STEAM STERILIZER

Instructions Manual

(18/23 D)

EU B Class

AISON INTERNATIONAL

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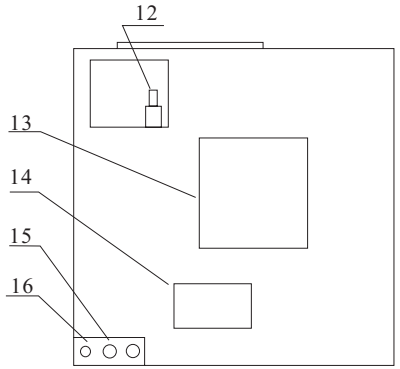
1 General

This sterilizer described in this manual is intended for the sterilization of re-useable surgical instruments and material.

It operates automatically with 134℃ and 121℃ sterilization temperatures.

It has been produced in accordance with the EN 13060.

1 Distilled water tank
2 LCD screen
3 Control panel
4 Bacteriological filter
5 Main switch
6 USB port
7 Drain connector of distilled water tank
8 Drain connector of used water tank



9 Print port
10 Door handle
11 Door
12 Safety valve
13 Condenser ventilation
14 Rating plate
15 Main fuses
16 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	18L	23L
Chamber	Φ247mmX350mm	Φ247mmX450mm
Rated Voltage	AC220V-240V(AC110V), 50-60Hz	
Main Fuses	T12A/250V(T20A/250V for 110V)	
Nominal power	1800VA	2000VA
Sterilization Temperature	121℃/134℃	
Capacity of the distilled water tank	Approx 2.5L (water at level MAX)	
	Approx 0.5L (water at level MIN)	
Operation temperature	5 - 40℃	
Net weight	47kg	51kg
Noise	<70dB	
Relative Humidity	max 80%, non condensing	
Atmospheric pressure	76kPa -106kPa	
Size	590x480x465 mm	690x480x465 mm

3 Packing Content

No	Item	Quantity
1	18L/23L 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

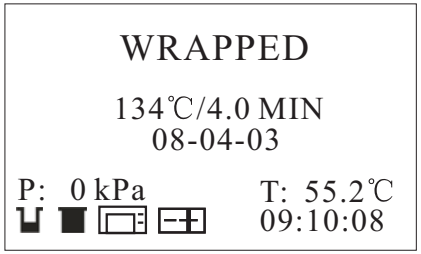
* There must leaves 10cm gap around sterilizer, and 20cm on top side. the clearance required for the movement of the door： leave an at least 450mm fan-shaped space in front of the door.
* The place which sterilizer located must be ventilated, make sure that the radiator not being jammed.
* The sterilizer 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 tray 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 inside the cover. After 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. After the test the following massage will be shown:

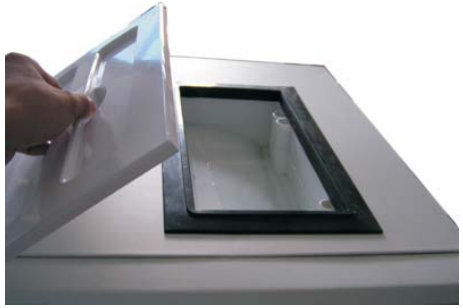


- Distilled water tank is lacking of water.
- Used water tank is full.
- Printer is disconnected if it is blinking.
- Door closed
- Door locked

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.
The light of screen will be closed if you haven't touch the button for a long time. You may lighten the screen by touch any button if you need.

5.1.4 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. The ■ will blink. Please stop filling immediately.



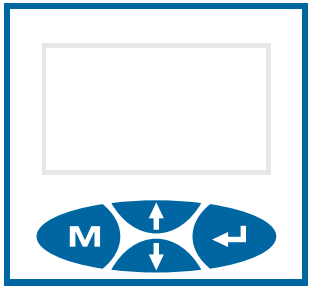
5.2 Prepare the material to be sterilized

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.



5.3 Selecting the sterilization program

5.3.1 LCD

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

5.3.2 Ⓜ MENU button

Select item and save adjustment.

5.3.3 ⇧ UP button

Select up button to select program or adjust and setup the parameter. Or open the door.

5.3.4 ⇩ DOWN button

Select up button to select program or adjust and setup the parameter. Or close the door.

5.3.5 ⏎ START button

Press this button to start the sterilization cycle, holding this button above 3 seconds to stop the cycle.

5.3.6 Select the program

Press Ⓜ button, enter the menu. then select the "Programs", you will see the available sterilization programs:

Programs Test Select Basic Set	SOLID (121℃) SOLID (134℃) WRAPPED(121℃) WRAPPED(134℃)

Select the program by ⇧ ⇩ button and confirm it by press Ⓜ button.
If you don't want to select a program you may press ⏎ to exit.

