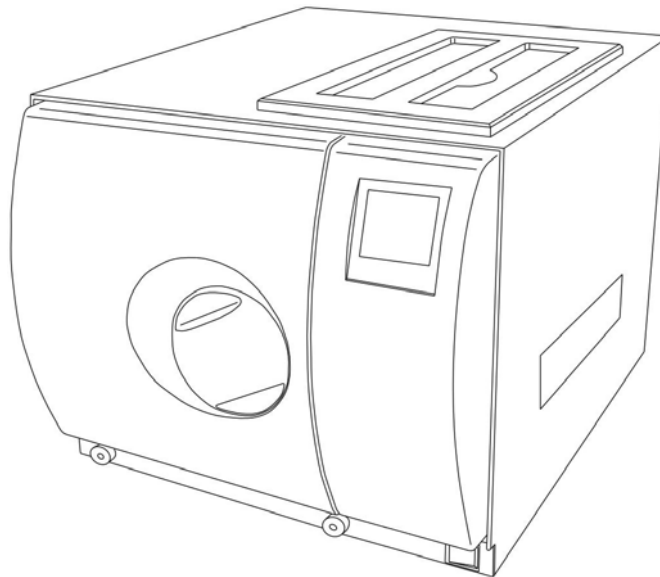


STEAM STERILIZER

Instruction manual

STE12L-C Class B



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FOREWORD

Thank you for purchasing this **STEAM STERILIZER**. It is manufactured to the highest standards using quality materials. Please follow all recommended maintenance, operational and safety instructions and you will receive years of troublefree service. This manual is an unseparated part of the device, Save this manual for future reference and keep in the vicinity of the product.

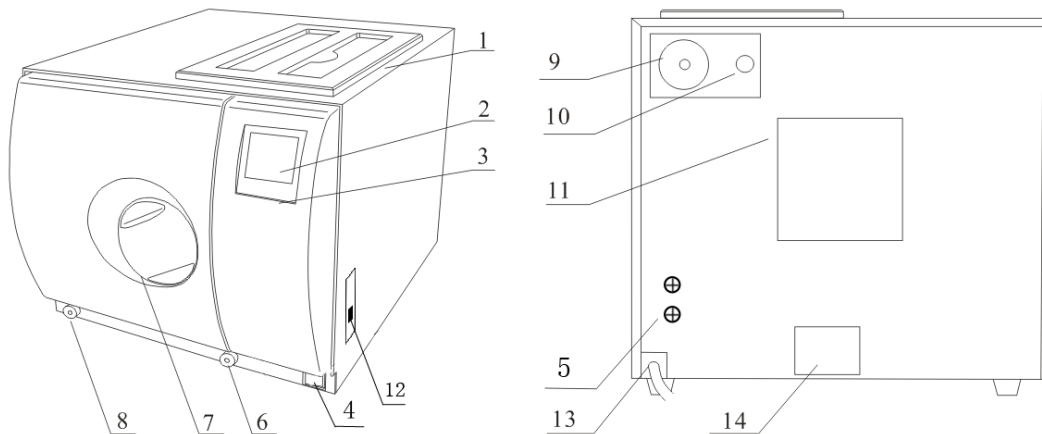
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1.GENERAL

This sterilizer described in this manual is intended for the sterilization of re-usable 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 EN13060.



1 Distilled water tank

2 LCD screen

3 Control panel

4 Main switch

5 Main fuses

6 Drain connector of distilled water tank

7 Door handle

8 Drain connector of used water tank

9 Air filter

10 Safety valve

11 Condenser ventilation

12 Printer port

13 Power supply cord

14 Rating plate

Security Notice:

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



Grounding protection

This symbol is grounding protection inside the machine.



Hot surface

This symbol is visible at the rear of the unit and on the front of the panel after opening 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

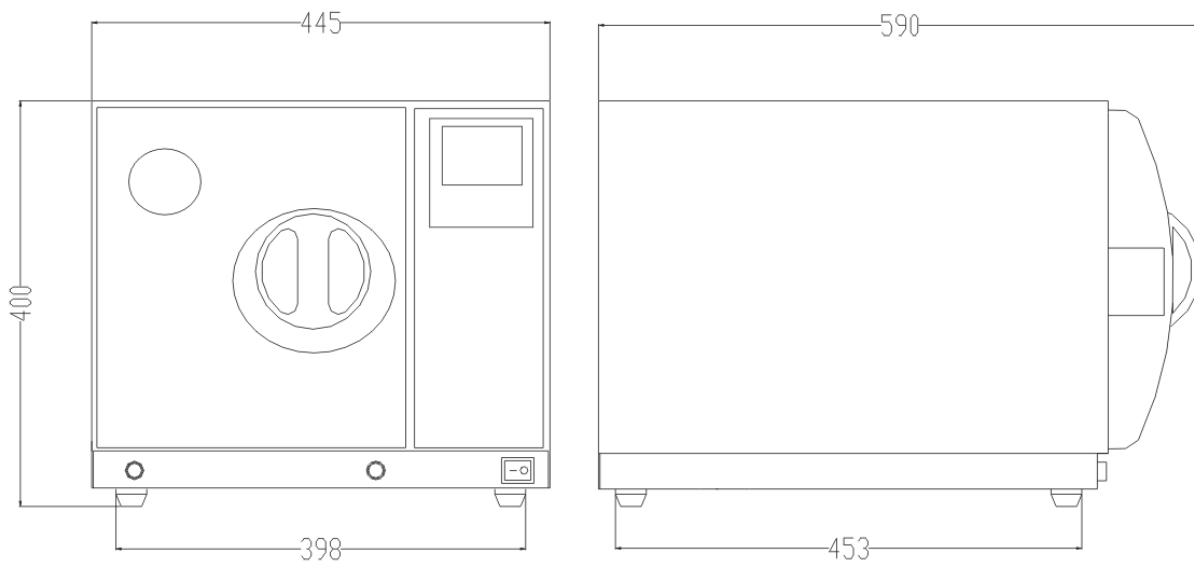
Item	STE12L-C Class B
Chamber volume	200mm x360mm
Rated Voltage	AC220V±22V(AC110V±11V),50±1HZ(60±1Hz)
Main Fuses	T12A/250V(T20A/250V for 110V)
Nominal Power	1750VA
Sterilization Temperature	121°C/134°C
Capacity of the distilled water tank	Approx 2.5L(water at level MAX)
	Approx 0.5L(water at level MIN)
Outside Dimensions	445mm(width)x440mm(height)x590mm(length)
Net Weight	45Kg
Noise	<70db
Relative Humidity	Max 80%, non condensing
Atmosphere pressure	76kPa-106kPa

