STEAM STERILIZER

Instructions Manual

(08C)

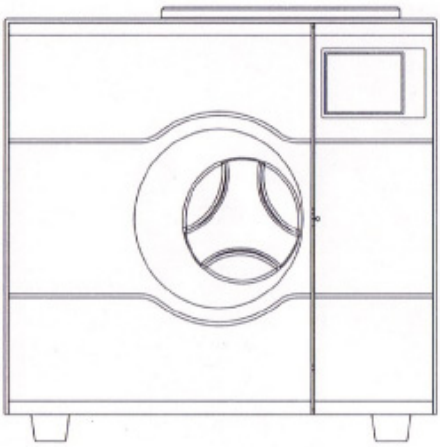


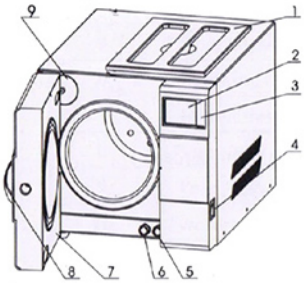
TABLE OF CONTENTS

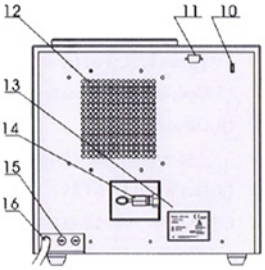
1 General

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.

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 LCD screen
3 Control panel
4 Main switch
5 Drain connector of distilled water tank
6 Drain connector of used water tank
7 Door
8 Door handle

9 Bacteriological filter
10 USB port (optional)
11 Printer port
12 Condenser ventilation
13 Rating plate
14 Safety valve
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

(1)Chamber: Φ170mm X 320mm

(2)Rated Voltage: AC220V-240V(AC110V), 50-60Hz

(3)Nominal power: 1550VA

(4)Sterilization Temperature: 121℃/134℃

(5)Main Fuses: T12A/250V(T20A/250V for AC110V)

(6) Capacity of the distilled water tank:

Approx 2.5L (water at level MAX)

Approx 0.5L (water at level MIN)

(7)Operation temperature: 5 - 40℃

(8)Outside size:

345mm(width) x 340mm(height) x 530mm(depth)

(9)Net weight: 34.5kg

(10)Noise: <70dB

(11)Relative Humidity: max 80%, non condensing

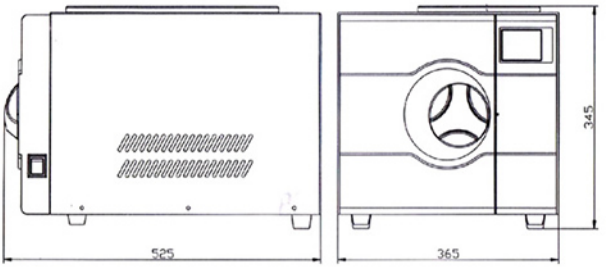
(12)Atmospheric pressure: 76kPa -106kPa

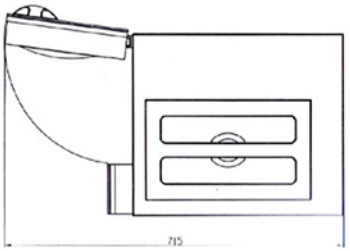
3 Packing Content

No	Item	Quantity
1	8L 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 for 110V)	2
9	Fuse for valve (T3A/ AC250V)	2
10	Fuse for mainboard (T1A/ AC250V)	2
11	Door seal	1

4 Installation

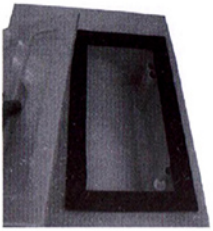
* There must leaves 10cm gap around sterilizer, and 20em on top side. the clearance required for the movement of the door(s): leave an at least 450mm fan-shaped space in front of the door.
* The place which sterilizer located must be ventilated, make sure that the radiator not being jammed.
* The sterilizer 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.





5.1.4 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 be displayed. 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 Select the sterilization program

5.3.1 LCD

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

5.3.2 TEMP button

Select temperature of sterilization.

5.3.3 PROGRAM button

Select program of sterilization.