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 the door.

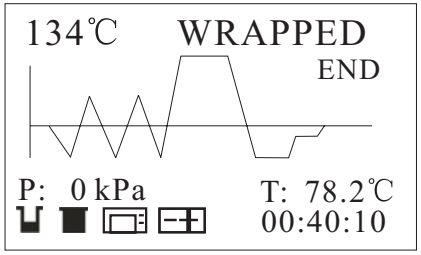
5.4.2 Start the sterilization program.

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

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

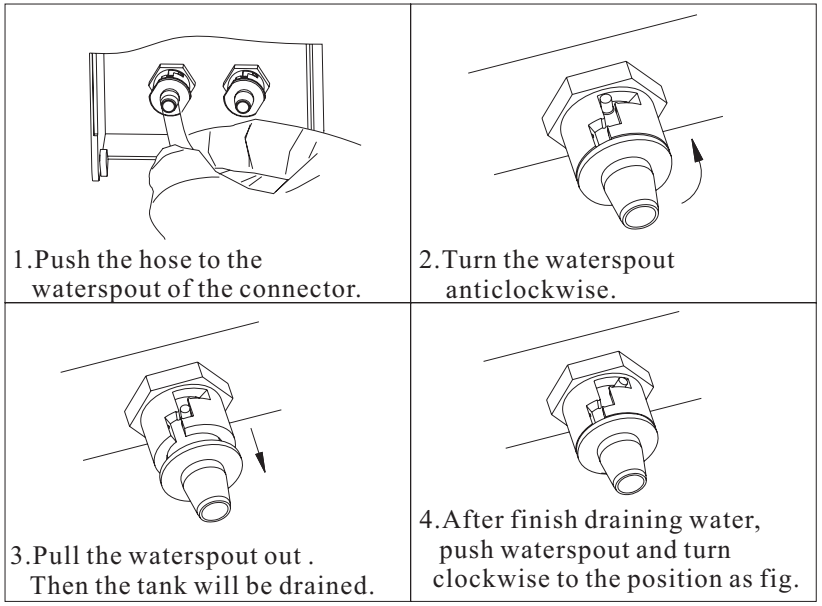
5.4.3 Sterilization cycle end

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



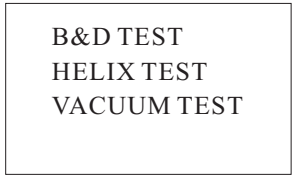
Always use the tray handle to load or unload the tray in order to avoid scald.

The drain connector



5.5 Test programs

5.5.1 Press M button , enter the menu.
And then select the "Test Select",you will see the test menu.

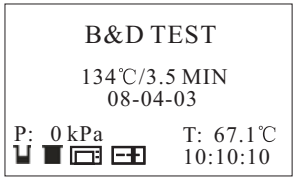


5.5.2 Select the "B&D TEST".

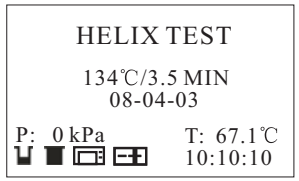
5.5.2.1 Put the Bowie-Dick pack into the chamber. Then close the door and press ⏎ .

5.5.2.2 After finish the cycle you check the indicator. And evaluate the result.

5.5.2.3 Open the door it will return to the initial interface.

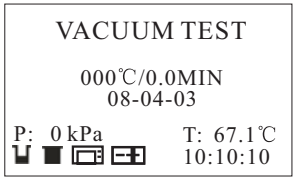


5.5.3 Select the "HELIX TEST"

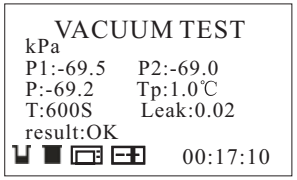


5.5.3.1 Put the indicator paper in the capsule.
5.5.3.2 Put the Helix tube into the chamber. Then close the door .
5.5.3.3 After finish the cycle you check the indicator. And evaluate the result.
5.5.3.4 Open the door it will return to the initial interface.

5.5.4 Select the "VACUUM TEST"



5.5.4.1 Then close the door and start program.

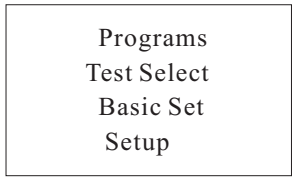


5.5.4.2 After finish the cycle it will show the result.
5.5.4.3 In compliance with EN 13060, the test requires the air leakage rate less than or equal 0.13kPa/min during the 10 minutes. If the leak on the screen is not greater 0.13,it will show OK. Or it will show failure.
5.5.4.5 "Tp" is the temperature difference between the max. temperature and the min. temperature during the cycle. If it is greater 3℃ it will show void. That means the result is void. You need run the test again after the chamber has cooled down.
5.5.4.6 Open the door it will return to the initial interface.

