

Operation and Maintenance
INSTRUCTION MANUAL
FOR

**PRESSURE STEAM
STERILIZER**

Automatic Sliding Door type

**Model HS-5035PT
HS-5035PTD**



HS-5035PT / HS-5035PTD



SINCE 1975

한신메디칼주식회사
HANSHIN MEDICAL CO., LTD.

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1. As HANSHIN's products are ceaselessly improved, the actual product may differ from the descriptions, specifications, drawings and pictures in this publication.
 2. This manual is supplied only together with the pertinent products. It is prohibited to reproduce or copy all or part of this manual.

Incoming Inspection

1. On receipt, the sterilizer should be unpacked and inspected for mechanical damage. Observe packing method and retain packing material until the sterilizer has been inspected. Mechanical inspection involves checking for signs of physical damage such as scratched panel surfaces, broken knob etc,
2. If damage is apparent, file a claim with the carrier. The manufacturer is responsible for products supplied Ex Factory. These products are carefully inspected prior to shipment and all reasonable precautions are taken in preparing them for shipment to assure safe arrival at their destination.

In the event of a serious incident

Any serious incident that has occurred in relation to the HS-5035PT, HS-5035PTD Should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

Please contact the following address to report and take appropriate action

EU AUTHORISED REPRESENTATIVE MT Promedt Consulting GmbH Address : Ernst-Heckel-Straße 7, 66386 St., Ingbert, Germany Tel + 49 6894 581020 Fax + 49 6894 581021	HANSHIN MEDICAL CO., LTD (82-32) 508-8118 (Trading Dept.)
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Technical Service Contact

If there is any difficulty with this sterilizer, and the solution is not covered in this manual, please contact our representative or us first.

IFU are not available online.



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HANSHIN MEDICAL CO., LTD.

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CAUTION



User must not alter this sterilizer at random without contacting us, otherwise the warranty does not apply to such a altered sterilizer and user is responsible for the problems caused by it.



SAFETY INSTRUCTION

The following instructions should be strictly observed to ensure the safety of life and property when operating, inspecting, and repairing this sterilizer.

The manufacturer and the supplier of this sterilizer shall not be held liable for human injury or unit damages caused by failure to correctly follow these safety instructions and the precautions of “ CAUTION” and “ WARNING” as well as the operating procedures detailed in this manual.

 **WARNING** indicates the potential for danger to personnel.

 **CAUTION** indicates the potential for damage to equipment.

1. The operator should carefully read this manual, and should have a good working knowledge and experience in sterilization. The sterilizer must be used according to the procedures in this manual. If the sterilizer is used in a manner that is not specified by the manufacturer, the protection system of the sterilizer may be impaired, that results in a human injury and damage.
2. Do not sterilize the toxic materials, and also items that may deteriorate, discolor, deform, explosive, malfunctioned when exposed to high pressure and temperature steam.
3. The sterilizer must put to earth perfectly for avoiding possible electrical shock.
4. The area where the sterilizer would be installed should be ventilated at least ten times an hour.
5. When sterilizing liquids, please observe the following:
 - 1) Use air-permeable(porous) closures. Do not use a screw cap or rubber stopper.
 - 2) Use only borosilicate glass bottles (type I). Do not use ordinary glass bottles or containers that are not designed for sterilization purposes.
 - 3) Avoid opening the door immediately after completing the sterilization cycles. Instead, slightly open the door and let it cool for about ten minutes.
 - 4) Do not shake or move the hot bottle, as doing so may lead it to burst.
 - 5) Small containers are preferable for sterilizing liquid rather than a large container or the different sized containers.
6. Only technically qualified and experienced personnel should inspect, adjust, and repair the sterilizer:
 - 1) Always wear protective gloves when operating the sterilizer.
 - 2) Disconnect the power plug and let the sterilizer cool down before conducting inspection and maintenance.
 - 3) Use only those spare parts designated by the manufacturer.
7. In sterilizing goods or materials whose physical and chemical properties have not been confirmed, please apply the sterilization methods specified in the literature provided by their respective manufacturers.