3. Packing Content

NO.	Item	Quality
1	STE12L-C Class B Steam sterilizer	1
2	Instrument tray	2
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(for110V))}	2
9	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: 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.Operation

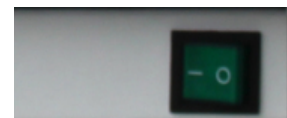
5.1 Filling the distilled water

5.1.1 *Open the door and take out all the instrument trays and other accessories inside, unpack and clean them.*

5.1.2 *Connect the power, and connect the printer (See 6.5)*

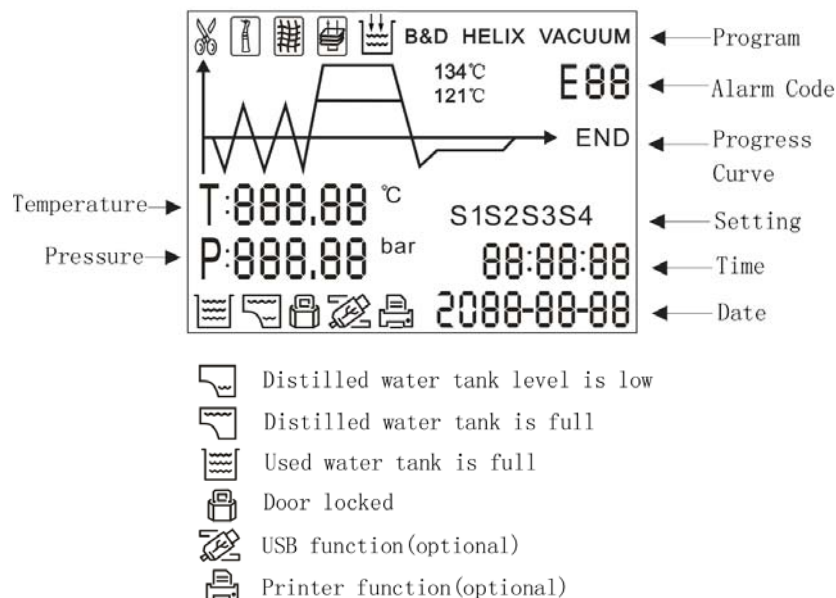
5.1.3 Switch on

Switch on the sterilizer through the mains switch mounted on the lower right side. At the switching on, the machine



turns on the LCD display. And it will show the door position, water level, working program, date, time and etc. .The machine will alert by beep sounds if there are problems.

Icon description:



Notice: *Before using the sterilizer at the first start-up or any time the signal blink, it is necessary to fill the distilled water tank with distilled water.*

5.1.4 Fill in 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.



5.2 Prepare the material to be sterilized

To get a 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.*

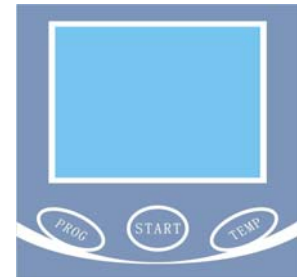


Always wrap the tools in case of prolonged store.

5.3 Selecting the sterilization program

5.3.1 LCD display

Displays the cycle temperature, pressure, error code, sterilization state and program.



5.3.2 TEMP button

Sterilization temperature select button.

5.3.3 PROGRAM button

Select sterilization procedure.

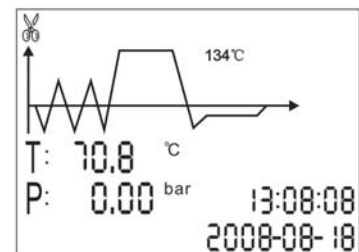
5.3.4 START button

Start a procedure ; hold on for 3 seconds to interrupt procedure.

5.3.5 SELECT a program

Press TEMP button to select sterilization temperature, then press PROGRAM button to select a sterilization procedure (refer to APPENDIX 2).

	SOLID
	WRAPPED
	TEXTILE
	PRION
	LIQUID
	B&D TEST
	HELIX TEST
	VACUUM TEST



Notice: There' er 10 seconds for self-test of control system with all of the

buttons locked at the starter when you turn on the sterilizer, not fault.

5.4 Running the sterilization program

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



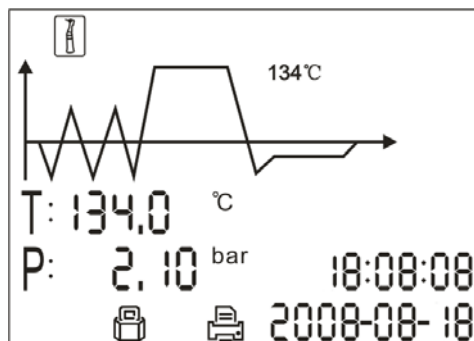
5.4.1 *After the instruments are loaded, you may close and lock the door by turning the door handle clockwise.*



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

5.4.2 Start the sterilization program.

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



← This is a total time of a cycle, but it will display countdown of holding time during holding time phase

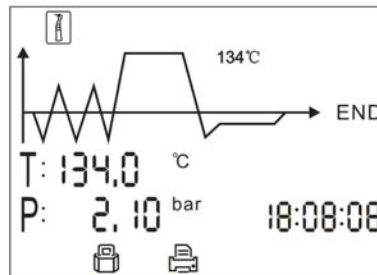
Caution:

When you press the "Start" button the door handle has not been turned to the maximum position, you will see the  blinks on the screen, It means you can not

start a cycle until you close the door completely and press the "Start" button again.


5.4.3 Sterilization cycle end



After a cycle completes, the printer will start work and print the report of the sterilization cycle data if you have install it. During the sterilization progress, alert beep would occur if temperature or pressure has any fault. After the pressure is 0, you may open the door, and take out the sterilized instruments.