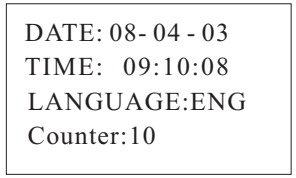
Caution: The test must be carried out with unit cold.
If the Tp is greater 3℃, it will show void.

6 Advanced Setting

6.1 Press M button, enter the menu.

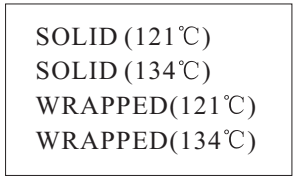


And then select the "Basic Set",you will see the set menu.
6.1.1 Select the item by press the M button.
6.1.2 Adjust the parameter by press the ⇧ ⇩ button.
6.1.3 If you want to finish the adjustment and save what you done, you may press M button until it return to the above menu.

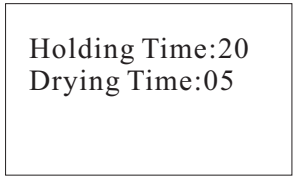


6.1.4 The "Counter" is the count of cycle. It can not be changed.
6.1.5 The ⏎ button is for cancel and exit.

6.2 Select the "Setup" to adjust the parameter of sterilization program.

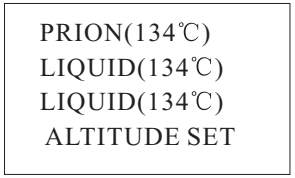


6.2.1 Press ⇧ ⇩ button to select a program. Press the M button to enter the menu.
6.2.2 Select the item by press the M .
6.2.3 Adjust the parameter by press the ⇧ ⇩ button.



6.2.4 Holding time is 1-60.
Drying time is N-1-20. It is not the total drying time, there is base time before the setting time. The data N means there is no vacuum drying.
Press ⏎ button to cancel and exit.
6.2.5 After you finish adjusting the parameter you may press M button to save the parameter and return the above menu.

6.3 Select the "Altitude set" to adjust the parameter.



If you can't enter the holding time and use this machine at a high altitude place is above 2 kilometres.
6.3.1 Press ⇧ ⇩ button to select "Altitude set" and press M button to enter the setting screen.

6.3.2 Adjust the parameter by press ⇧ ⇩ button. Press Ⓜ button to save.
6.3.3 The value is 0~2.

Offset:1.0

Note: The standard atmospheric pressure is about 100kPa. And the pressuredecrease 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.

Notice: We don't suggest the operator to adjust the parameter if it is not necessary.

6.4 Select the "Info. output" to print the cycle information

It can store 20 records in the memory. The new record will overwrite the oldest one.

6.4.1 Press ⇧ ⇩ button to select "Info. Output" and press Ⓜ button to enter the display.

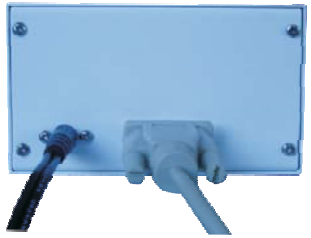
Basic Set
Setup
Altitude set
Info. output

6.4.2 Choose one record(the cycle no.) . Press Ⓜ button, the printer will print the information.

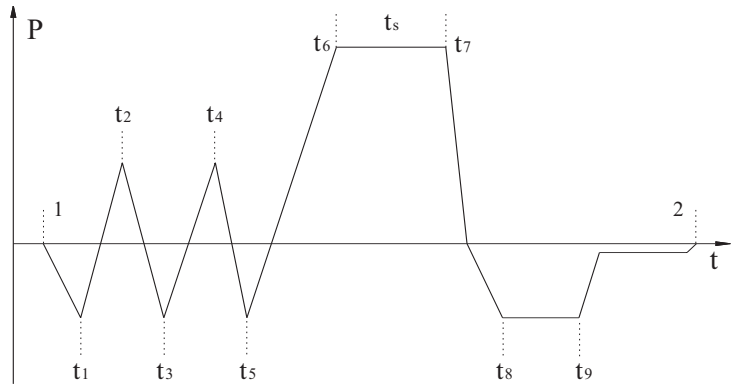
00010
00011
00012
00009

6.5 Pinter (Optional)

6.5.1 Connect the printer cable to socket at the back of the sterilizer.
6.5.2 Connect the printer power.



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



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

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	time	temp.	pressure
Start	15:24:20	42.0℃	
T1:	15:32:11	40.0℃	-78.2kPa
T2:	15:36:08	105.3℃	52.7kPa
T3:	15:39:21	61.3℃	-80.4kPa
T4:	15:44:32	110.3℃	51.6kPa
T5:	15:47:12	67.0℃	-80.4kPa
T6:	16:00:11	135.2℃	220.3kPa
TS:		134.8℃	221.6kPa