8. Observe the following points in loading the items to be sterilized:

- 1) Load the items to be sterilized in the chamber only using the loading equipment provided by the manufacturer.
- 2) Do not put the items to be sterilized on the chamber floor directly and avoid bring the packages of the items to be sterilized in contact with the chamber wall.

9. Do not sterilize saline solutions. If it has sterilized inevitably, immediately clean the chamber.

10. When cleaning the door or chamber, do not use a wire brush, steel wool, abrasives, or materials containing chlorides.

11. During sterilization, the operator should stay near sterilizer enough to watch over it and hear any warning or unusual sounds that may indicate equipment failure. Be sure to turn off the sterilizer when sterilization has been completed and leaving work.

12. The contaminated waste at the workplace of sterilization should be packed in the bags or container marked correctly and there should be no leaks.

13. Liquids intended for transfusion or administration must not be sterilized.

14. Never sterilize flammable materials or liquids. This can cause fatal damage to the sterilizer.

15. Materials that cannot be sterilized (Vaseline, powder, oil, etc)

16. Types of liquids that can be sterilized (e.g., Medium, buffer, etc)

1. GENERAL INFORMATION

1.1 Features

- 1) This sterilizer uses high pressurized vapor supplied from the built-in or external steam generator as sterilant, and the operating temperature range of sterilization process is 121℃ ~ 135℃.
 - Intended Purpose : Sterilization of various medical devices and supplies by a validated process used to render a product free from viable microorganisms.
 - Intended Users : Trained medical or paramedical staff who understand how to operate the Large steam sterilizer and to interpret the data.
 - Limitations:
 - a. The device must not be used in locations where hazardous gases or vapours are present.
 - b. Provide adequate ventilation.
 - c. It must be connected to a circuit breaker equipped with an earth ground.
- 2) 5 kinds of basic cycle program and 2 kinds of test cycle program(vacuum leak test and air removal performance test) are embedded in the sterilizer, therefore operator can select a proper cycle program conveniently for sterilizing according to the material of item to be sterilized(textile, metal device or instruments, liquid contained in the bottle), packaging type(wrapped or unwrapped) and air removal method(pre-vacuum or gravity).
- 3) If an error has been occurred during operating, the error code is displayed on the touch screen accompanying an audible alarm and a cycle in progress is aborted after venting the chamber automatically for safety.
- 4) All the processes of cycle including the operation of automatic vertical sliding door by motor control are proceeded automatically by the microprocessor controls. Operator can operate and control the sterilizer easily by one touching the functional buttons designed graphically on the touch screen type color LCD, and monitor the operating situations conveniently including the set parameters of executing cycle, process progressing, occurred errors etc. in real time on the touch screen. The built-in panel printer prints out the cycle performance recorder after cycle completion for analyzing the results of sterilization.
- 5) At least 11 years of cycle execution records are automatically stored in the Flash memory of controller. The user can automatically retrieve the result of the sterilization cycle that was executed in the past as needed and print the contents with the panel printer mounted on the sterilizer, and use the result as an evidence of sterilization quality.
- 6) The automatic sliding door is divided to the single door type and double door type, the advantage of double door is that the risk of recontamination after sterilization can be removed because the sterilized loads can be taken out in the clean area. The double door type sterilizer is designed to load the items to be sterilized in the chamber through the front door in the loading area and unload items sterilized through the rear door in the clean area in

general. The two areas should be separated and blocked completely by the bio-seal device for preventing recontamination after sterilization, and doors are controlled automatically not to be opened at the same time, therefore the front door keeps close during the rear door open or operate in reverse naturally.