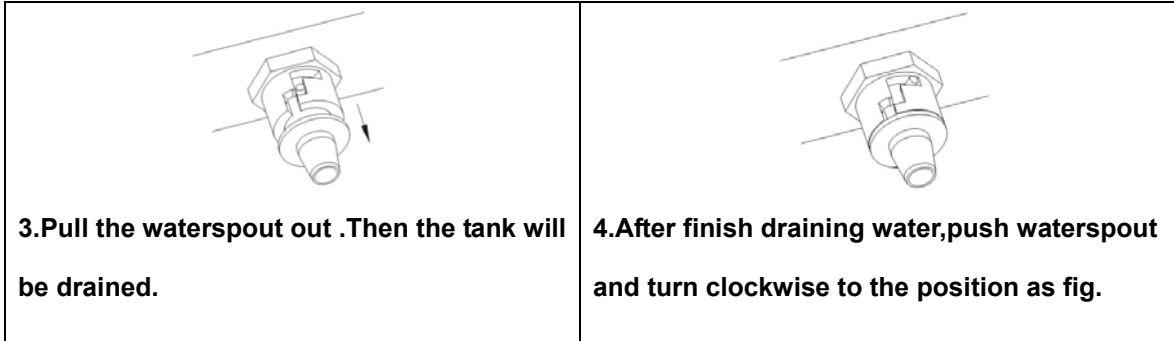


Please use the tray handle to load or unload the tray in order to avoid scald.

5.4.4 Drain

Whenever  blinks, it means the used water tank is full, you need to drain it immediately in the way as following described.

 <p>1. Push the hose to the waterspout of the connector.</p>	 <p>2. Turn the waterspout anticlockwise.</p>
--	--

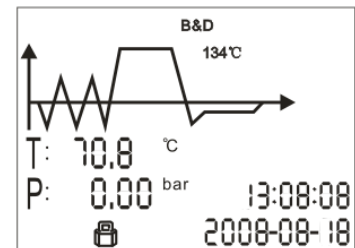


5.5 Test program

5.5.1 Press PROGRAM button, select B&D TEST program.

5.5.1.1 Put the Bowie-Dick pack into the chamber.

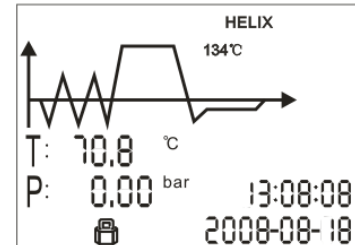
5.5.1.2 Then close the door and start it. After finish the cycle, check the indicator. And evaluate the result.



5.5.2 Press PROGRAM button, select HELIX TEST program.

5.5.2.1 Put the indicator paper in the capsule.

5.5.2.2 Put the Helix tube into the chamber. Then close the door.



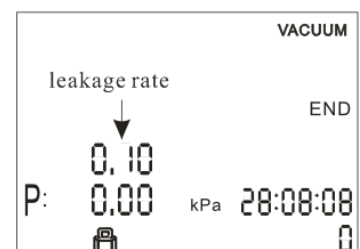
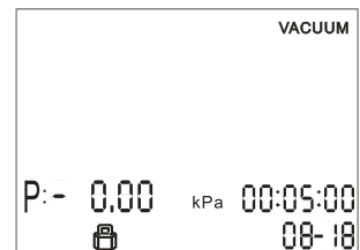
5.5.2.3 After finish the cycle, check the indicator and evaluate the result.

5.5.3 Press PROGRAM button, select CACUUM TEST program.

5.5.3.1 Then close the door and start program.

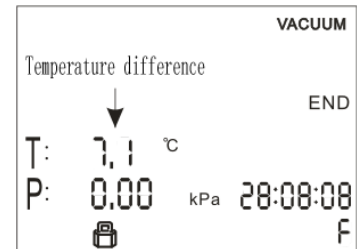
5.5.3.2 After finish the cycle it will show the result.

5.5.3.3 In compliance with EN 13060, the test requires the air leakage rate less than or equal 0.13kPa/min



during the 10 minutes. If the leak on the screen is not greater 0.13, it will show OK. Or it will show failure.

5.5.3.4 "Tp" is the temperature difference between the max. temperature and the min. temperature during the cycle. If it is greater 3°C it will show void. That means

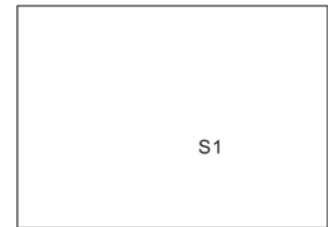


the result is void. You need run the test again after the chamber has cooled down.

6. Advanced Setting

6.1 Enter the setting menu

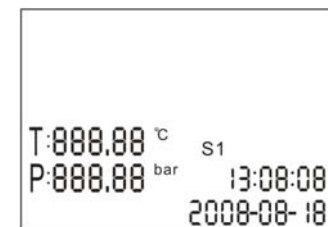
6.1.1 Hold START button and then turn on the main power switch. Keep holding for about 5 seconds, you will enter setting menu.



6.1.2 Press PROGRAM button, you can select to set S1, S2, S3, S4. The chosen option will blink. Press START button and enter the sub menu.

6.2 S1 setting

You can adjust units of pressure and temperature as you like, also of the date and time.



6.2.1 For example, you can adjust temperature unit as

following: Press PROGRAM button to switch setting option, when the temperature unit is blinking, press TEMP button, and it will change between F and °C. Press PROGRAM button again to switch to the next setting option.

6.2.2 The other option can be adjusted as the same way above.

6.2.3 After finish it, press START button to exit this menu, all of the data you have

adjusted are saved.

6.3 S2 setting(Reserved setting, no adjust it)

6.4 S3 setting

6.4.1 S3 is used to adjust sterilization holding time and drying time.

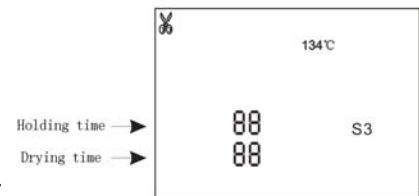
Press PROGRAM button to select intended parameters of sterilization

cycle.     

Press TEMP button to select sterilization temperature.

(121°C/134°C)

Press START button to enter sub-menu for adjustment.



6.4.2 In this menu, PROGRAM button is for option selecting, TEMP button is for number adjustment.

6.4.3 After finish it, press START button to save and exit back to upstream menu.

6.4.4 Holding time range: 1~60min.

Drying time range: 0~20min. (The drying time here refers to adjustable part of the whole drying time. Default time of device is 7 min. The real drying time is the total value of default and adjusted value here.)

Caution:

We don't suggest to change these parameters if not necessary.

6.5 S4--Altitude setting

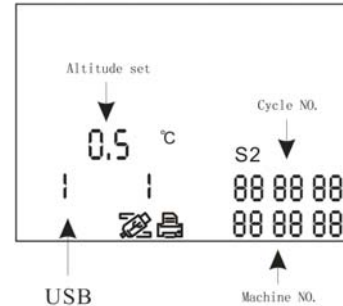
You need to adjust altitude parameter when use the device at a high altitude level.