MAX.Temperature:135.5℃
MIN.Temperature:134.1℃
MAX.Pressure:230.4kPa
MIN.Pressure:212.9kPa

T7:	16:04:02	135.0℃	223.5kPa
T8:	16:06:32	92.8℃	-60.1kPa
T9:	16:09:22	90.4℃	-60.1kPa
End	16:14:12	78.2℃	

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

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Program：Vacuum test
Tp：1℃
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：

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6.5 USB Flash memory (Optional)

If you want to store the information of program cycle in flash memory you need to insert the flash in the usb socket before the program end.
The information will be stored into files.
The name of file is according to the Number of machine and the cycle number.

8 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

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

8.2 Clean the chamber weekly.

8.2.1 Remove the trays and rock from the chamber.
8.2.2 Clean the chamber with non-plush cloth saturated with distilled water.
8.2.3 Apply the same procedure for the trays and rock.

8.3 Replacement of the bacteriological filter

8.3.1 The bacteriological filter is at the back of the sterilizer.
8.3.2 Unscrew the filter by hand (anti-clockwise).
8.3.3 Replacing the bacteriological filter.
8.3.4 Screw the new filter by hand clockwise.

8.4 Cleaning the door seal

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

8.5 Replacement of the door seal

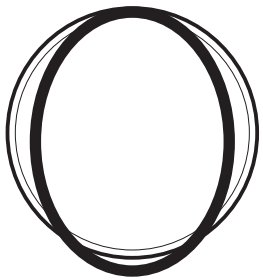
8.5.1 Fully open the door.

8.5.2 Remove the door seal ring carefully by hand.

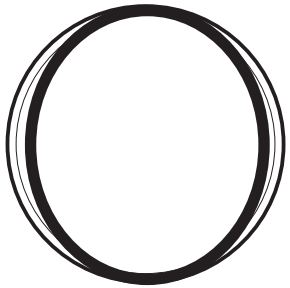
8.5.3 Clean the door seal ring carefully with a non-plush cloth saturated with distilled water.

8.5.4 Moisten the new seal ring with medical disinfectant .

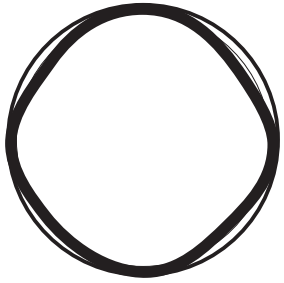
8.6.5 Insert the new seal ring and press in sequence as the following.



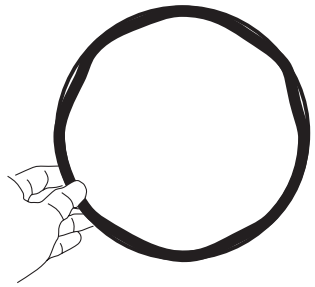
1). Press the up and down of the seal ring.



2). Press the left and right of the seal ring.



3). Press the left place of the seal ring cornerways.



4). Press the seal surface and make it feel smooth by finger.

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

8.6 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.

9 Transportation and Storage

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

9.2 Drain the distilled water tank and the used water tank

9.3 Conditions for transportation and storage:

Temperature: -20 ℃ ~ +55℃

Relative humidity: ≤85%

Atmospheric pressure: 50kPa~106kPa

10 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	Failure to lock or loose the door	Check the switch and motor
E13	vacuum failed	Check the vacuum pump
E20	Program manually interrupted	Shut off the power and restart the power

11 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 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

