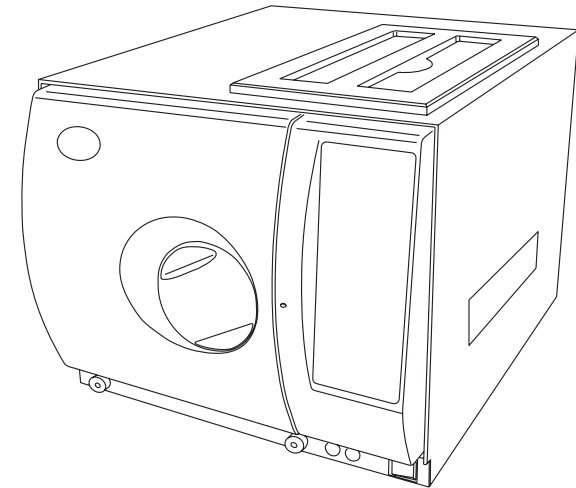


# STEAM STERILIZER

## Instructions Manual

(12B/16B V 1.0)

EU B Class



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Thank you for choosing this Steam Sterilizer.

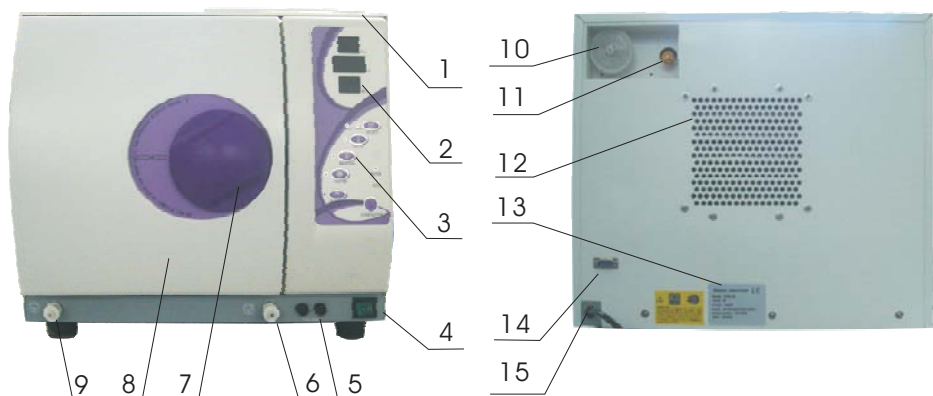
Please read the instructions manual carefully in order to install the equipment and operate the equipment correctly.

## TABLE OF CONTENTS

1.GENERAL .....	1
2.TECHNICAL PARAMETER .....	2
3.PACKING CONTENT .....	3
4.INSTALLATION .....	4
5.CONTROL PANEL .....	5
6.OPERATION .....	6
6.1 SWITCH ON .....	6
6.2 FILL THE DISTILLED WATER .....	6
6.3 PREPARING THE MATERIAL TO BE STERILIZATION .....	6
6.4 SELECTING THE STERILIZATION PROGRAM .....	7
6.5 RUNNING THE STERILIZATION PROGRAM .....	7
7. THE DRAIN CONNECTOR .....	9
8. ADVANCED SETTING .....	10
9. PRINTER (OPTIONAL) .....	11
10. MAINTENANCE .....	12
11. TRANSPORT AND STORAGE .....	15
12. ALARM .....	16
13. SAFETY DEVICES .....	17
APPENDIX	
1. CHARACTERISTICS OF THE FEEDING WATER .....	18
2. DIAGRAMS OF THE STERILIZATION PROGRAMMES .....	19
3. ELECTRICAL DRAWING .....	23
4. HYDRAULIC DRAWING .....	24

## 1 General

This sterilizer described in this manual is intended for the sterilization of re-useable surgical instruments and material. It operates automatically with 134°C and 121°C sterilization temperatures. The sterilizer is a Medical device class IIa, in accordance with article 15-Appendix IX of the European Directive 93/42/CEE and it has been produced in accordance with the EN 13060.



- 1 Distilled water tank
- 2 Screen
- 3 Control panel
- 4 Main switch
- 5 Main fuses
- 6 Drain connector of reservoir
- 7 Door handle
- 8 Door

- 9 Drain connector of used water reservoir
- 10 Bacteriological filter
- 11 Safety valve
- 12 Condenser ventilation
- 13 Rating plate
- 14 Printer port
- 15 Power supply cord

### Security Notice

In order to proper use the sterilizer, please be sure to read the warning and attention carefully for safety.



