature resistance, unwrapped and solid items.
Wrapped	134	360	600	3	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	3	75min	Rubber and fabric items without heat resistance.
User01	134	360	300	3	60min	Can be ordered according to the custom parameters
Liquid(45L Equipment)	121	1200			90min	Liquid items put in the cap-opened container (45L Equipment)
N-Quick	134	210	30		20min	Unpacked solid items.
B-Quick	134	210	30	2	30min	A small amount of bare cavity class objects (Type B)
Prion	134	1080	300	3	90min	Containing a load are harder to kill bacteria
BD& Helix	134	210	120	3	30min	To detect the performance of steam penetration and cold air discharging. (Type B)
B-Quick	vacuum pumping: 300s; testing:900s 40min					To detect leakage. (Type B)
Preheat	134	210	30	0	30min	To fully preheating equipment
Drying			600		15min	For drying
Cleaning	Time: 1200s					Rinse evaporator

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

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

Puls.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.

**Note:** 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).

**NOTICE** Liquid program (45L Equipment) 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 13 (45L Equipment: 13, 18/24L Equipment: 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, Cleaning 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 cannot sterile the lumen instruments. Please refer to the nameplate for the details.

➤ 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°C). 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°C). 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.
  - Program cleaning, to avoid dirt or other impurities adhere to the heating tube
    of steam generator, this cleaning program should be operated once a month to
    clean the steam generator.

## 6 Sterilization procedure

## **6.1** Cleaning before sterilization

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

## 6.2 Packing

 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.

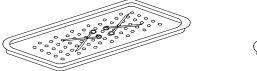
- Pack the dressing and instrument separately. It is better to put medical dishes upside down. Put gauze in between the dishes.
- All the instruments must be tightly packed on same direction.

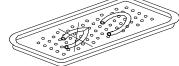
#### Sterilizer capacity:

Equipment volume	Maximum load for	Maximum load for	Maximum load for single
	instrument kind	fabric	package
18L	4.5 kg	2kg	1.5 Kg
24L	5.5 kg	2.5kg	1.5 Kg
45L	10.5 kg	5kg	3.0 Kg

#### 6.3 Placement

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





- Classify the instruments and rightly place them in trays.
- 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

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



NOTICE Caution: Please add water if the water level below the

below the

HIGHLEVEL

LOWLEVEL

low level mark. The buzzer will sound when the water level exceeds the probe of water quality monitoring. Keep adding

water till the level in between the low and high level mark (about 4L). When the water level is higher than the high level, it would affect the vacuum performance of the equipment, and easily make the water splash out from water tank!

• Turn on the power and twist the switch to '|' position. Close the door (Refer to the introduction of "Door switch operation")

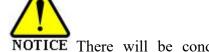
- Select a program needed(The detailed please refer to the specific program introduction).
- Operate as screen operation.

## 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

• 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.

• 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

- The sterilized items should be stored in dust-free, sealed and dry place with stable temperature.
- 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
	14 days	The valid time is only 7 days if the
		storage requirement (requirement:
Fabric material		environment temperature $<$ 24 $^{\circ}\mathrm{C}$ ,
		environment humidity $\leq$ 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	6 months	
paper-plastic packing bag	o 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	Located in the
		dirt		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	Water meet the requirement	
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 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 cloth and clear water to wipe the water tank.

# 7.1.2 Cleaning of door gasket

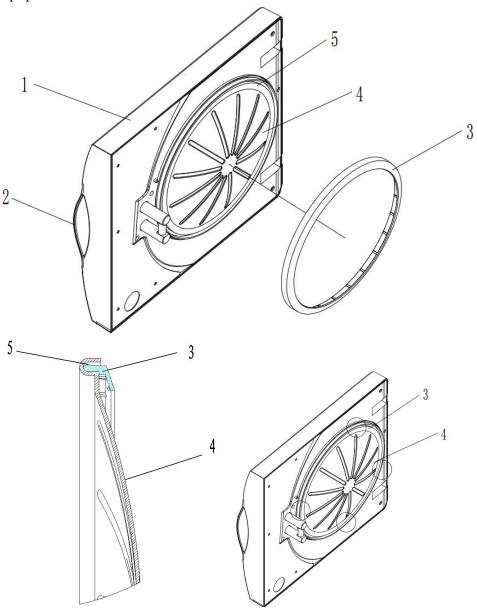
Remove the door gasket and wipe it by a clean and wet cloth with cleaning detergent. Rinse the gasket after wiping it. Wipe the gasket groove by a clean and wet cloth.