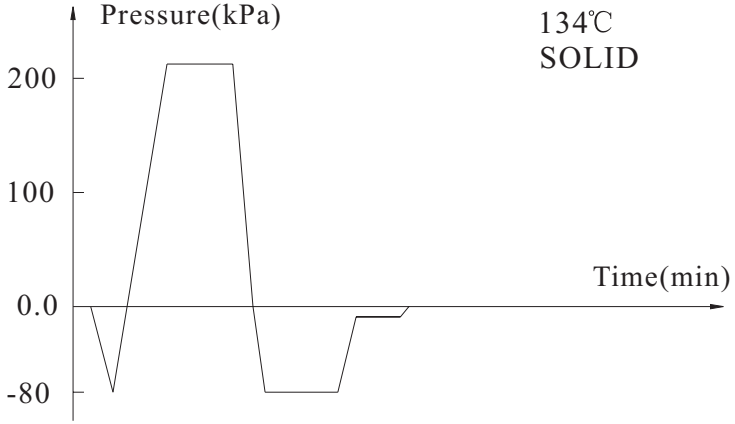
DESCRIPTION	FEED WATER	CONDENSATE
Evaporate residue	≤10 mg/l	≤1.0 mg/kg
Silicium oxide sio_2	≤1 mg/l	≤0.1 mg/kg
Iron	≤0.2 mg/l	≤0.1 mg/kg
Cadmium	≤0.005 mg/l	≤0.05 mg/kg
Lead	≤0.05 mg/l	≤0.1 mg/kg
Rest of heavy metals, excluding iron, cadmium, lead	≤0.1 mg/l	≤0.1 mg/kg
Chloride	≤2 mg/l	≤0.1 mg/l
Phosphates	≤0.5 mg/l	≤0.1 mg/l
Conductivity (at 20℃)	≤15 μ s/cm	≤3 μ 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

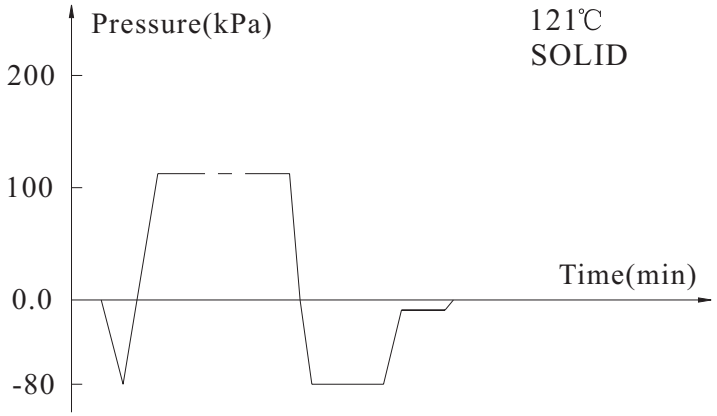
APPENDIX 2

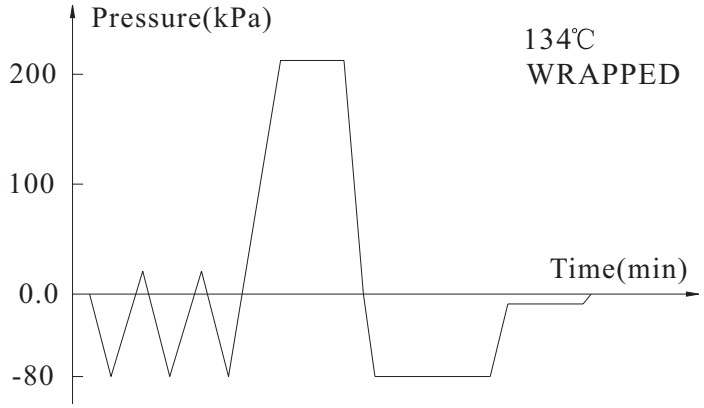
DIAGRAMS OF THE STERILIZATION PROGRAMMES

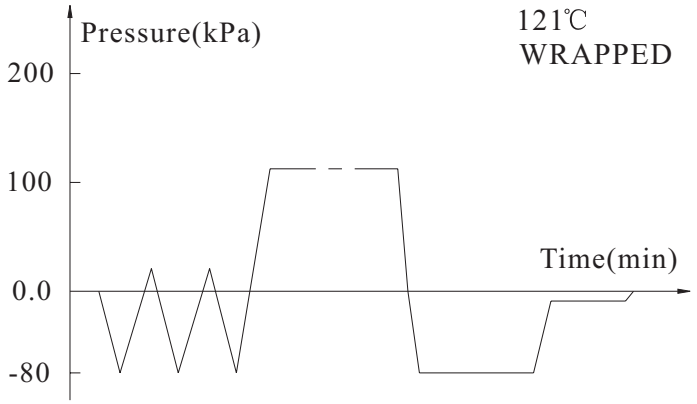
PROGRAM	Temperature (℃)	Pressure (kPa)	Holding time (min)	Total time (min)	TYPE	MAXLOAD (kg)
SOLID	134	210	4	18~40	Unwrapped solid material	5.00
	121	110	20	30~50		5.00
LIQUID	134	210	6	30~55	Liquid	5.00
	121	110	30	35~60	Liquid	4.00
TEXTILE	134	210	4	45~65	Unwrapped porous material	1.25
					Single-wrapped porous material	1.00
					Dual-wrapped porous material	0.75
	121	110	20	50~75	Single-wrapped Hollow material	4.00
					Dual-wrapped solid and hollow material	2.00
PRION	134	210	18	45~70	Unwrapped porous material	1.25
					Single-wrapped porous material	1.00
					Dual-wrapped porous material	0.75
					Single-wrapped Hollow material	4.00
					Dual-wrapped solid and hollow material	2.00
B&D TEST	134	210	3.5	22~35	—	—
HELIX TEST	134	210	3.5	22~35	—	—
VACUUM TEST	—	—	—	15~20	—	—