Hold PROGRAM and TEMP button and then turn on the main power switch. Keep holding for about 5 seconds, you will enter S4 setting menu-Altitude setting. Press

TEMP button to adjust, press START button to confirm it.

Please set the parameter as following:

Altitude	Parameter	Altitude	Parameter
1.0>h>0.5 km,	0.5;	1.5>h>1.0 km,	1.0;
2.0>h>1.5 km,	1.5;	2.5>h>2.0 km,	2.0;
3.0>h>2.5 km,	2.5;	3.5>h>3.0 km,	3.0;
4.0>h>3.5 km,	3.5;	4.5>h>4.0 km,	4.0;



Note:

The standard atmospheric pressure is about 100kPa. And the pressure decrease 5kPa for each 0.5 kilometers of altitude increased.



If the parameter is set above 2, you need to reevaluate the sterilization result. And you may correct the effect by prolong the holding time.

6.3.3 Print and USB setting

'1' means it is effective, '0' means it is noneffective. The left number refers to USB, and the right one refers to print function.

6.3.4 Identification code

You shall not change the identification code of your device, it is used for maintenance trace.

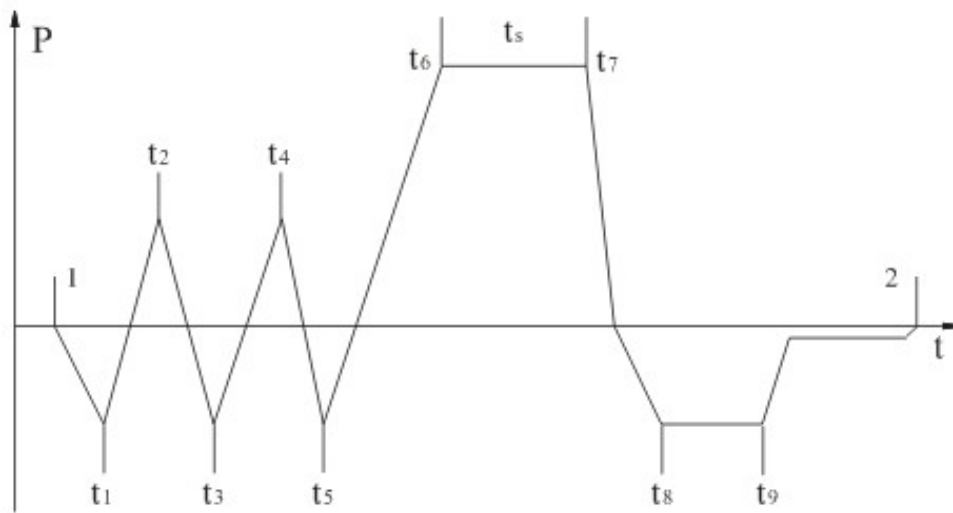
6.6 Printer(Optional)

6.6.1 Connect printer to the connector of device located on the right panel. When a

cycle is finished, it will print the sterilization report automatically.



The sample of content of print and files in memory is as below:



```

=====
Program: TEXTILE
Temperature: 134
Pressure: 210.0 kPa
Vacuum Num: 3
Dry Time: 10Min
Ster Time: 4.0Min
-----

```

```

-----
      time    temp.  pressure
Start 15:24:20 42.0°C
T1: 15:32:11 40.0°C -78.2kPa
T2: 15:36:08 105.3°C 52.7kPa
T3: 15:39:21 61.3°C -80.4kPa
T4: 15:44:32 110.3°C 51.6kPa
T5: 15:47:12 67.0°C -80.4kPa
T6: 16:00:11 135.2°C 220.3kPa
TS:          134.8°C 221.6kPa
MAX.Temperature:135.5°C
MIN.Temperature:134.1°C
MAX.Pressure:230.4kPa
MIN.Pressure:212.9kPa
T7: 16:04:02 135.0°C 223.5kPa
T8: 16:06:32 92.8°C -60.1kPa
T9: 16:09:22 90.4°C -60.1kPa
End 16:14:12 78.2°C
-----

```

```

-----
Cycle NO: 0005
Ster Value: Success
Date: 2009-02-18
S/N:E00001
Operator:
=====

```

```

=====
Program: Vacuum test
Tp: 1°C
P1: -70.0kPa
P2: -69.0kPa
rate of pressure rise: 0.10kPa
Start Time: 08:22
End Time: 09:01
Date: 2008-07-19
Test Value: Success
S/N: E00001
Operator:
=====

```

7. Maintenance

Frequency	Operation
Daily	Cleaning the door seal
	Cleaning the external surface
Weekly	Cleaning the reservoir
	Cleaning the chamber
3~6 months	Replace the air filter
Every year	Replace the door seal

7.1 Clean the distilled water tank every week with medical disinfectant .



7.2 Clean the chamber weekly.

7.2.1 Remove the trays and rock from the chamber.

7.2.2 Clean the chamber with non-plush cloth saturated with distilled water.

7.2.3 Apply the same procedure for the trays and rock.



7.3 Cleaning the door seal

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



7.4 Replace the air filter

Air filter is at the back of the device, remove it by turning it anti-clockwise and install a new one instead.



7.5 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.

7.5.1 *Open the door firstly.*

7.5.2 *Insert the spanner into 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.*

7.5.3 *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.*

Caution:

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

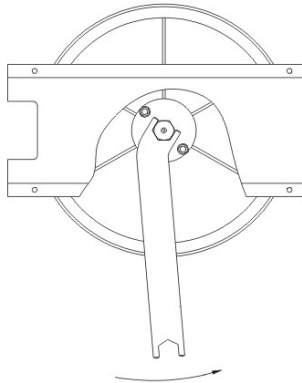


Fig 1



Fig 2

7.6 Replacement of the door seal

7.6.1 Fully open the door.

7.6.2 Remove the door seal ring carefully by hand.

7.6.3 Clean the door seal ring carefully with a non-plush cloth saturated with distilled water.





7.6.4 Moisten the new seal ring with medical disinfectant.

7.6.5 Insert the new seal ring and press in sequence as the following.







Caution: Please ensure the chamber and the door has been cool down before you replace the seal ring in order to avoid scalding.