**This symbol is grounding protection inside the machine.**



**HOT SURFACE.**

**This symbol is visible on the front of the panel after open the door.**



**Important safety information.**

**This symbol is used to draw the attention of the reader to particularly important notions for operator safety.**

## 2 Technical Parameters

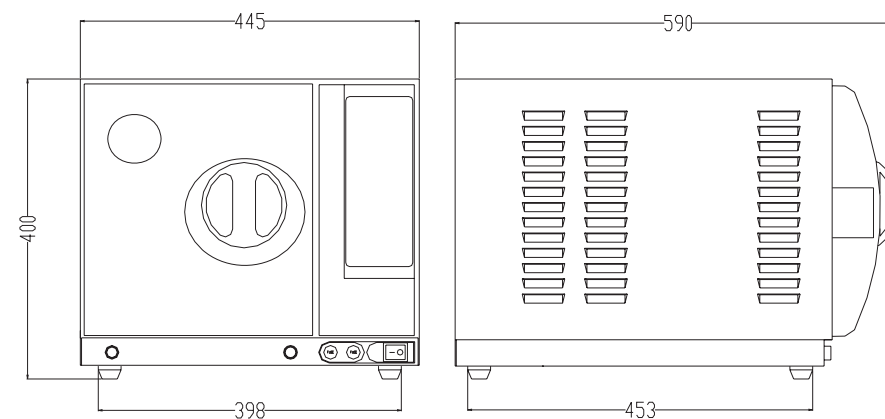
Item	12L	16L
Chamber	Φ200mmX360mm	Φ230mmX360mm
Rated Voltage	AC220V-240V(AC110V), 50-60Hz	
Main Fuses	T12A/250V(T20A/250V for 110V)	
Nominal power	1750VA	1750VA
Sterilization Temperature	121°C/134°C	
Capacity of the distilled water tank	Approx 2.5L (water at level MAX)	
	Approx 0.5L (water at level MIN)	
Operation temperature	5 - 40°C	
Outside size	445mm(width)X 400mm(height)X 590mm(depth)	
Net weight	41kg	45kg
Noise	<70dB	
Relative Humidity	max 80%, non condensing	
Atmospheric pressure	76kPa -106kPa	

### 3 Packing Content

No	Item	Quantity
1	12L/16L Steam sterilizer	1
2	Instrument tray	3
3	Instrument tray rack	1
4	Instrument tray handle	1
5	Door adjustment tool	1
6	Draining hose	2
7	Instructions manual	1
8	Power fuse( T12A/ AC250V T20A/ AC250V for 110V)	2
9	Fuse for valve (T3A/ AC250V)	2
10	Fuse for mainboard (T1A/ AC250V)	2
11	Door seal	1

### 4 Installation

- \* There must leaves 10cm gap around sterilizer, and 20cm on top side. the clearance required for the movement of the door(s): leave an at least 450mm fan-shaped space in front of the door.
- \* The place which sterilizer located must be ventilated, make sure that the radiator not being jammed.
- \* The sterilizer should be placed on a level worktable.
- \* Don't cover or block the door, ventilation or radiation openings on the sterilizer.
- \* Don't place the sterilizer near a sink or in a location where it is likely to be splashed.
- \* Keep away from all sources of heat.



## 5 Control panel

### 5.1 Pressure display window.

Display the chamber pressure during the working cycle.

### 5.2 Temperature display window.

Display the chamber temperature.

### 5.3 State display window/alarm code.

Display the cycle state and error code, (see the **working state**) Error code (Please see chapter 12 **Alarm**).

### 5.4 “SELECT” button

Choose the correct sterilization temperature according to your instrument.

### 5.5 “SOLID” button、“WRAPPED” button、“COTTON” button、“PLASTIC” button

Choose the sterilization program. (please see Appendix2)

### 5.6 “WATER” indication lamp

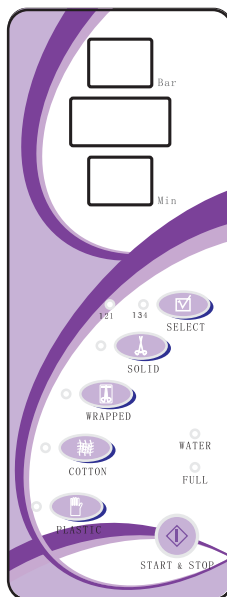
This lamp will lighten when the distilled water tank is lack of water. Please filling the tank otherwise the machine can not work.

### 5.7 “FULL” indication lamp

When this lamp lightens, it means the used water tank is full of water. The machine will not work until you drain the tank.

### 5.8 “START & STOP” button

Press this button to start the sterilization cycle, holding this button above 3 seconds to restart the system, and back to the initial state.



### Working State

Digital display	State	State description
Ld	preheating	The machine is preparing before a cycle start
Do	door state	display “do” , it means the door is closed
Po	vacuuming	The machine is vacuuming during a cycle
HE	heating	The machine start to rise up the temperature and pressure.
Display time	sterilization/drying	Display the cycle time and count down.
PL	exhaust	The machine is releasing steam.
Ed	end	The cycle is over, you can open the door and take out the sterilized instrument.
Display error code	Error state	Display the error code, press “Start/Stop” button to come back the initial state.

## 6 Operation

### 6.1 Switch on

**6.1.1 Open the door and take out all the instrument tray and other accessories inside, unpack and clean them when it work for the fist time.**

**6.1.2 Connect the power.**

**6.1.3 Switch on**

Switch on the sterilizer through the mains switch  
After the switching on, the machine turns on the LED.  
The machine will alerts by beep sounds if there are problems.  
Over the test the state window will show **Ld**.