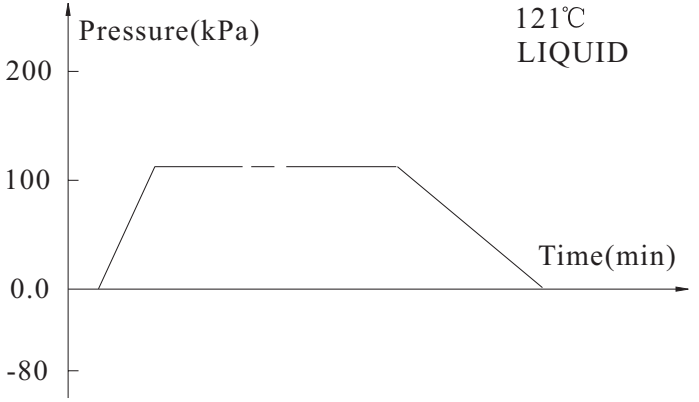
The time required for sterilizer to be ready for routine use after the power is switched on less than 5 minutes.
The max. temperature of the 134℃ sterilization cycle is 137℃
The max. temperature of the 121℃ sterilization cycle is 124℃

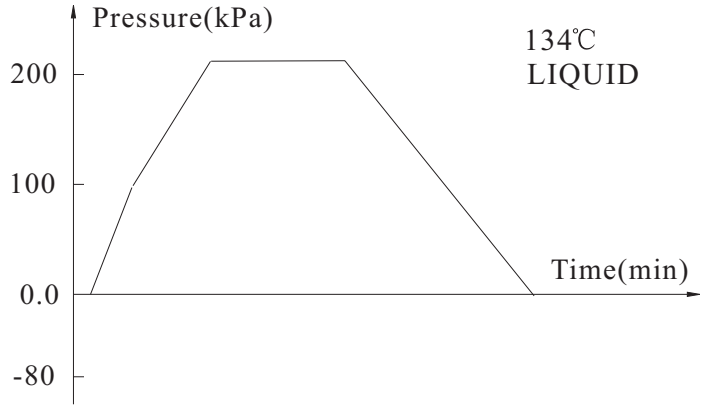

Pressure(kPa)
134℃
SOLID
200
100
0.0
-80
Time(min)

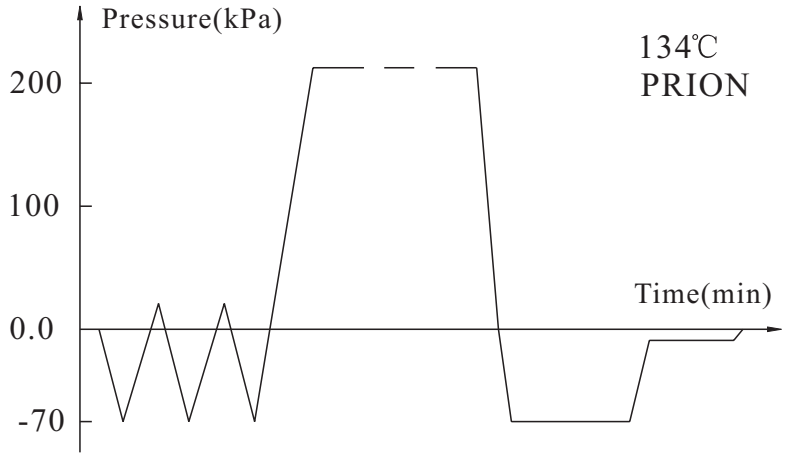

Pressure(kPa)
121℃
SOLID
200
100
0.0
-80
Time(min)