 <p>1). Press the up and down of the seal ring.</p>	 <p>2). Press the left and right of the seal ring.</p>
 <p>3). Press the left place of the seal ring cornerways.</p>	 <p>4). Press the seal surface and make it feel smooth by finger.</p>

7.7 Replace fuse

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

8 Transportation and Storage

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

8.2 Drain the distilled water tank and the used water tank.

8.3 Conditions for transportation and storage:

Temperature: -20 °C ~ +55°C

Relative humidity: ≤85%

Atmospheric pressure: 50kPa~106kPa

9 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
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.
E10	Door closed failure	Check the microswitch
E13	Vacuum failed	Check the vacuum pump



E20	Program manually interrupted	Shut off the power and restart the power
------------	------------------------------	--

10 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.

(7) Door safety lock

Protection against accidental opening of the door.

Action: Impediment of the accidental opening of the door during the program.

(8) Self-leveling hydraulic system

Hydraulic system for the natural pressure leveling 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 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 $\mu\text{s/cm}$	≤3 $\mu\text{s/cm}$
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

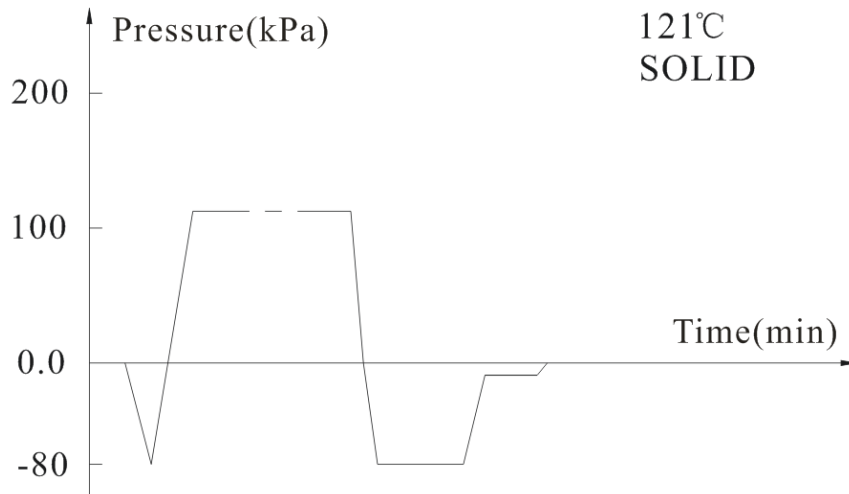
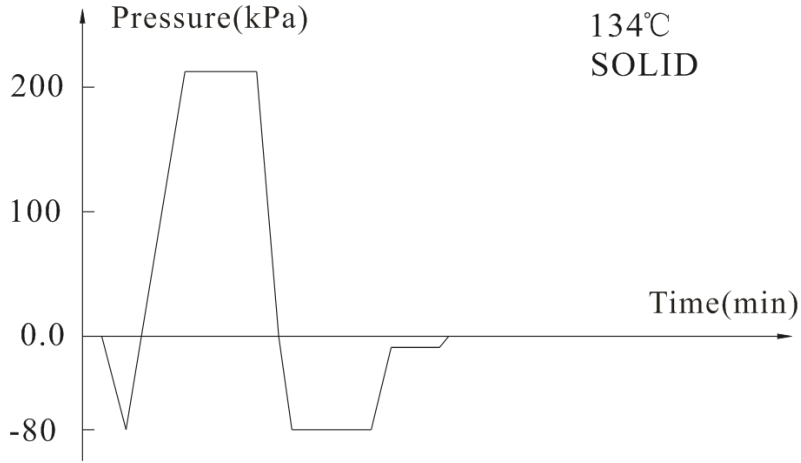
DIAGRAMS OF THE STERILIZATION PROGRAMMES

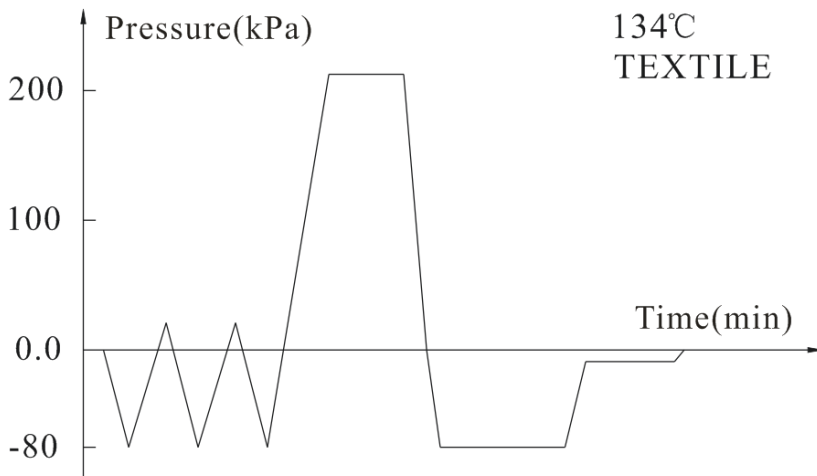
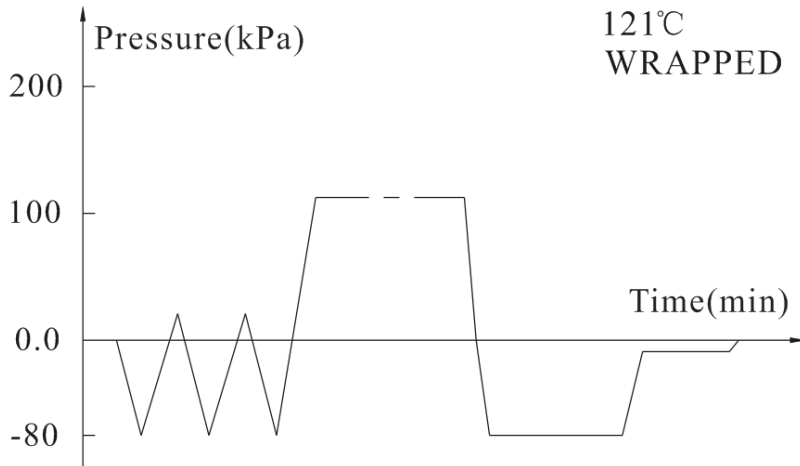
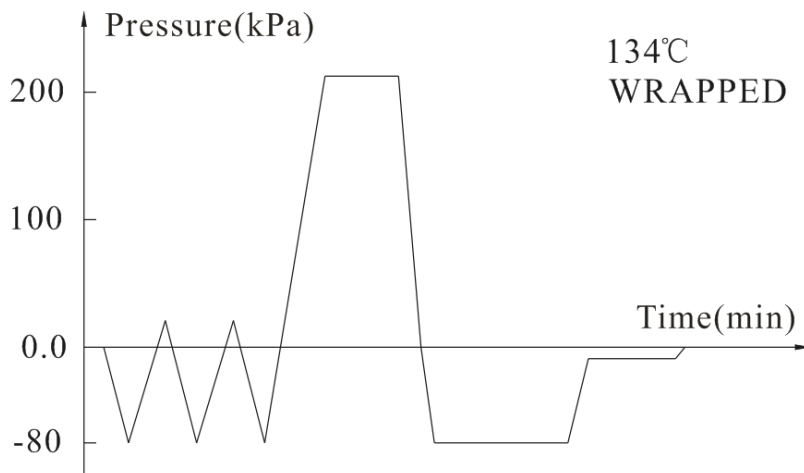
Program	Temperature (°C)	Pressure (bar)	Holding time(min.)	Total time (min.)	Type	Max.load total(Kg)	Max.load per tray(Kg)
SOLID	134	2.10	4	15~20	Unwrapped solid material	4.5	1.25
	121	1.10	20	30~45		4.5	1.25
WRAPPEN	134	2.1	4	30~40	Unwrapped hollow material	3.0	1
	121	1.0	20	35~50	Single-wrapped solid material	3.0	1
TEXTILE	134	2.1	4	35~45	Unwrapped porous material	1.2	0.4
					Single-wrapped porous material	0.9	0.3
					Dual-wrapped porous material	0.75	0.25
	121	1.1	20	40~55	Single-wrapped hollow material	4.5	1.25
					Dual-wrapped solid and hollow material	1.5	0.6
PRION	134	2.1	18	45~60	Unwrapped porous material	1.2	0.4
					Single-wrapped porous material	0.9	0.3
					Dual-wrapped porous material	0.75	0.25
					Single-wrapped hollow material	4.5	1.25
					Dual-wrapped solid and hollow material	1.5	0.6
LIQUID	134	2.1	8	45~65	Wrapped liquid	1.5	-
	121	1.1	30	50~75	Wrapped liquid	1	-
B&D Test	134	2.1	3.5	22~35	-	-	
HELIX Test	134	2.1	3.5	22~35	-	-	
Vacuum Test	-	-	-	15~20	-	-	