### 6.2 Fill the distilled water

Open the top lid, and fill the tank with distilled water by cup or tank. When you hear a beep signal, it means the water level is exceed the max. level. Please stop filling immediately.



### 6.3 Prepare the material to be sterilized

To get the better effectiveness of the sterilization process and to preserve the material in time, follow the indications below reported.

- \* Arrange the tools of different metal (stainless steel, moderate steel, aluminum, etc.) on different trays or however well separate between them;
- \* In case of not stainless steel tools, interpose a sterilization paper napkin or muslin cloth between tray and tool, avoiding direct contacts between the two different materials;

- \* Verify all the tools are sterilized in open position;
- \* Arrange the containers (glasses, cups, test-tubes, etc.) on one side or inverted position, avoiding possible water stagnation;
- \* Don't overload the trays over the stated limit (see Appendix 1).
- \* Don't stack the trays one above the other or put them in direct contact with the walls of the sterilization chamber.
- \* Always use the instrument tray handle.
- \* Wrap the tools one by one or, if more tools have to be set in the same wrap, verify that they are of the same metal;
- \* Seal the wrap with sterilization adhesive ribbon or by a thermal sealer.
- \* Don't use metallic clips, pins or other, as this jeopardizes the maintenance of the sterility;
- \* Turn the sterilization paper in order to set the plastic part downward (tray side) and the paper part upward.



Always wrap the tools in case of prolonged store.

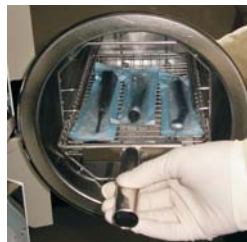
#### 6.4 Select the sterilization program

Select the sterilization program according to your instrument. See the **Appendix 2**, and select the fittest program and sterilization temperature.



#### 6.5 Running the sterilization program

After selecting program, put the instruments into the chamber by tray handle.



6.6 After the instruments are loaded, you may close and lock the door by turning the door handle clockwise.



Caution: You must turn the door handle to the maximum position, otherwise the machine will alarm and stop working during the cycle.

#### 6.7 Start the sterilization program.

Press START button, the machine will start a cycle automatically. It will take 30-75 minutes. (See **Appendix 2**)



Caution: When you press the "Start" button the door handle has not been turned to the maximum position, you will see the **do** blinks on the State display window, It means you can not start a cycle until you close the door completely and press the "Start" button again.

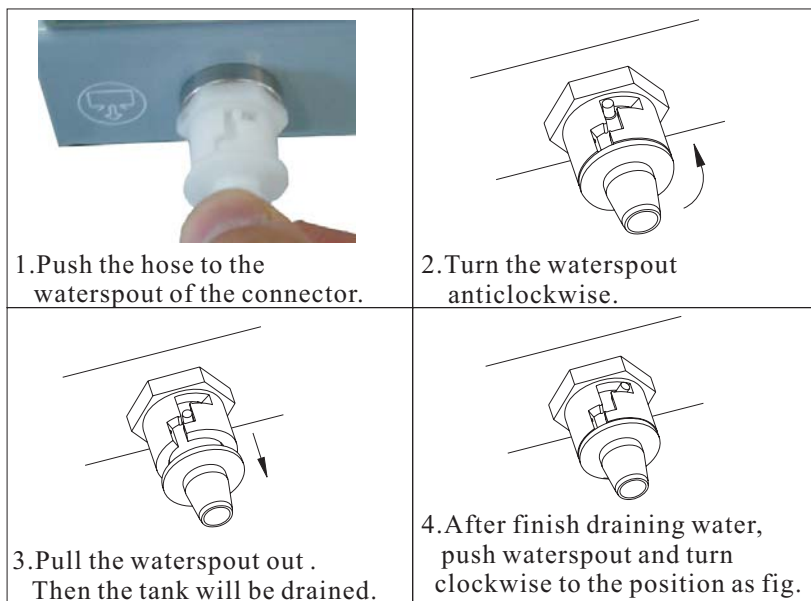
#### 6.8 Sterilization cycle end

After a cycle completes, the printer will start working and print the report of the sterilization cycle data. After the pressure is 0, you may open the door, and take out the sterilized instruments.



Always use the tray handle to load or unload the tray in order to avoid scald.

## 7 The drain connector



## 8 Advanced Setting

### 8.1 Adjustment of sterilization time and drying time

- 8.1.1 Holding the **SOLID** button for 30 seconds. After hearing the sound, release the button, then you may adjust the parameter.
- 8.1.2 The pressure display window show  $\pm 0$ , the temperature display window show ---, the state display window show the time parameter.
- 8.1.3 Select the sterilization program. For example,  
If you want to adjust the parameter of **WAPPED**. Press the **WAPPED** button. Press the button again, it will show  $\pm 1$ .  
 $\pm 0$  means the 121°C sterilization time. (The range from 3 to 40)  
 $\pm 1$  means the 134°C sterilization time. (The range from 3 to 40)  
 $\pm 2$  means the drying time. (The range from 3 to 20)
- 8.1.4 Press **Select** button, the value of time parameter will plus one.
- 8.1.5 After finishing the adjustment, press **START** button to confirm it.
- 8.1.6 To **PLASTIC** program, there is only two states of  $\pm 0$  and  $\pm 2$ .  $\pm 0$  means 105°C disinfection time.  $\pm 2$  means drying time.