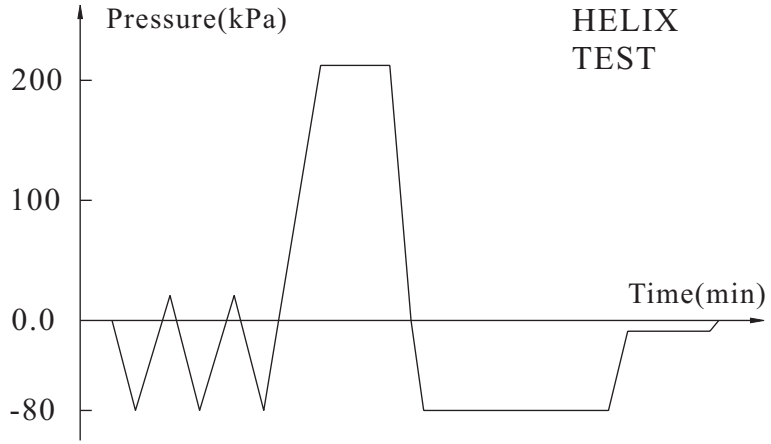

Pressure(kPa)
134℃
WRAPPED
200
100
0.0
-80
Time(min)

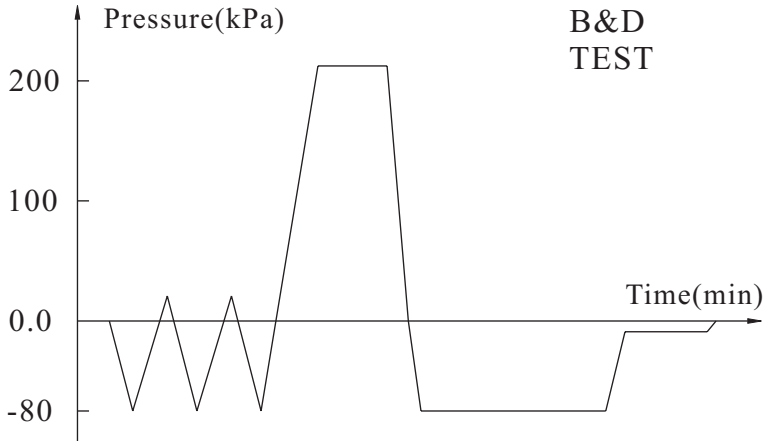

Pressure(kPa)
121℃
WRAPPED
200
100
0.0
-80
Time(min)

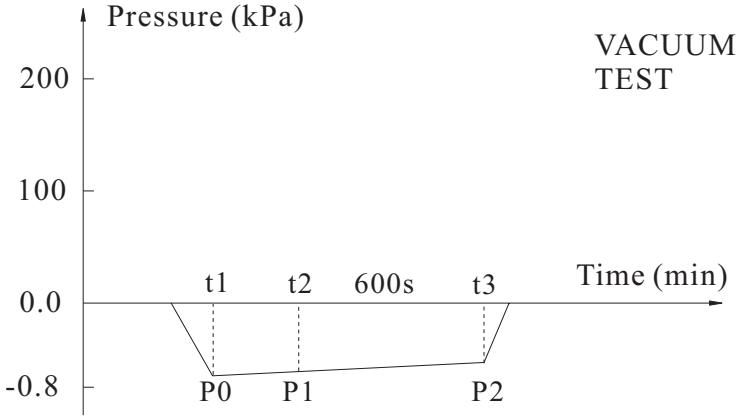

Pressure(kPa)
121℃
LIQUID
200
100
0.0
-80
Time(min)


Pressure(kPa)
134℃
LIQUID
200
100
0.0
-80
Time(min)


Pressure(kPa)
134℃
PRION
200
100
0.0
-70
Time(min)