1.2 Applicable Directive and Standards

The large steam sterilizers of HANSHIN MEDICAL Co., Ltd. are designed and manufactured to comply with the following international directives and standards;

Medical Devices Regulation (MDR (EU) 2017/745)

Pressure Equipment Directive (PED 2014/68/EU)

CE Medical Device Mark 0044, TÜV NORD CERT GmbH, Germany

EN ISO 13485: 2016, TÜV NORD CERT GmbH, Germany

EN ISO 14971: 2019, Risk Management to Medical Devices

European Standard, Safety (EN 61010-1 / EN 61010-2-040)

European Standard, EMC (EN 61326-1)

European Standard, Large Steam Sterilizers (EN 285)

KS, Korea Industrial Standards

KGMP, Korea Good Manufacturing Practice

1.3 Symbol Descriptions

Number	Symbol	Publication	Description
1		IEC 60417, No. 5032	Alternating Current
2		IEC 60417, No. 5019	Protective Conductor Terminal
3		IEC 60417, No. 5007	On (Supply)
4		IEC 60417, No. 5008	Off (Supply)
5		ISO 7000-043A	Caution
6		IEC 60417, No. 5041	Caution, Hot Surface Background colour- yellow; symbol and outline- black

1.4 Utility Labels

Utility	Specification
Steam (Supply Pressure)	3.50~5.00 bar
Tap Water (Supply Pressure)	2.10~5.00 bar
Rated Power Source	Refer to the specification of each model

NOTE

Pressure indicated in this manual is the gauge pressure, but the chamber and jacket pressure are the absolute pressure.

1.5 Specification

Model	HS-5035PT	HS-5035PTD
Style	Single Door type	Double Door type (D)
Overall Dimension	W872 x D1,300 x H1,972 (mm)	W872 x D1,350 x H2,008 (mm)
Chamber	W500 x D1,000 x H700 (mm) Vol: 350ℓ, Material: STS 316L	
Loading Equipment	Loading Car: W460xD950xH598 (mm) Carriage: W450xD1,453xH1,215 (mm)	
Operating Temperature	121.0℃ ~ 135.0℃	
Air Removal	Vacuum / Gravity	
Controls	Microprocessor	
Display	Touch Screen type Color LCD (LED back-light)	
Panel Printer	Direct Thermal printing, Printing Paper Roll; W58×Ø40mm (length: 13m)	
A-Weighted Sound Power Level (L _{WA})	70dB(A) max.	
Power Source (Power Consumption)	In case of using Built-in Steam Generator: AC 400V, 3ph 4wire, 50/60Hz, 32A	
	In case of using External Steam Generator : AC 230V, 50/60Hz, 5A	
Steam Source	Built-in Steam Generator	
	External Steam Generator: Saturated Steam of 97% Dryness Pressure : 3.50bar~5.00bar, Flow Rate: max. 50kg/hr	
Water Source	Pressure: 2.10bar~5.00bar, Flow Rate: max. 50 ℓ/min	
Vacuum System	Water Ejector, Water Pump	
Weight	Unit: 803kg L/Car: 36kg	Unit: 982kg L/Car: 36kg

	Carriage: 30kg	Carriage: 30kgx2
Environment Conditions	(Operating) * Altitudes up to 2,000 meters. * Temperature range of +5℃ to +40℃. * Maximum relative humidity 80% for temperature up to 31℃ decreasing linearly to 50% relative humidity at 40℃ * Main supply voltage fluctuation of ±10% of nominal. * Installation Category (Overvoltage Category) II, Pollution Degree 2. (EN 61010-1, 1.4 Environmental Conditions) (Storage) * Temperature range: -40℃ ~ +70℃. * Maximum relative humidity: 10% ~ 100% (rainfall will be permitted)	
	* Drainage System : Resistant to water at 100℃ (EN 285, 13.8 Drains). * Ventilation System : A ventilation system should be designed and constructed to remove the heat transmitted from the sterilizer and from the sterilized load during unloading (EN-285, 13.10 Environment). * Water : Potable quality and supplied at a temperature not exceeding 20℃, the hardness value of water should be between 0.7mmol/l and 2.0mmol/l (EN 285, 13.5 Water). * Compressed Air Supply : A pressure of 600kPa~800kPa (5bar~7bar), free of liquid water, filtered to 25μm and free from oil droplets greater than 2μm (EN 285, 13.6 Compressed air).	