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

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

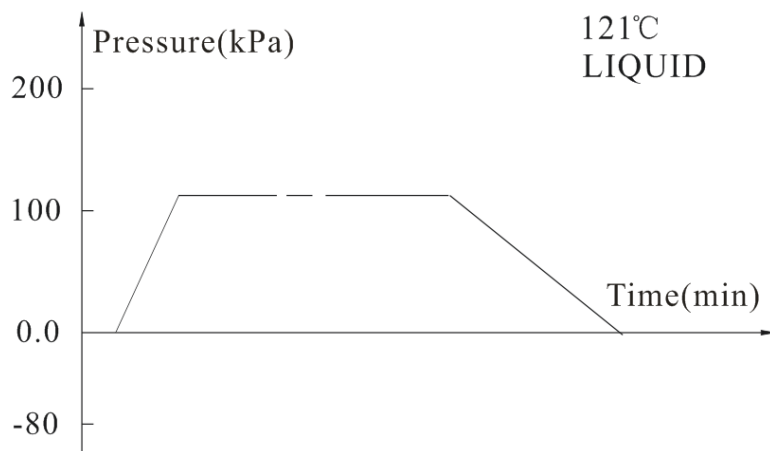
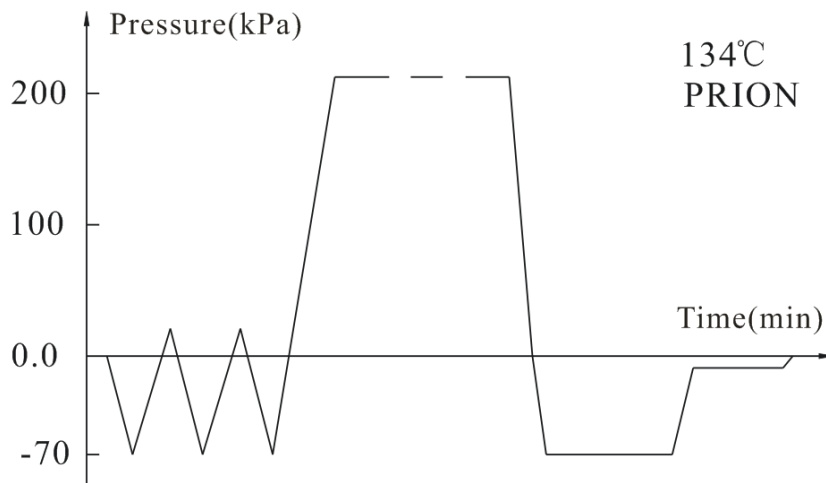
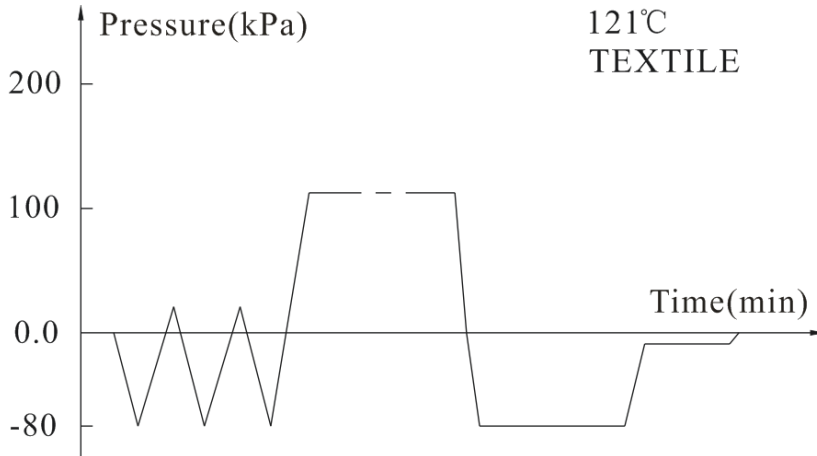
APPENDIX 3 PROGRAM RUNNING DIAGRAM