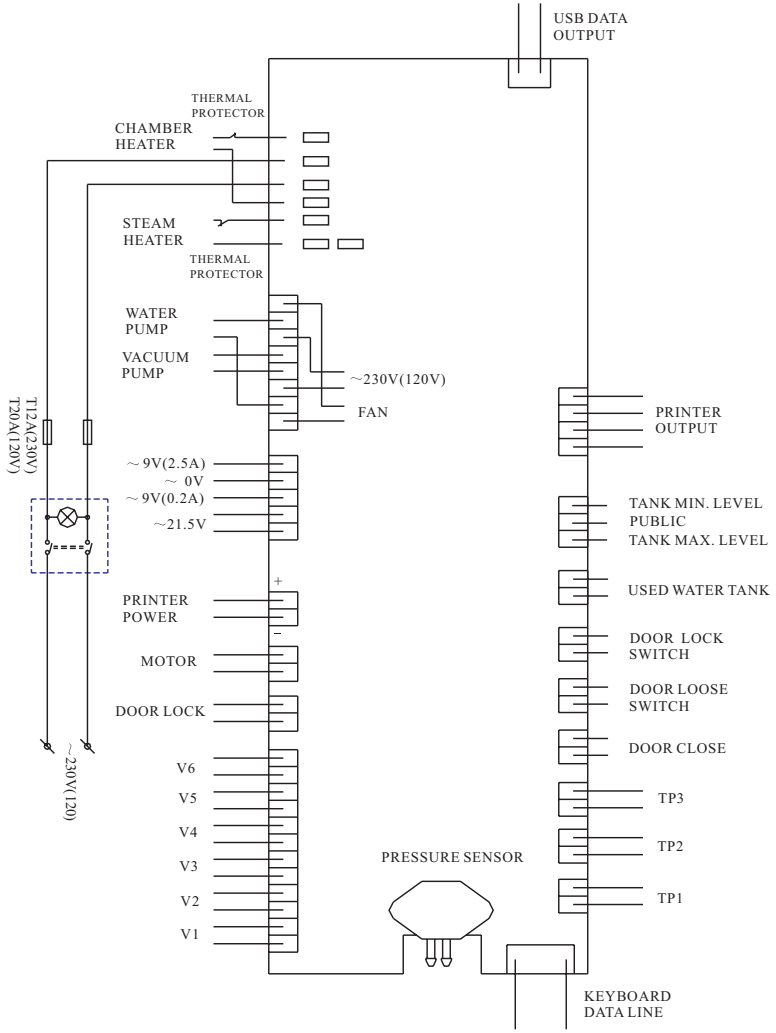

Pressure(kPa)
HELIX
TEST
200
100
0.0
-80
Time(min)


Pressure(kPa)
B&D
TEST
200
100
0.0
-80
Time(min)


Pressure (kPa)
VACUUM
TEST
200
100
0.0
-0.8
t1
t2
600s
t3
Time (min)
P0
P1
P2

APPENDIX 3

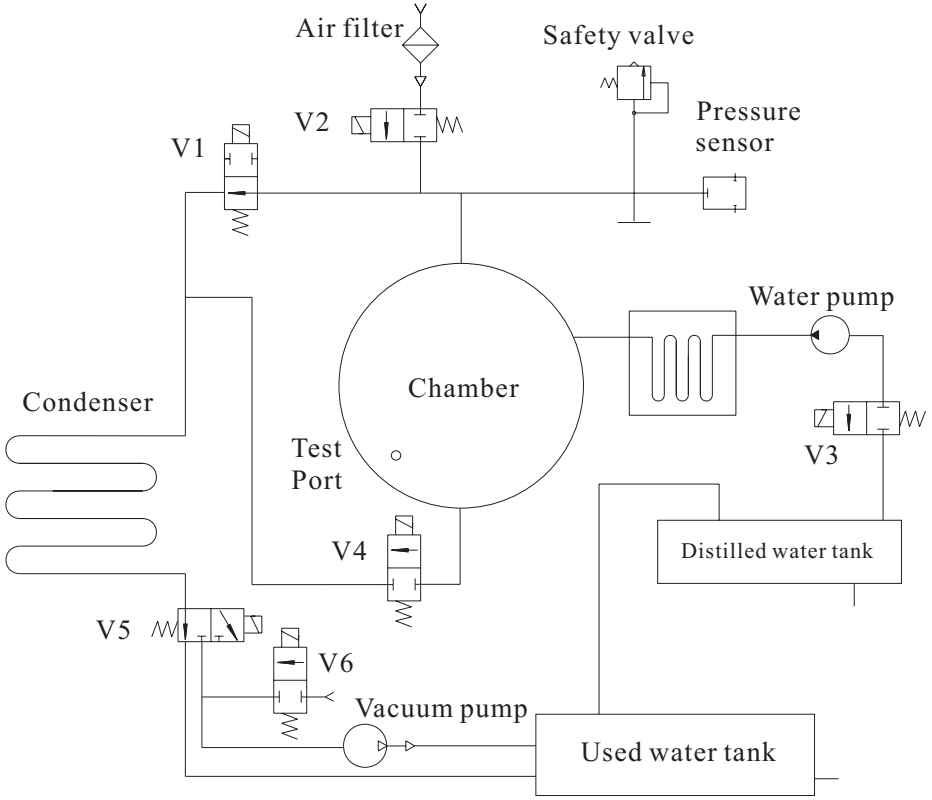
ELECTRICAL DRAWING



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: Water pump valve
V4: Water release valve
V5: Vacuum pump valve
V6: Auxiliary valve

APPENDIX 4

HYDRAULIC DRAWING



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