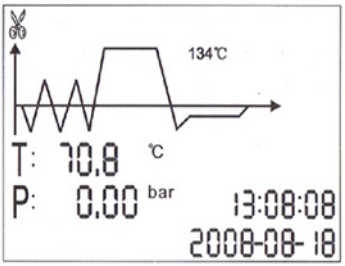
5.3.4 START/STOP button

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

5.3.5 Select the program

Press TEMP button to select the temperature. And press PROGRAM button to select the program.

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



Notice: The button will be locked for 10 seconds after you switch on. It initializes its system and check the states during that time.

5.4 Running the sterilization program

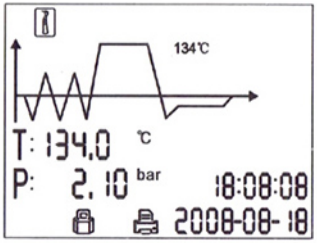
After selecting program, put the instruments into the chamber by tray handle.

5.5 After the instruments are loaded, you may close and lock the door by turning the door handle clockwise.
The icon will be lightened.

Caution: You must turn the door handle to the maximum position, otherwise the machine will 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)



total time or time count down of holding time and end time

Caution: When you press the "Start" button the door have not to be closed. you will see the blinks on the screen,
You can not start a cycle until you close the door to the max. position and press the "Start" button again.

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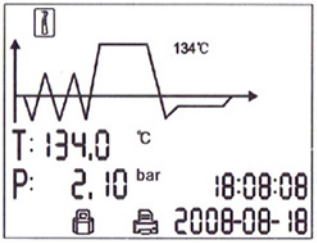
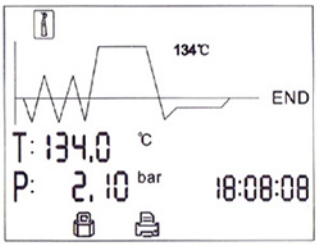


total time or time count down of holding time and end time

Caution: When you press the "Start" button the door have not to be closed. you will see the blinks on the screen,
You can not start a cycle until you close the door to the max. position and press the "Start" button again.

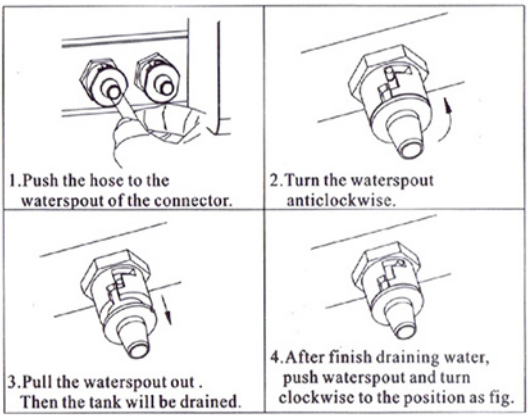
5.4.3 Sterilization cycle end

After a cycle completes, the printer will start work and print the report of the sterilization cycle data.(if you connect the printer)
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.

The drain connector

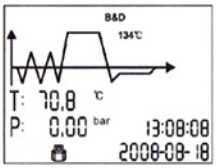


5.5 Test programs

5.5.1 Press PROGRAM button, select the "B&D TEST".

5.5.1.1 Put the Bowie-Dick pack into the chamber. Then close the door and press "START".

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



5.5.2 Select the "HELIX TEST"

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 and press "START".

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

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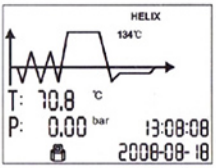


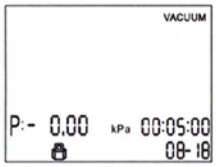
5.5.3 Select the "VACUUM TEST"

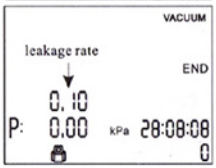
5.5.3.1 Then close the door and press "START" button.

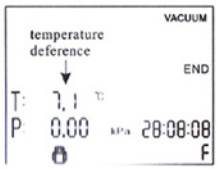
5.5.3.2 After finish it will show the result.

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 leakage rate is not greater 0.13, it will show 0 means success.
Or it will show F means failure.

5.5.3.4 If the temperature deference between the max. temperature and the min. temperature is above 3, it will show the value T on the screen and show F. That means the result of test is void. You need run the vacuum test again after the chamber cools down.