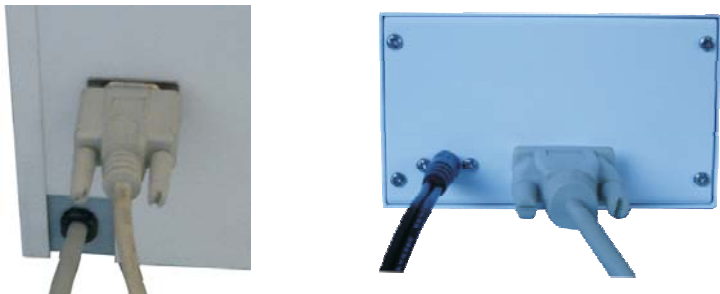
Caution: We do not recommend the customer to adjust the parameter. Unless the customer think it is necessary and have inform the agent.

### 8.2 B&D/HELIX test

- 8.2.1 Put the B&D test package into the chamber.
- 8.2.2 Close the door.
- 8.2.3 Hold the **WAPPED** button for 5 seconds. When you hear the indicated voice release the button. Then you may start the B&D test. The State window display **bd**.
- 8.2.4 Press the **START** button to start B&D test program.
- 8.2.5 After finishing work, the program returns to the original state.

## 9 Pinter (Optional)

- 9.1 Connect the printer cable to socket at the back of the sterilizer.
- 9.2 Connect the printer power. Then switch on the printer.
- 9.3 Switch on the sterilizer.
- 9.4 After finishing sterilization, the printer will start working.



### Example of the print report

S/N: \_\_\_\_\_

Program: wrapped  
 Temperature: 121°C  
 Pressure: 1.1bar  
 Vacuum Num: 3  
 Dry Time: 05Min  
 Ster Time: 20Min  
 Cycle No: 00013

-----  
 MAX • Temp  
 MIN • Temp  
 Time P:bar T:°C  
 00:12 1.25 122.6  
 00:13 1.13 121.2  
 AVE.Temp: 121.9°C

Operator: \_\_\_\_\_  
 Date: \_\_\_\_\_

## 10 Maintenance

Frequency	Operation
Daily	Cleaning the door seal
	Cleaning the external surface
Weekly	Cleaning the reservoir
	Cleaning the chamber
Every 3/6 monthly (depending on the use frequency)	Replacing the bacteriological filter
Every year	Replacing the door seal

### 10.1 Clean the distilled water tank every week with medical disinfectant .



### 10.2 Clean the chamber weekly.

- 10.2.1 Remove the trays and rock from the chamber.
- 10.2.2 Clean the chamber with non-plush cloth saturated with distilled water.
- 10.2.3 Apply the same procedure for the trays and rock.



### 10.3 Replacement of the bacteriological filter

- 10.3.1 The bacteriological filter is at the back of the sterilizer.
- 10.3.2 Unscrew the filter by hand (anti-clockwise).
- 10.3.3 Replacing the bacteriological filter.
- 10.3.4 Screw the new filter by hand clockwise.





## 10.4 Cleaning the door seal

Clean the door seal weekly, with non-plush cloth saturated with the distilled water.



## 10.5 Door adjustment

On normal circumstance the chamber door lock don't need to adjust. Once steam leaking occurs (the seal fails), you may use the spanner to adjust door seal.

10.5.1 Open the door first

10.5.2 Insert the spanner in the gap beneath the plastic cover; use the spanner to lock on the adjusting nut (Fig 1). Turn the nut counter clockwise as the figure below (Fig 2). This will tighten the sealing plate.

10.5.3 Turn the nut until the sealing plate is tight. If the door knob is too tight, you may also turn the nut clockwise to loosen it.

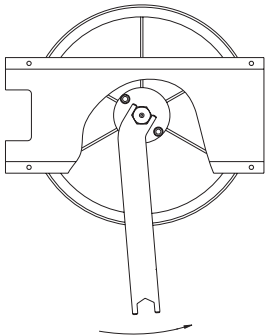


Fig 1



Fig 2

Caution:

Never try to readjust the chamber door while the door is locked.