## 7.1.3 Cleaning of tray rack

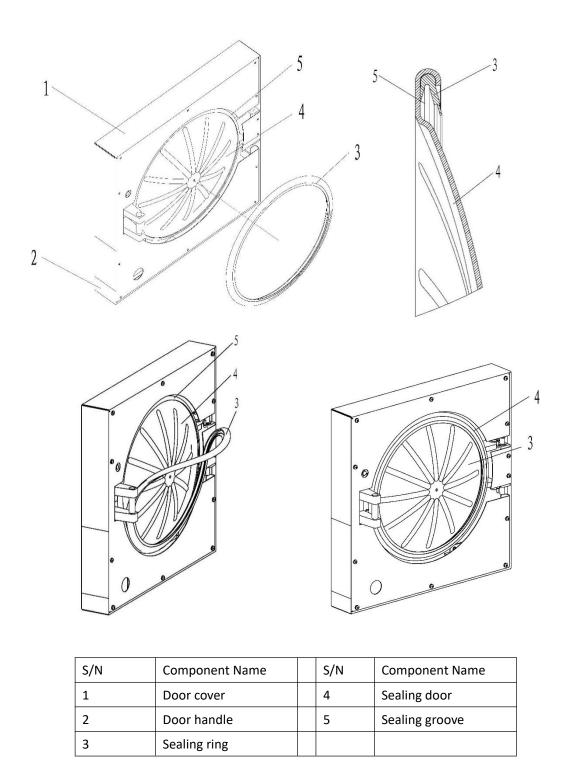
Wipe the tray rack by a clean and wet cloth and rinse it after that.

# 7.2 Replacement of door gasket

18/24L Equipment:



45L Equipment:



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, cannot 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

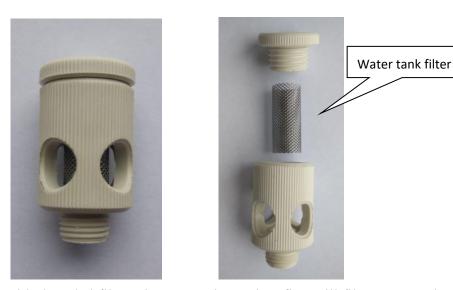
## 7.3.1 Cleaning of chamber filter

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, and the filter is shown as following diagram:



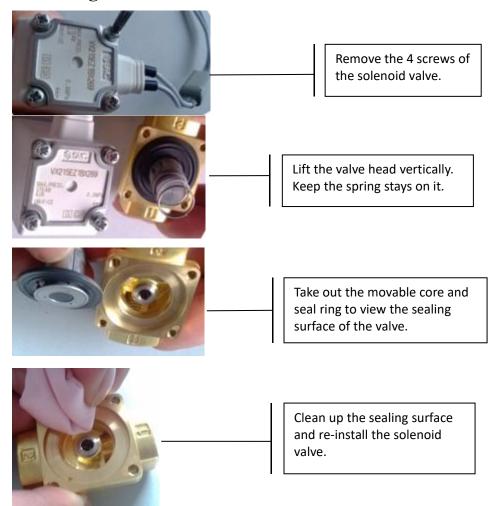
After removed the nuts, remove the filter net, clean the filter impurities by clear water. After leaning re-install it. Cleaning of solenoid valve

### 7.3.2 Water tank filter



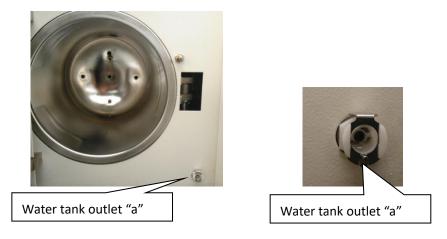
Tank with threaded filter, clean or replace when first will filter counterclockwise from the water tank filter, to remove it. According to the above filters for decomposition, decomposition and brush with water after cleaning filter. After completion of cleaning will filter recovery and will reinstall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