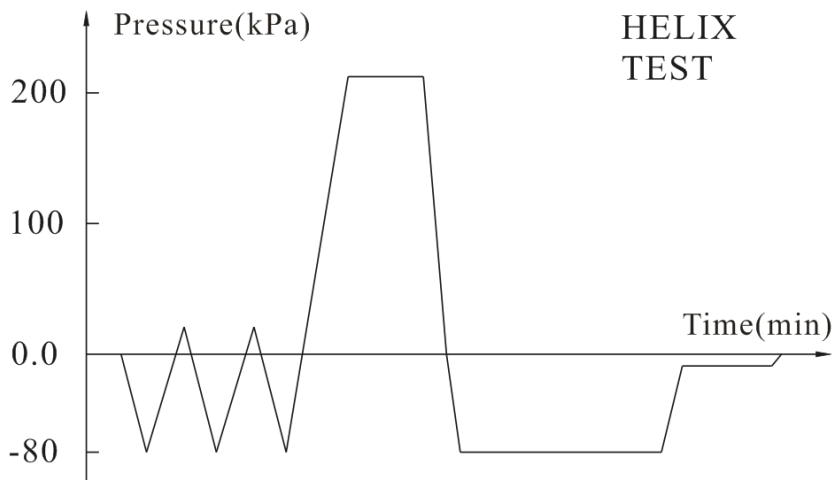
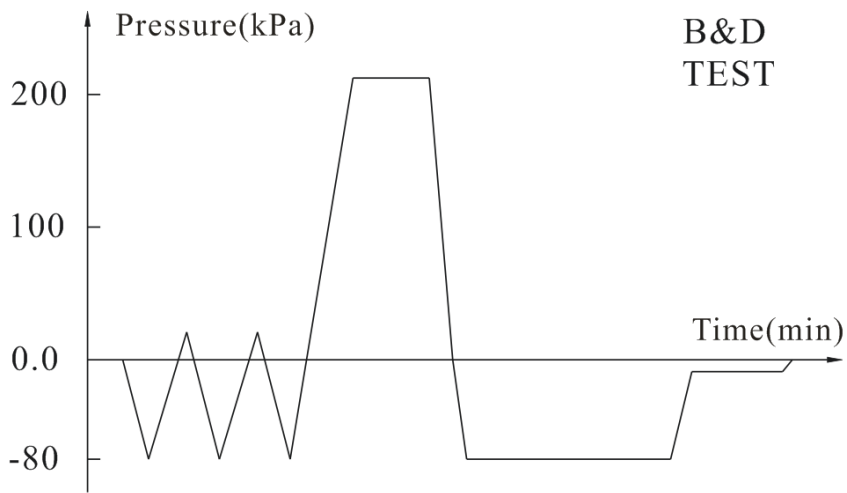
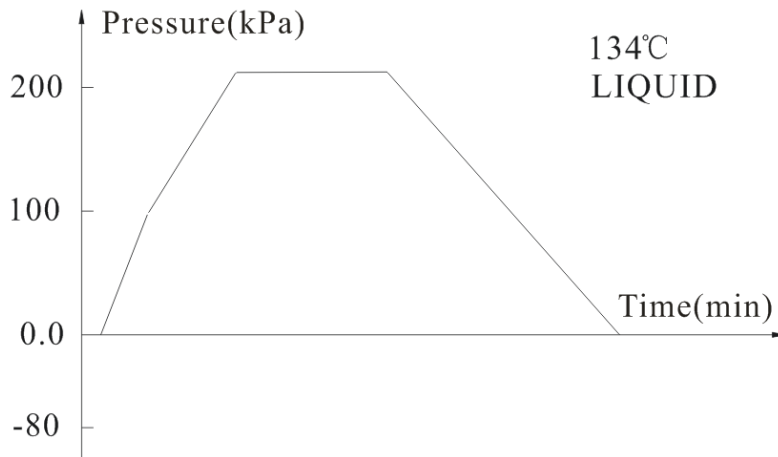


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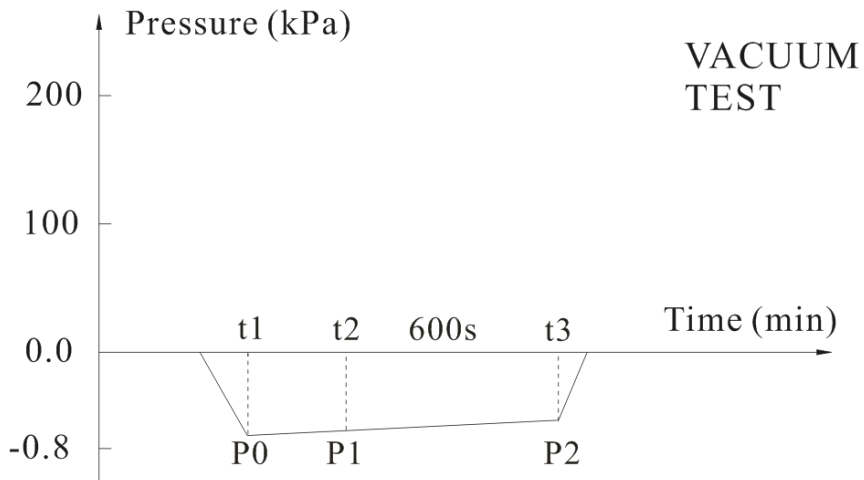