## 10.6 Replacement of the door seal

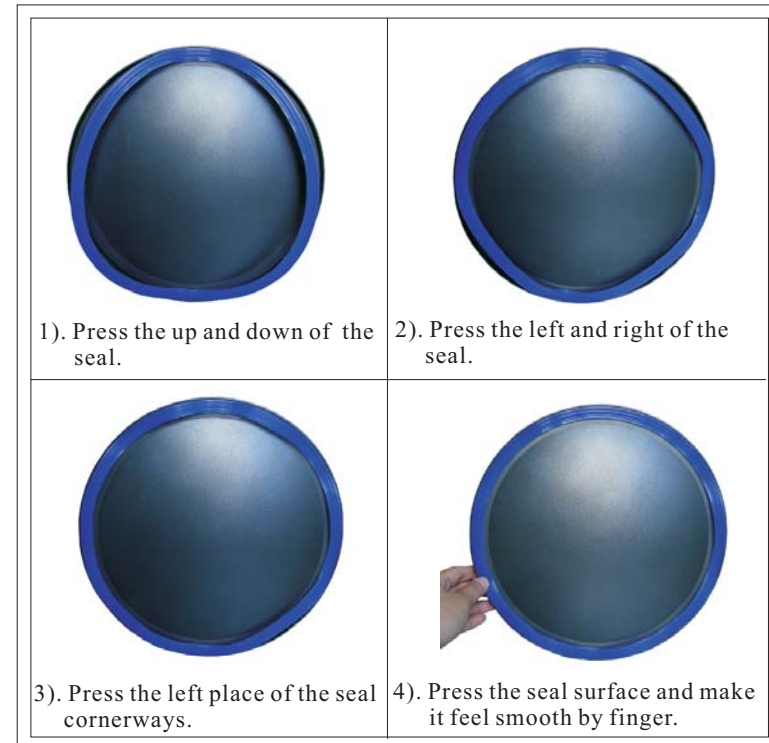
10.6.1 Fully open the door.

10.6.2 Remove the door seal carefully by hand.

10.6.3 Clean the door seat carefully with a non-plush cloth saturated with distilled water.





10.6.4 Moisten the new seal with medical disinfectant .

10.6.5 Insert the new seal and press in sequence as the following.



Caution: Please ensure the chamber and the door has been cool down before you change the seal.

## 10.7 Replace fuse

1). Switch off the power.	
	
2). Push the fuse by a screw driver first, then unscrew the fuse holder counter clockwise.	3). Pull the fuse holder out.
	
4). Make sure to replace the correct fuse.	5). Put back the fuse holder and push it, then screw it clockwise with a screw driver.

## 11 Transportation and Storage

11.1 Switch off the sterilizer before transportation or storage. Pull out the plug to let the machine cool down.

11.2 Drain the distilled water tank and the used water tank

11.3 Conditions for transportation and storage:

Temperature: -20 °C ~ +55°C

Relative humidity: ≤85%

Atmospheric pressure: 50kPa~106kPa

## 12 Alarm

Code	Description	Proposed solution
E1	Steam generator temperature sensor error	Check steam generator temperature sensor
E2	Inner temperature sensor error	Check inner temperature sensor
E3	Temperature sensor of chamber wall error	Check temperature sensor of chamber wall
E4	Fail to rise temperature	Check water pump or the seal of the machine
E5	Fail to release the steam	Check the air release valve
E6	Door is opened during working	Make sure you have turned the door handle to the max. position or check the door switch
E7	Overtime	Check the water pump Check the air release valve
E8	Steam generator overheat	Check steam generator temperature sensor
E9	Holding temperature is failed.	Check the reservoir if the water is not enough or ask authorized people to check the heating system and temperature sensors.
EE	Program manually interrupted	Shut off the power and restart the power
EF	System have not initialized	Shut off the power and restart the power

## 13 Safety devices

### (1) Main fuses

Protection of the whole equipment against possible failures of the heating resistor .

Action: Interruption of the electric power supply.

### (2) Thermal cutouts on the mains transformer windings

Protection against possible short circuit and mains transformer primary winding overheating .

Action: Temporary interruption (up to the cooling) of the winding.

### (3) Safety valve

Protection against possible sterilization chamber over-pressure .

Action: release of the steam and restoration of the safely pressure.

### (4) Safety micro-switch for the door status

Comparison for the correct closing position of the door .

Action: signal of wrong position of the door.

### (5) Manually reset thermostat on chamber heating resistors

Protection for possible overheating of the chamber heating resistors .

Action: Interruption of the power supply of the chamber resistors.

### (6) Manually rest thermostat on steam generator

Protection for possible overheating of the steam generator .

Action: Interruption of the power supply of the steam generator.

### (8) Self-leveling hydraulic system

Hydraulic system for the natural pressure levelling in case of manual cycle interruption, Alarm or black-out .

Action: automatic restoration of the atmospheric pressure inside chamber.