2. INSTALLATION

2.1 Matters to be attended before installation



CAUTION

1. Sterilizer should be installed by the service personnel of the manufacturer or the supplier after checking the location environment and preparing all the matters required for installation, therefore user must not operate sterilizer randomly until the installing process has completed.
2. After installation, the service person provides the in-service training including the correct operating method of the sterilizer, the procedures of routine and periodic maintenance and the matters to be attended while operating and maintaining the sterilizer for the operators. User should fully understand those contents and observe the safety instruction, cautions and warnings described in this manual for safe and smooth sterilization.
3. User should not change the control programs of sterilizer arbitrarily, but if needed inevitably, should contact the service personnel of the supplier or the manufacturer.
4. The supplier and manufacturer are not liable about the person injury and equipment damages caused by neglecting to observe the safety instruction, cautions and warnings described in this manual.

1) Incoming inspection

Upon delivery, you should thoroughly check the inside and outside of sterilizer, and if there is any problem such as damaged part or lost accessories during delivery, please inform our representative in Europe (see back cover of this instruction manual) or supplier immediately for proper service.

2) Unpack the sterilizer as follows,

- (1) Separate all the partition of wooden box.
- (2) Remove the styrofoam for absorbing shock
- (3) Lift the sterilizer down from the wooden pallet.
- (4) Remove the plastic wrap from the sterilizer unit.

3) Transportation and location

- (1) Lift up the sterilizer using a proper lifter for moving and position the sterilizer in its permanent location.
- (2) Adequate space must be allowed at the sides and rear of sterilizer for maintenance and service. Service access requires a minimum clearance of 600 mm above the top and 1000 mm on each side of sterilizer. The sterilizer should not be placed closer than 500 mm from the rear wall.

2.2 Installation Environments

- 1) The sterilizer should be placed in the location where could support the total load, level and vibrationless.

- 2) The ambient atmosphere around the sterilizer must not exceed 40°C, 80% relative humidity, and the room should be ventilated more than 10 air changes per hour.
- 3) In case of using an external steam source, its conformity should be verified in accordance with the article 13.3 of EN-285:2015. The shutoff valves and switches of all utilities such as the mains, the steam and the water source etc. should be marked individually to be identified clearly, and located in the unrestricted area where allows user to access easily.
- 4) The saturated steam, water and electric power should meet the required quality and the drainage always has to keep not to be clogged.



WARNING

Never install and use the sterilizer in the location where there is a dangerous gas or vapor.

2.3 Preparation for installation

1) Power Supply

(1) External Steam Type : AC 230V, 1ph, 50/60Hz, 5A (Power cable; 0.7mm²)

(2) Built-In Steam Generator Type :

AC 400V, 3ph, 4wire, 50/60Hz, 32A (Power cable; 6.0mm²)

*External over current circuit breaker to be connected; 50A MCCB

2) Steam Supply

(1) Steam Supply Facility : Saturated Vapor of more than 97% dryness,

Pressure; 3.50~5.00 bar, Flow Rate; max. 50 kg/hr

(2) Connection on Sterilizer : 1/2" FPT

(3) Connection on External : 3/4" FPT

3) Cooling(Tap) Water Supply

Pressure; 2.10~5.00 bar, Flow Rate; max. 50 ℓ/min.

(1) Connection On Sterilizer : 1/2" FPT

(2) Connection On External : 3/4" FPT

4) Drain

A drainage is recommended to install separately for each sterilizer and shall use the metallic pipe so as not to be melt or deformed by the hot drain water, it should keep always not to be clogged.

(1) Connection On Sterilizer : 3/4" FPT

(2) Connection On External : 2" MPT, Metal Pipe

5) Location condition

The floor shall be leveled, firm, clean and free from vibration.