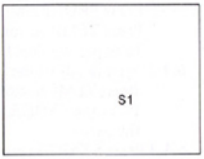
Caution: The VACUUM TEST must be carried out with unit cold. If the Tp is greater 3℃, it will show failure.

6 Advanced Setting

6.1 Enter the setting

6.1.1 Holding the START button and open the main switch. After about 5 seconds it will enter the setting screen.

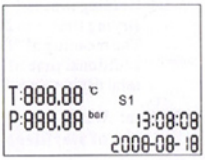
6.1.2 Select the state by press PROGRAM button. The state you selected will glitter. Press the START button to enter the setting.



6.2 S1 state

If you select the S1 and enter the state. You may change the unit of temperature and pressure, adjust time and date.

6.2.1 You will select the unit of temperature first. Press TEMP button to select ℃ or ℉. The unit you select ed will be lighted. Press the PROGRAM button to the next item.



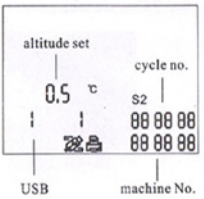
6.2.2 You may set the pressure unit as the same method.

6.2.3 Then press PROGRAM button to the next item to adjust the time and date After the last word of the date or time is set , then the data is permitted to be saved. If you want to finish the setting you shall press START. It will return to the screen of selecting states.

6.3 S2 state

6.3.1 You may check the count of sterilization cycle. It can not be changed by operator.

6.3.2 Set the parameter for high altitude. If you can't enter the holding time and use this machine at a high altitude place is above 0.5 kilometres or atmospheric pressure is below 95kPa and you need set the 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 kilometres 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.

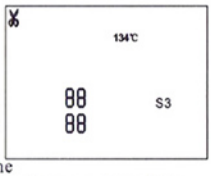
6.3.3 USB memory and printer setting. "1" means open this function. "0" means close this function. The left parameter is for USB. The right is for printer.

⚠ The operator must not change the Machine No. It is set in factory.

6.4 S3 state.

6.4.1 Adjust the holding time of sterilization and drying time.
Press PROGRAM button to select the program.( )
Press TEMP button to select the temperature of program.
Then press START to adjust the drying time and holding time.

6.4.2 First to adjust the holding time.
Press TEMP button to adjust the data.
Press the PROGRAM button to select the items.



6.4.3 Press START to save .

6.4.4 Holding time is 1-60.
Drying time is 0-20.
The meaning of "Drying time" is the additional time of drying time. It is not the total drying time. The total time depends on the current condition.

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

6.5 S4 is reserved for factory and after service. The operator must not adjust the parameter.

6.6 Pinter (Optional)

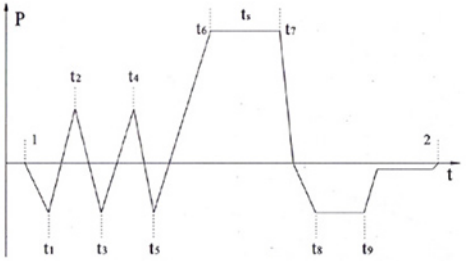
6.6.1 Connect the printer cable to socket at the back of the sterilizer.

6.6.2 Connect the printer power.

6.7 USB Flash memory (Optional)

If you want to store the information of program cycle in flash memory you need to insert the memory in the usb socket before the program end.
The information will be stored to file. The name of file is according to the No. of machine and the cycle No.

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



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

Start Time:05:38
T1:05:40/84.7℃/-70.0kPa
T2:05:42/101.8℃/52.0kPa
T3:05:44/79.4℃/-70.0kPa
T4:05:46/108.5℃/50.3kPa
T5:05:49/91.6℃/-70.0kPa
T6:05:57/134.5℃/229.3kPa
TS:134.5℃/225.2kPa
MAX • Temperature:135.0℃
MIN • Temperature:134.0℃
MAX.Pressure:230.4kPa
MIN.Pressure:220.0kPa
T7:06:00/134.5℃/223.8kPa
T8:06:03/110.7℃/-60.2kPa
T9:06:06/102.3℃/-60.2kPa
End Time:06:10

Cycle NO: 0015
Ster Value: Success
Date: 2008-06-30
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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7 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

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.