## APPENDIX 1 Characteristics of the feeding water

DESCRIPTION	FEED WATER	CONDENSATE
Evaporate residue	≤10 mg/l	≤1.0 mg/kg
Silicium oxide $\text{SiO}_2$	≤1 mg/l	≤0.1 mg/kg
Iron	≤0.2 mg/l	≤0.1 mg/kg
Cadmium	≤0.005 mg/l	≤0.05 mg/kg
Lead	≤0.05 mg/l	≤0.1 mg/kg
Rest of heavy metals, excluding iron, cadmium, lead	≤0.1 mg/l	≤0.1 mg/kg
Chloride	≤2 mg/l	≤0.1 mg/l
Phosphates	≤0.5 mg/l	≤0.1 mg/l
Conductivity (at 20°C)	≤15 $\mu$ s/cm	≤3 $\mu$ s/cm
pH value	5-7.5	5-7
Appearance	Colorless, clean, without sediments	Colorless, clean, without sediments
Hardness	≤0.02 mmol/l	≤0.02 mmol/l

## APPENDIX 2

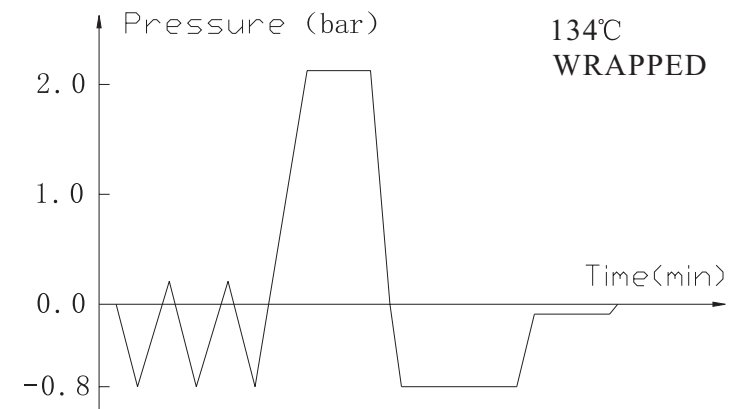
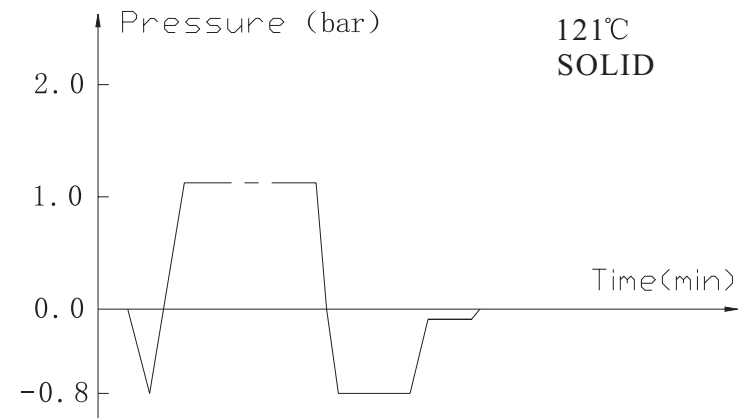
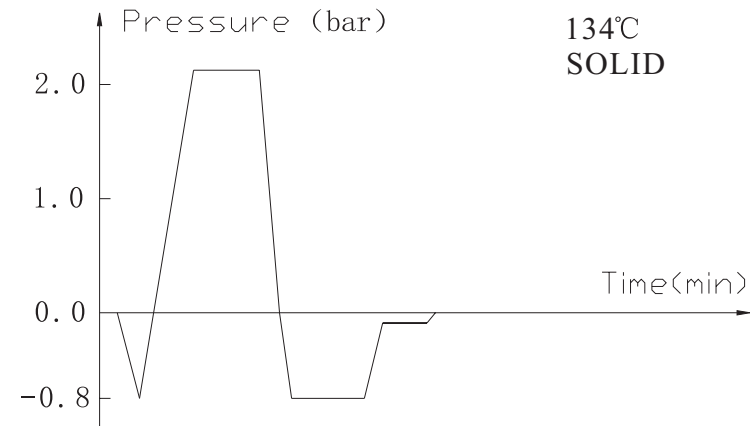
### DIAGRAMS OF THE STERILIZATION PROGRAMMES