CAUTION

1. The place of installing must be well ventilated.
2. Avoid installing the sterilizer near fire source.
3. Do not store or use a flammable materials (gas or liquid etc.) in the installing area.
4. Install the sterilizer to keep the level of it's chamber with the floor.
5. Do not remove or damage all the CAUTION/WARNING labels and name plate attached on the sterilizer.

6) Water Quality

- (1) The water for generating steam should be used the distilled water or the purified water by the reverse osmosis technology(RO Water), and acceptable limit of contaminants in the water for sterilizing are shown in Table 2-1. and it's compatability should be verified according to the authorized analysis method.

Table 2-1. Contaminants in Feed Water and Condensate		
Determinant	Condensate	Feed Water
Evaporate residue	–	≤ 10 mg/ℓ
Silicium oxide, SiO ₂	≤ 0.1 mg/ℓ	≤ 1 mg/ℓ
Iron	≤ 0.1 mg/ℓ	≤ 0.2 mg/ℓ
Cadmium	≤ 0.005 mg/ℓ	≤ 0.005 mg/ℓ
Lead	≤ 0.05 mg/ℓ	≤ 0.05 mg/ℓ
Rest of heavy metals, excluding iron, cadmium, lead	≤ 0.1 mg/ℓ	≤ 0.1 mg/ℓ
Chloride	≤ 0.1 mg/ℓ	≤ 0.5 mg/ℓ
Phosphate	≤ 0.1 mg/ℓ	≤ 0.5 mg/ℓ
Conductivity (at 20°C)	≤ 4.3 μs/cm	≤ 5 μs/cm
pH (20°C) value	5 to 7	5 to 7.5
Appearance	colourless, clean without sediment	colourless, clean, without sediment
Hardness	≤ 0.02 mmol/ℓ	≤ 0.02 mmol/ℓ
REFERENCE : EN 285:2015, 13.3.4(Condensate) & Annex B (informative; Feed Water)		

- (2) The water which is supplying for general operation of sterilizer shall be of potable quality and supplied at a temperature not exceeding 20°C. The hardness value of water should be between 0.7~2.0 mmol/ℓ, it can cause scaling and corrosion problems if hardness value exceeds in this limit (EN 285:2015 13.5).



CAUTION

1. Using hard or soft water containing much minerals may shorten the working life of the boiler and sterilizer.
2. Change the boiler water periodically considering the water quality used for preventing the boiler from the scale and corrosion.

2.4 Installation

1) Mounting of Sterilizer

- (1) Place the sterilizer in the specified location according to the setting drawing.
- (2) Leave proper service clearance required for operating and maintaining the sterilizer.
- (3) Make sure the bottom side of chamber is level.

2) Connecting of Cooling Water Source

- (1) Connect the tap water source to the water inlet of sterilizer(TAP WATER IN).
- (2) The water used for general operation of the sterilizer is a potable quality and should be supplied at a temperature not exceed 20°C. Higher water temperature affects vacuum performance.
- (3) The hardness value of water should be between 0.7 mmol/l and 2.0 mmol/l and higher hardness may lead to accumulation of scale in the piping or corrosion(EN 285:2015 13.5).

3) Connecting of Feed Water for Generating Steam

Connect the reservoir filled the distilled water or the RO water to the inlet of steam generator in the sterilizer(R.O WATER IN).

4) Connecting of Drainage

- (1) Connect the drain pipe in the service area to the drain of sterilizer.
- (2) The drainage pipe should be used the metallic pipe which is not melted or deformed at the water temperature 100°C (EN 285:2015, 13.8 Drains).
- (3) The drainage should be vented and kept not clogged for draining smoothly.

5) In Case of Using an External Steam Source

- (1) Connect the external steam supply pipe to the steam inlet of sterilizer.
- (2) The required steam dryness is not less than 95% and supply pressure is 3.5~5.0 bar.
- (3) The steam trap on the external steam supply should be within 2 meters from the sterilizer.

6) Power Source

Plug the power cord in the wall concent which is supplying the electric power compatible with the rate voltage, frequency and power consumption specified to the name plate of sterilizer.