## 7.4 Cleaning of solenoid valve

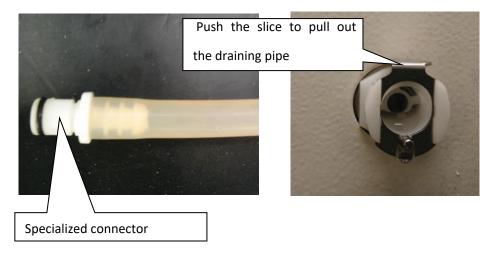


Thoroughly clean the parts after removing them. And then have a re-installation.

# 7.5 Tank drainage



Before dewatering, please insert a dewatering pipe into the water outlet. Push the little slice on the top of the connector to pull out the draining pipe.



## 7.6 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.

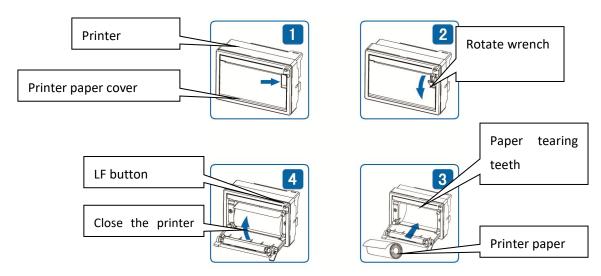
**NOTICE** Relief valve need on a regular basis (once a year) according to the regulation to the designated inspection agencies for calibration.

#### 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.

## 7.7 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-gyrate it until the paper cover opened as shown in Fig 2.

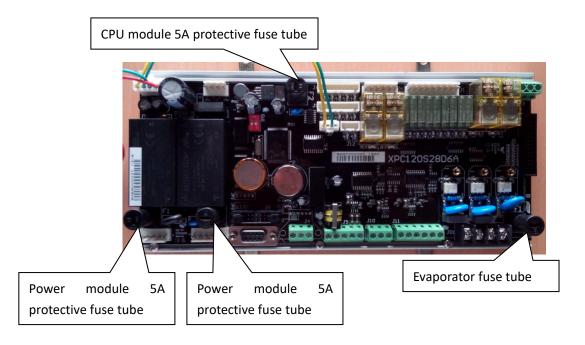
Undrawn the paper cover, and insert the paper into the printer, then pull out a small amount of paper. Notice the direction of the paper according to Fig.4.

Close the paper cover. Press the platen roller back to the printer head, then push the circumrotated wrench to the original position.

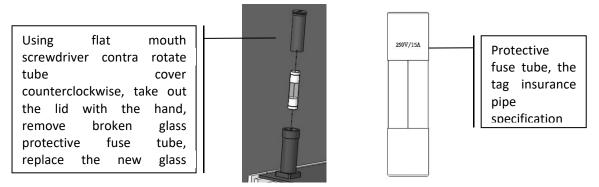
Power the printer on, then press LF button, make the print head to run, and the paper will come out. Turn off the power.

Fuse protector change

## 7.7.1 Mother board fuse protector

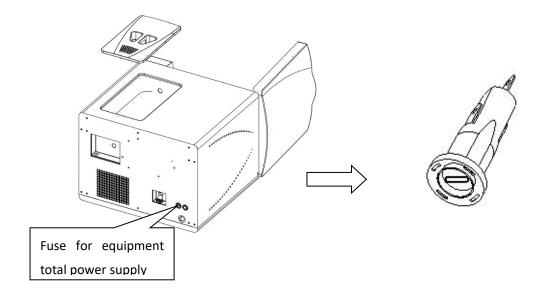


There are corresponding fuse in the equipment accessories, if there is a fuse burn out, find corresponding specification of fuse to replace it.



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

# 7.7.2 Fuse for equipment total power supply (only applicable to 18L, 24L equipment)



Firstly cut off the power supply connected to the equipment.

Use flat-mouth (dash word) screwdriver to rotate the fuse seat in direction of counterclockwise, pull the lid holding the insurance fuse.

reReReReReplace the fuse. While replacing, must check whether the parameters of the new fuse is consistent with the original specifications.