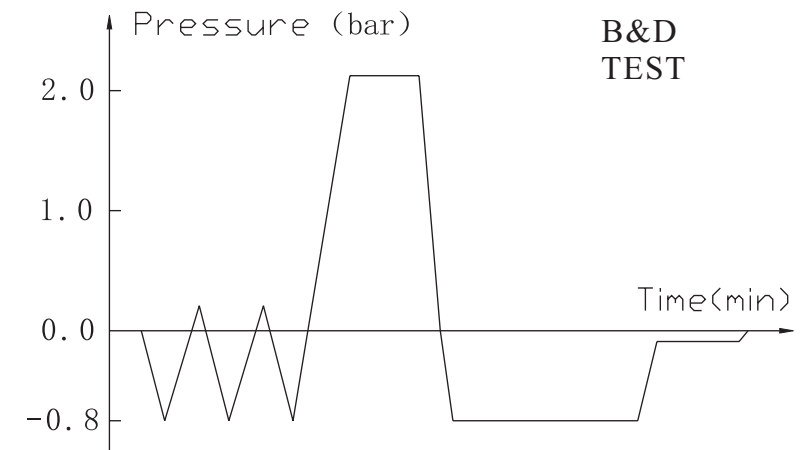
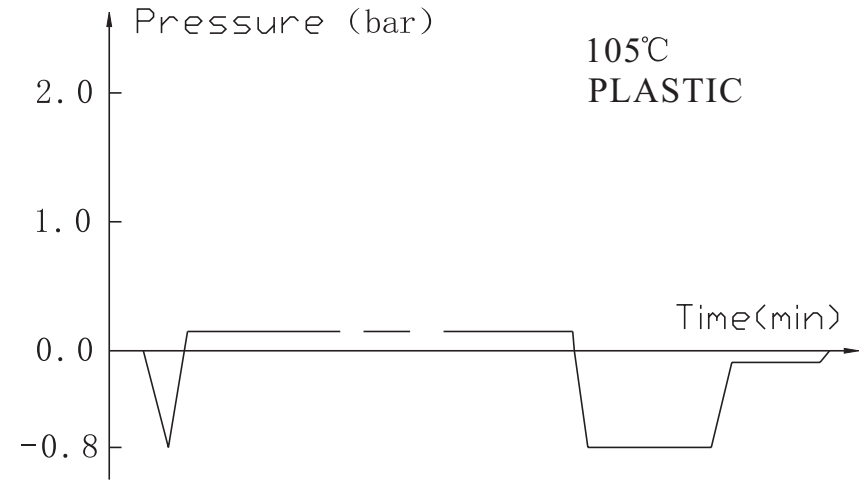
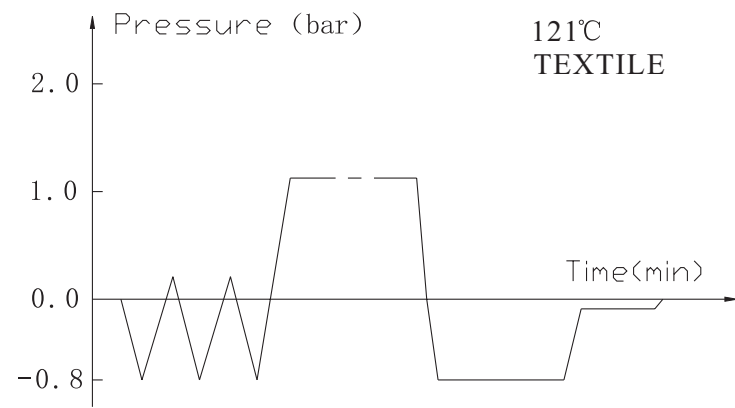
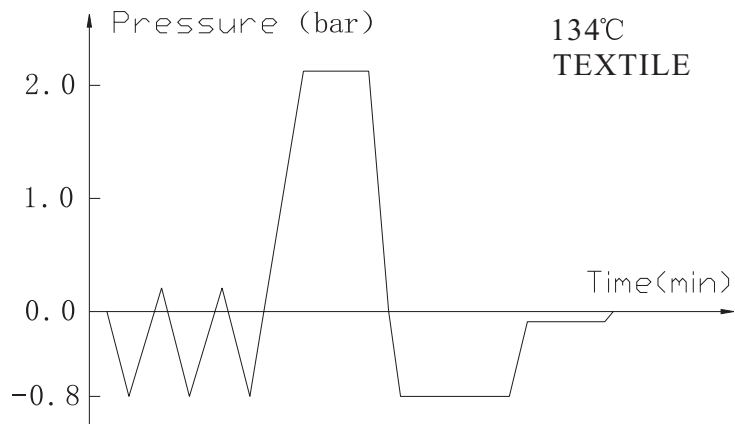
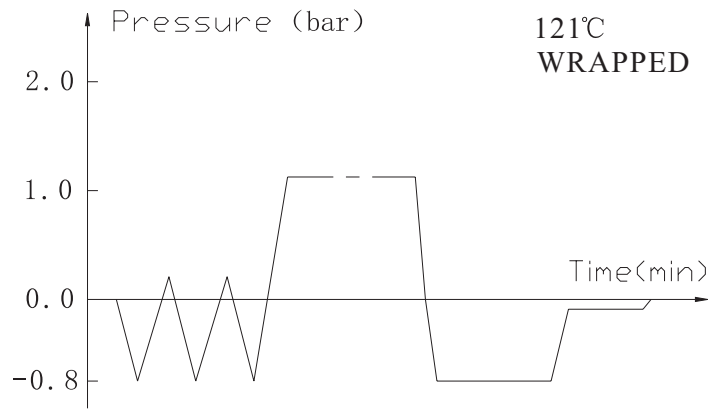
PROGRAM	Temperature (°C)	Pressure (bar)	Holding time (min)	Total time (min)	TYPE	MAXLOAD (kg)
SOLID	134	2.10	4	18~30	Unwrapped solid material	5.00
	121	1.10	20	30~45		5.00
WRAPPED	134	2.10	6	30~40	Unwrapped hollow material	5.00
	121	1.10	20	35~50	Single-wrapped solid material	4.00
COTTON	134	2.10	10	45~65	Unwrapped porous material	1.25
					Single-wrapped porous material	1.00
					Dual-wrapped porous material	0.75
	121	1.10	30	50~75	Single-wrapped Hollow material	4.00
					Dual-wrapped solid and hollow material	2.00
PLASTIC	105	0.20	30	50~65	Unwrapped plastic material disinfection	3.00
B&D TEST	134	2.10	3.5	22~35	—	—

The time required for sterilizer to be ready for routine use after the power is switched on less than 5 minutes.