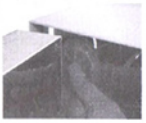
7.3 Replacement of the bacteriological filter

7.3.1 The bacteriological filter is at the back of the sterilizer.

7.3.2 Unscrew the filter by hand (anti-clockwise).

7.3.3 Replacing the bacteriological filter.

7.3.4 Screw the new filter by hand clockwise.



7.4 Cleaning the door seal

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

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 first

7.5.2 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.

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.

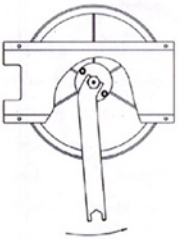


Fig 1

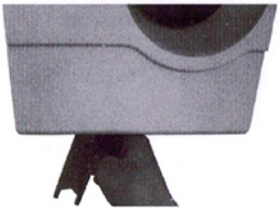


Fig 2

Caution:

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

7.6 Replacement of the door seal

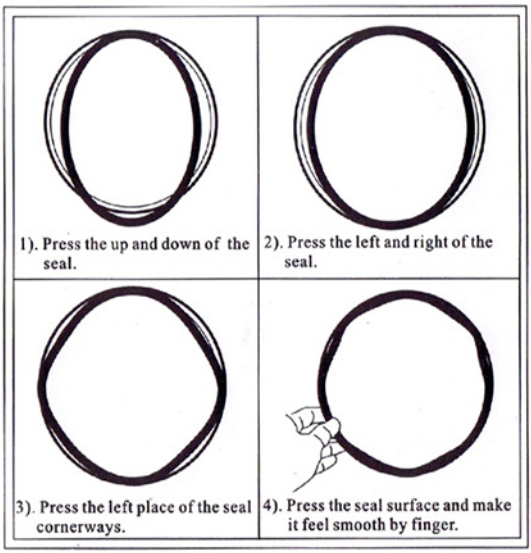
7.6.1 Fully open the door.

7.6.2 Remove the door seal carefully by hand.

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

7.6.4 Moisten the new seal with medical disinfectant .

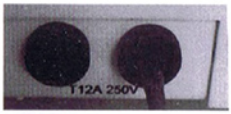
7.6.5 Insert the new seal and press in sequence as the following.



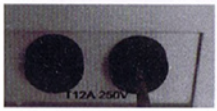
Caution: Please ensure the chamber and the door has been cool down before you change the seal.

7.7 Replace fuse

1). Switch off the power.

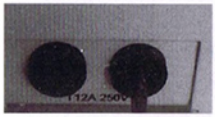


2). Push the fuse by a screw driver first, then unscrew the fuse holder counter clockwise.



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.

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 ℃ ~ +55℃

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
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.
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 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

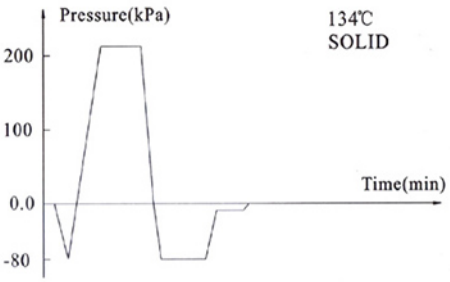
DESCRIPTION	FEED WATER	CONDENSATE
Evaporate residue	≤10 mg/l	≤1.0 mg/kg
Silicium oxide sio_2	≤1 mg/l	≤0.1 mg/kg
Iron	≤0.2 mg/l	≤0.1 mg/kg
Cadmium	≤0.005 mg/l	≤0.05 mg/kg
Lead	≤0.05 mg/l	≤0.1 mg/kg
Rest of heavy metals, excluding iron, cadmium, lead	≤0.1 mg/l	≤0.1 mg/kg
Chloride	≤2 mg/l	≤0.1 mg/l
Phosphates	≤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