After the replacement, insert the cap filled with a fuse into the fuse base; align it toward the guide groove of the fuse base. Rotate the fuse clockwise to tight it, make it no longer rebound.

**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 Trouble removal

## 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  $\pm$  5KPa 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 close	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°C.	Check the temperature detecting parts or contact us.	
4	E03 Ch-out-T2 high	The detected chamber wall temperature exceeds $160^{\circ}$ C.	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	Check the chamber and water	

NO.	Warning Code	Reason	Solutions	
		the lower limit during the preset	tank filter and wash them if there is	
		time.	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.	
			Check whether there is any steam	
			leakage.	
7	EOC Hoot failed		Check whether the solenoid valve	
/	E06 Heat failed	Heating timeout.	is well sealed.	
			➤ Check whether the Temperature	
			of the evaporator T3 is well (>130 $^{\circ}$ C)	
	E09 Motor Overtime	During the process of door	Reinstall the door gasket.	
8		closing, the door motor working	> The wire is loose or disconnected.	
		time exceeds the preset time.	Please rewire.	
9	E10 Over Pressure	The chamber pressure exceeds	Check the pressure sensor.	
9		the preset pressure.		
10	E12 ChamberT1	The detected chamber	Check the chamber temperature	
10	Error	temperature is 0 $^{\circ}\mathrm{C}$ or 200 $^{\circ}\mathrm{C}$ .	sensor.	
11	E13 Ch-out-T2 Error	The detected chamber wall	Check the temperature sensor of	
11	LI3 CII-OUL-12 LITOI	temperature is $0^{\circ}\mathbb{C}$ or $200^{\circ}\mathbb{C}$ .	chamber wall.	
12	51.4 Comparet D2 bish	The detected pressure of steam	Check the pressure sensor of steam	
12	E14 Generat.P2 high	generator is -100kPa or 300kPa.	generator.	
12	E15 Genera.P1 Error	The detected chamber pressure is	Charleth a sharehar areas areas	
13		-100kPa or 300kPa.	Check the chamber pressure sensor.	
			> Check whether the tank has been	
14	E16 Water1 Lack	The low level signal of clean	filled with pure water.	
		water tank cannot be detected.	➤ Check the water quality detecting	
			device setting of water tank.	
15	E23 MoterSW unclosed	The signal of door	Check the electro-magnetic lock and	
		locking-position cannot be		
		detected.	door-locking micro switch.	
16	E50 Communic Error	Communication error between	Charletha annan and arrive barrel	
		screen and maid board.	Check the screen and main board.	

## 9 Appendix

Conventional 18L/24L/45L equipment accessory (Special equipment may different, the take the actual as standard, please prevail in kind) .

USB Reading Data software: The software installation need a "Activation code". Please send the "Machine code" to us which is generated in the install process. We will generate the "Activation code" and send it to you."

S/N	Name	Specification	Photo	Usage	
1		13100-0170702			
		(18L)		For holding articles that to	
	Disinfection tray	13101-0230702		be sterilized.	
		(24L)			
2	Sterilization net	13100-0450301 (45L)		For load sterilization items, placed on sterilization rack	
	Tray rack	13100-0170701		For holding disinfection trays.	
		(18L)			
3		13101-0230701			
		(24L)			
4	Sterilization rack	13100-0450302 (45L)		Lower layer for sterilization items, top for sterilization net cover	
5	Dish holder	13100-0230701 (18L/24L)		For holding dishes and avoid scald.	
6	Water outlet pipe(with connector)	964100349		After open the door ,insert water outlet joint, let the water flows out from water tank	
7	Glass fuse tube	5A 5*20		Fuse of main power board.	
7		15A 5*20		Fuse of thyristor circuit.	
8	Ceramic fuse	20A 6*32	5-	Fuse of cable.	
9	Corrugated pipe	13002-00301		Door insurance accessory for pressure switch	
10	Printing paper (optional)	901990159		Product printing paper (E26)	

#### **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:

Appendix 2 Electric installation drawing (18L/24L/45L)