The max. temperature of the 134°C sterilization cycle is 136°C

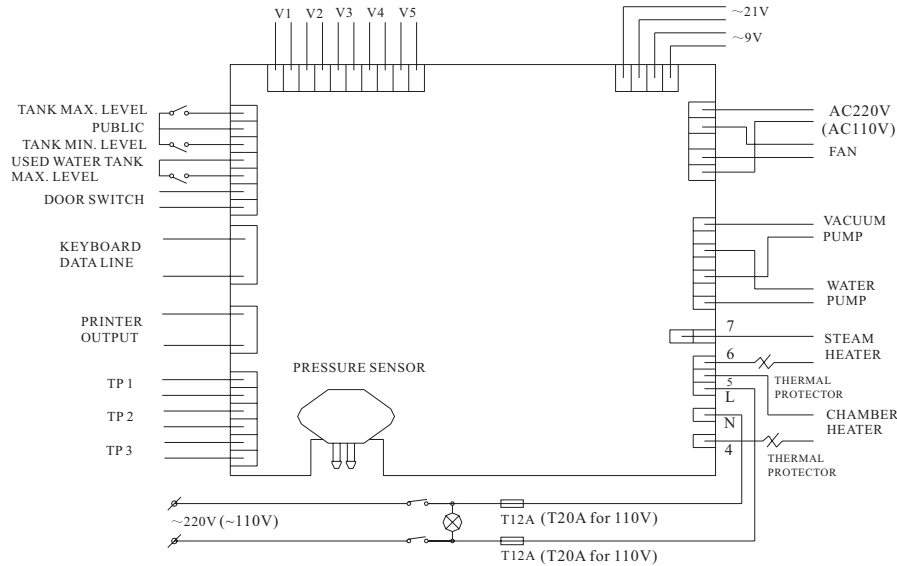
The max. temperature of the 121°C sterilization cycle is 123°C





## APPENDIX 3

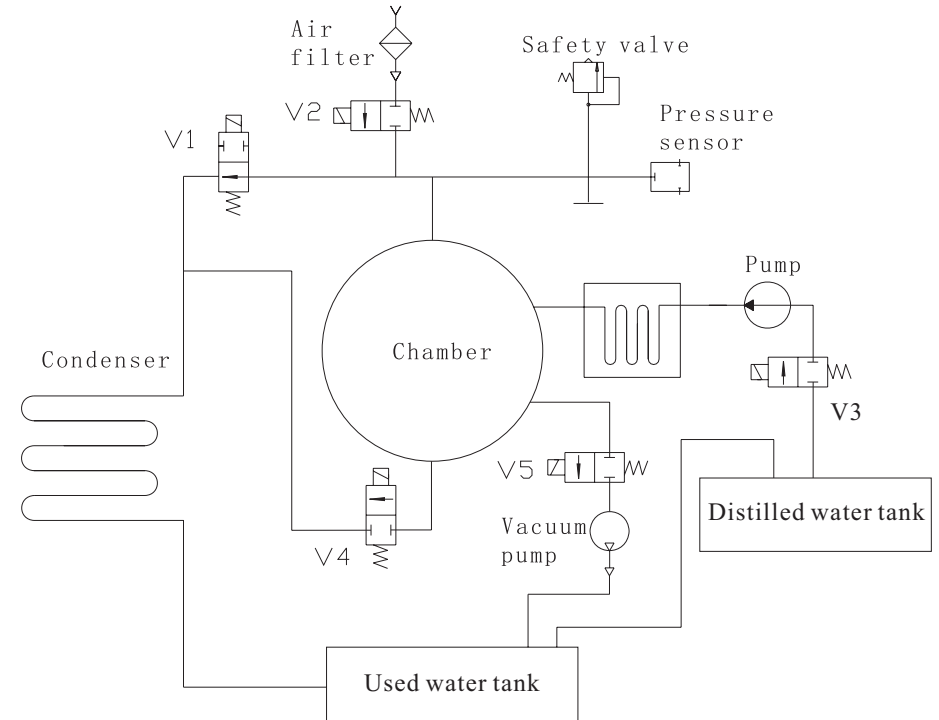
### ELECTRICAL DRAWING



- TP1: Steam generator temperature sensor
- TP2: Inner temperature sensor of chamber
- TP3: Temperature sensor of chamber wall
- V1: Air release valve
- V2: Air filter valve
- V3: Pump valve
- V4: Water release valve
- V5: Vacuum pump valve

## APPENDIX 4

### HYDRAULIC DRAWING



- V1: Air release valve
- V2: Air filter valve
- V3: Water pump valve
- V4: Water release valve
- V5: Vacuum pump valve