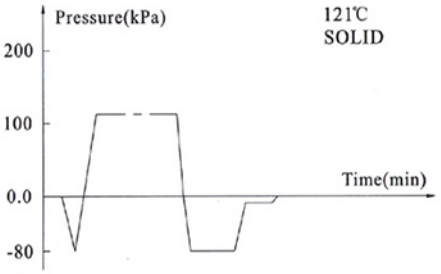
APPENDIX 2

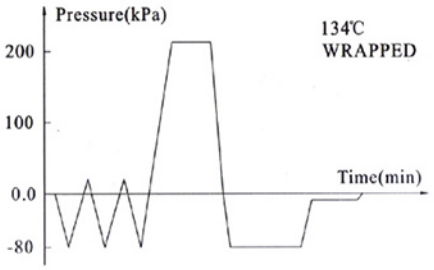
DIAGRAMS OF THE STERILIZATION PROGRAMMES

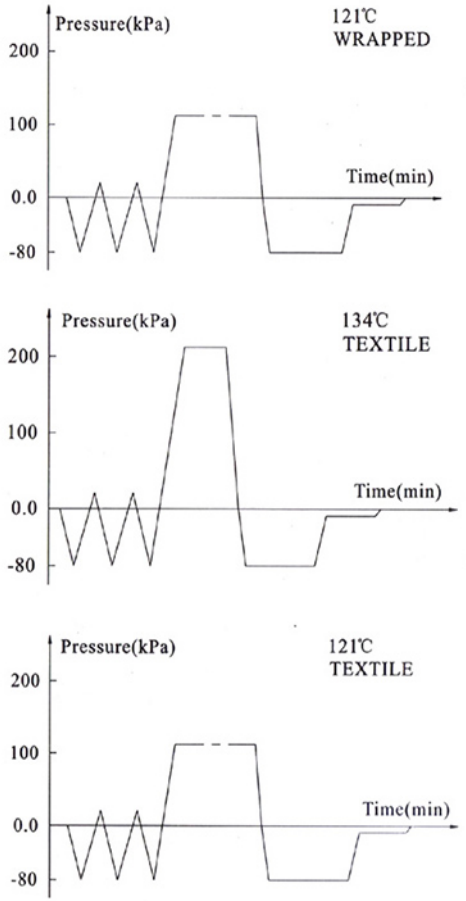
PROGRAM	Temperature (℃)	Pressure (kPa)	Holding time (min)	Total time (min)	TYPE	MAXLOAD (kg)
SOLID	134	210	4	14~20	Unwrapped solid material	2.00
	121	110	20	30~45		2.00
WRAPPED	134	210	4	30~40	Unwrapped hollow material	2.00
	121	110	20	35~50	Single-wrapped solid material	1.50
TEXTILE	134	210	4	45~65	Unwrapped porous material	0.5
					Single-wrapped porous material	0.50
					Dual-wrapped porous material	0.25
	121	110	20	50~75	Single-wrapped Hollow material	2.00
					Dual-wrapped solid and hollow material	1.00
PRION	134	210	18	45~70	Unwrapped porous material	0.75
					Single-wrapped porous material	0.50
					Dual-wrapped porous material	0.50
					Single-wrapped Hollow material	2.00
					Dual-wrapped solid and hollow material	1.00
B&D TEST	134	210	3.5	22~35	—	—
HELIX TEST	134	210	3.5	22~35	—	—
VACUUM TEST	—	—	—	15~20	—	—

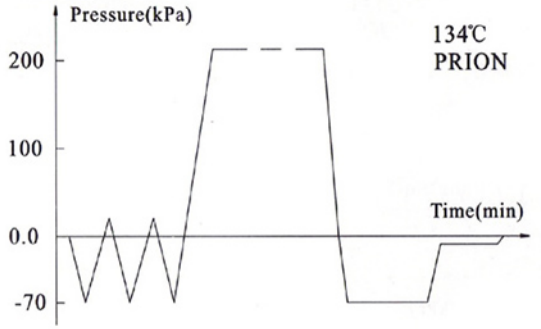
The time required for sterilizer to be ready for routine use after the power is switched on less than 5 minutes.
The max. temperature of the 134℃ sterilization cycle is 137℃
The max. temperature of the 121℃ sterilization cycle is 124℃

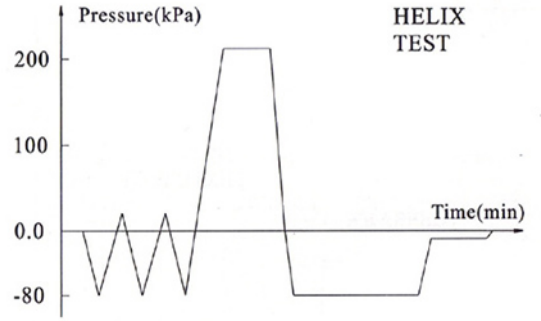

Pressure(kPa)
134℃
SOLID
200
100
0.0
-80
Time(min)