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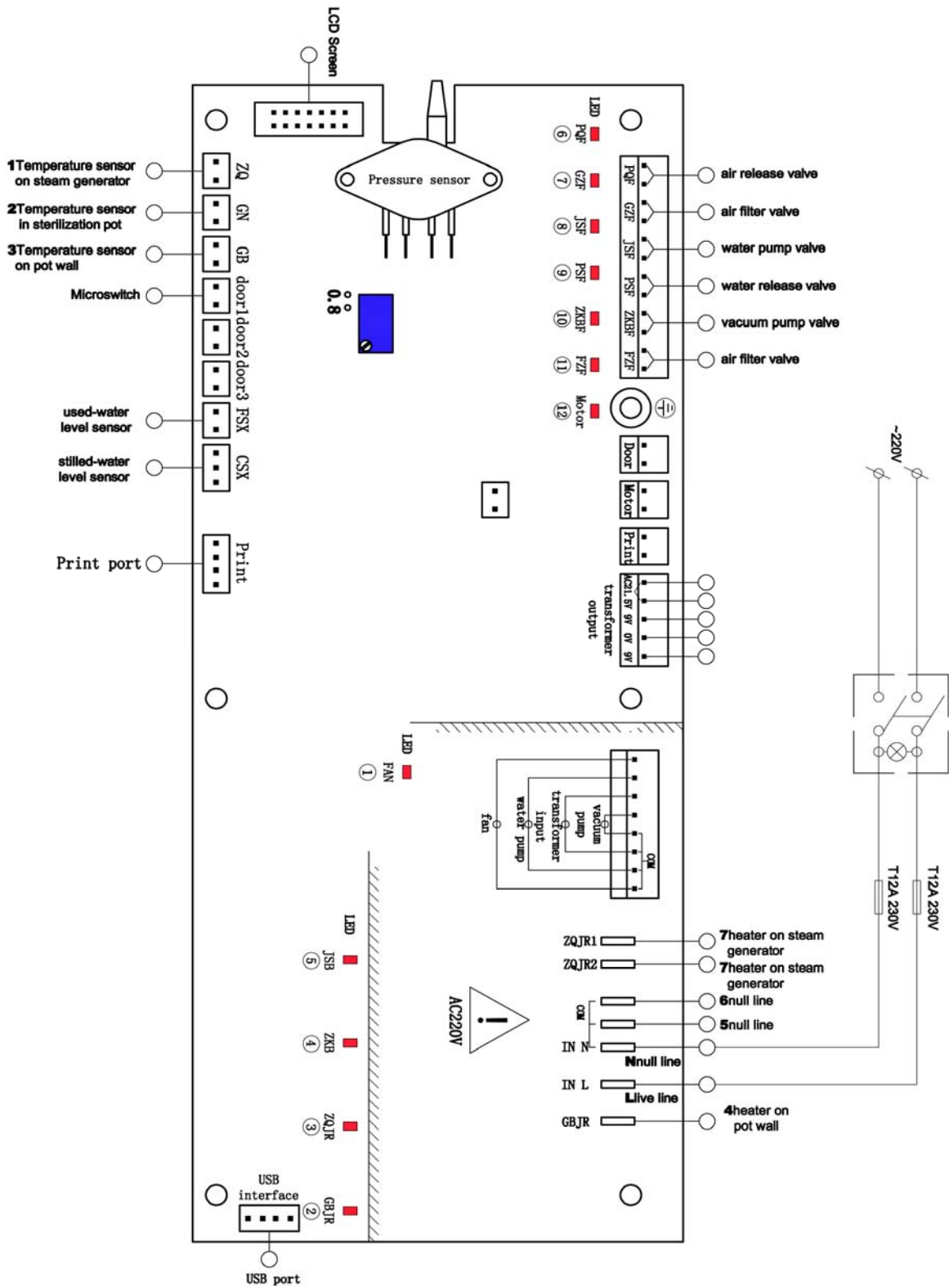




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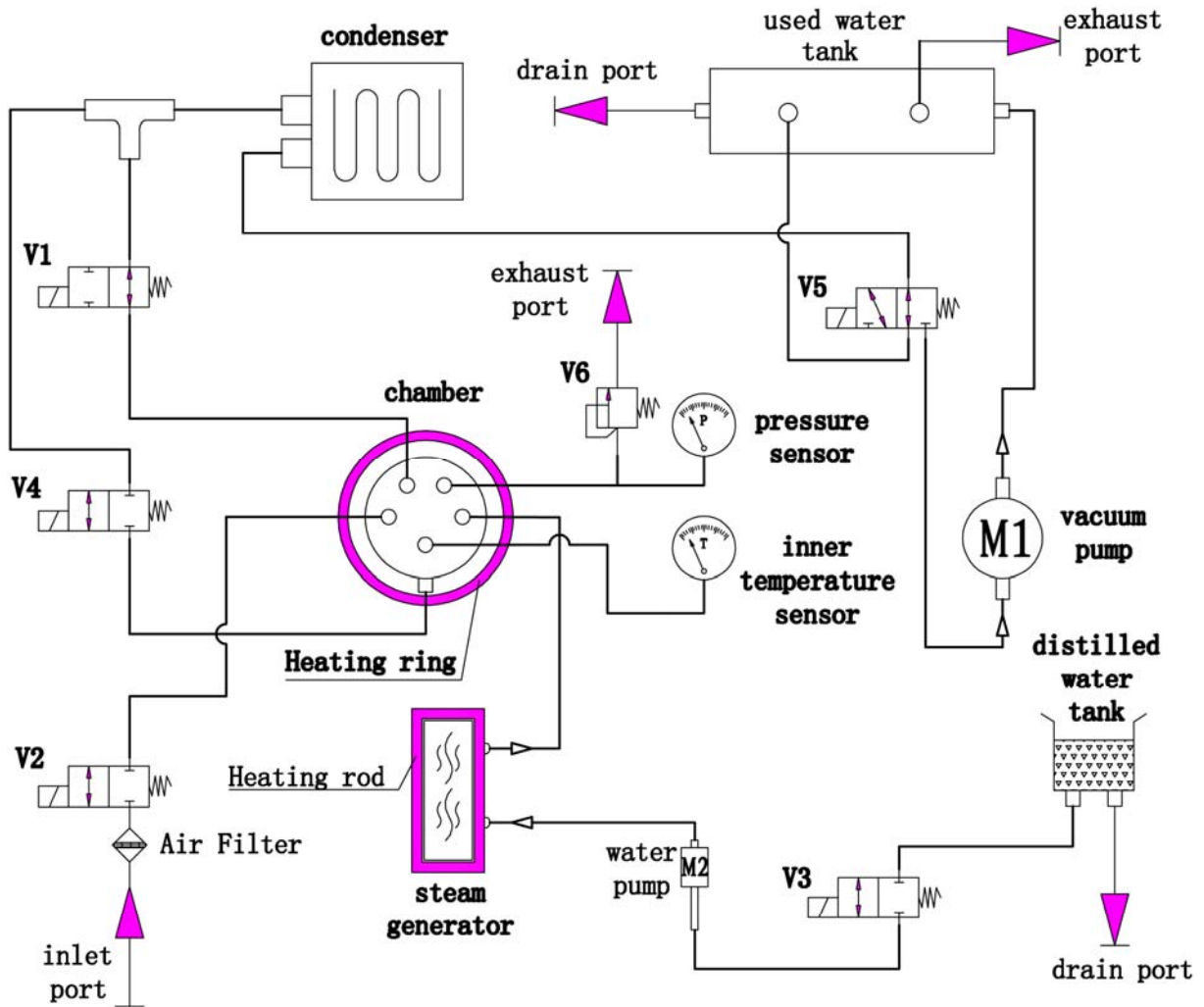


APPENDIX 4 ELECTRICAL DRAWING



APPENDIX 5

HYDRAULIC DRAWING



NOTICE: V1 is a normally open valve, V5 is a two position three ways valve, the rest are normally closed.

V1: Air release valve	V2: Air filter valve
V3: Water pump valve	V4: Water release valve
V5: Vacuum pump valve	V6: Safety valve