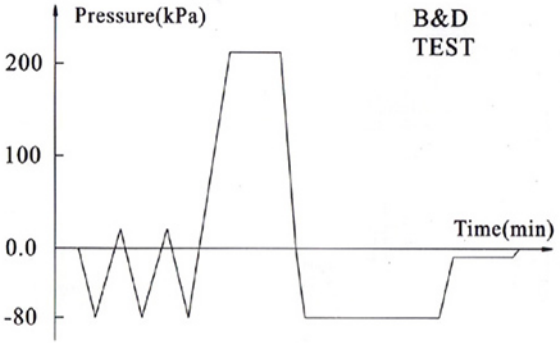

Pressure(kPa)
121℃
SOLID
200
100
0.0
-80
Time(min)

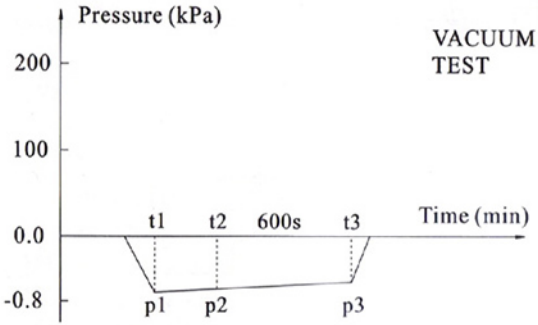

Pressure(kPa)
134℃
WRAPPED
200
100
0.0
-80
Time(min)


Pressure(kPa)
121℃
WRAPPED
200
100
0.0
-80
Time(min)
Pressure(kPa)
134℃
TEXTILE
200
100
0.0
-80
Time(min)
Pressure(kPa)
121℃
TEXTILE
200
100
0.0
-80
Time(min)


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

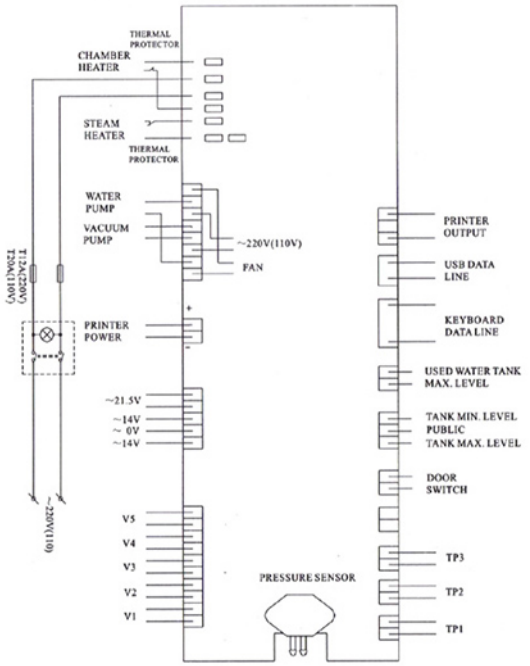

Pressure(kPa)
HELIX
TEST
200
100
0.0
-80
Time(min)


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)
p1
p2
p3

APPENDIX 3

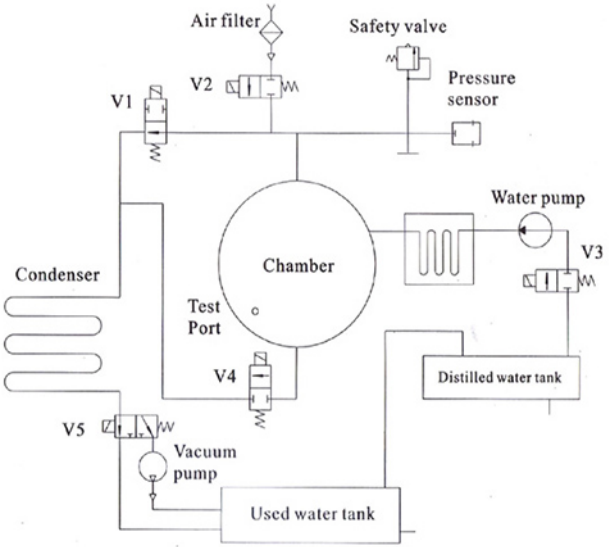
ELECTRICAL DRAWING



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

APPENDIX 4

HYDRAULIC DRAWING



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