CAUTION

1. Avoid connecting the sterilizer together with the other electric appliances in the same concent or using an extend cord, and the power cord shall not be pressed or folded.
2. Make sure to connect the sterilizer to the circuit breaker grounded electrically.

Table 2-1. Installation Information (continued)	
MODEL	HS-5035PT
Overall dimensions of the sterilizer and net weight.	W872xD1,350xH1.973 (mm) 1,078 kg
Weight per support area (N/m ²) when the built-in steam generator is filled with water and the chamber contains a maximum load. NOTE: If a water pressure test is required, e.g. by pressure vessel regulations, this weight should be considered.	-Max. weight of the built-in steam generator water: 16kg -Max. weight of items to be loaded: 40kg, -Weight for water pressure test (including jacket water): 410kg, -Total load per support area: 9,441N/m ² (include max. load) -Total load per support area: 12,854N/m ² (when applying the water pressure test)
Overall clearance required (left, right, rear, top)	1000/1000/500/600 mm respectively

2.5 Check Before Operation

- 1) Check tightness of all the nuts and screws on the sterilizing system.
- 2) Check the integrity of water supply for generating steam and general use, steam supply, electric power supply and the status of draining.
- 3) Check the earth status and leak current of the main power.
- 4) Adjust the height of casters of the carriage to be horizontal to the chamber rail.
- 5) Ask an authorized technician to perform the installation and operation test(IQ & OQ) for the sterilizer.

2.6 Overall Dimension

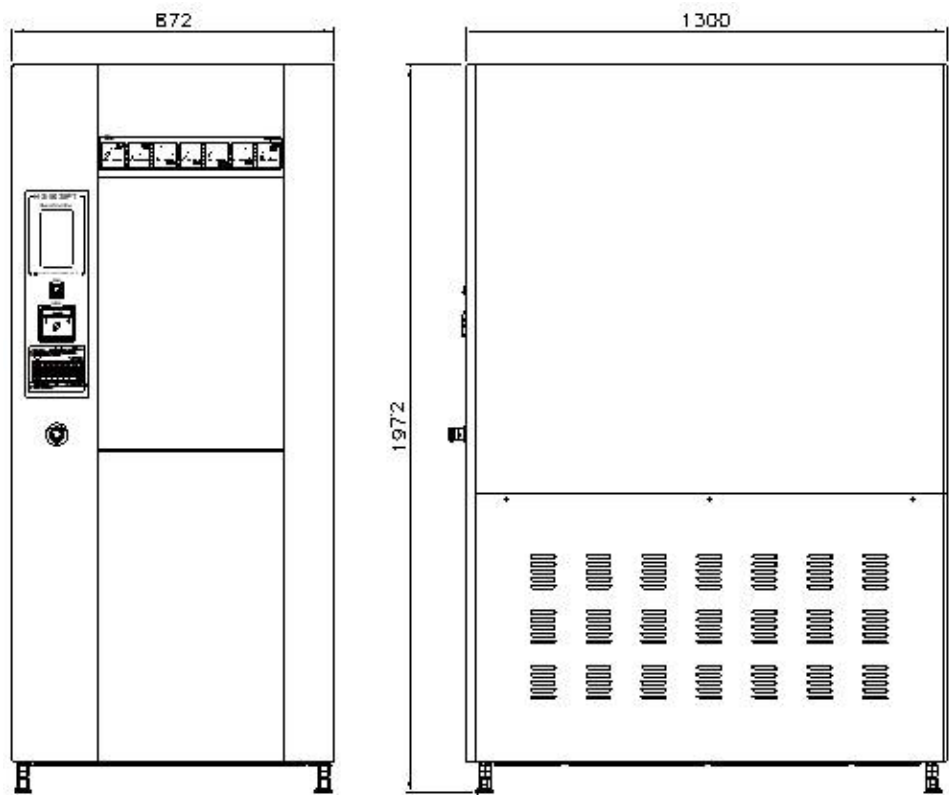


Figure 2-1. Overall Dimension of HS-5035PT Single Door (unit: mm)

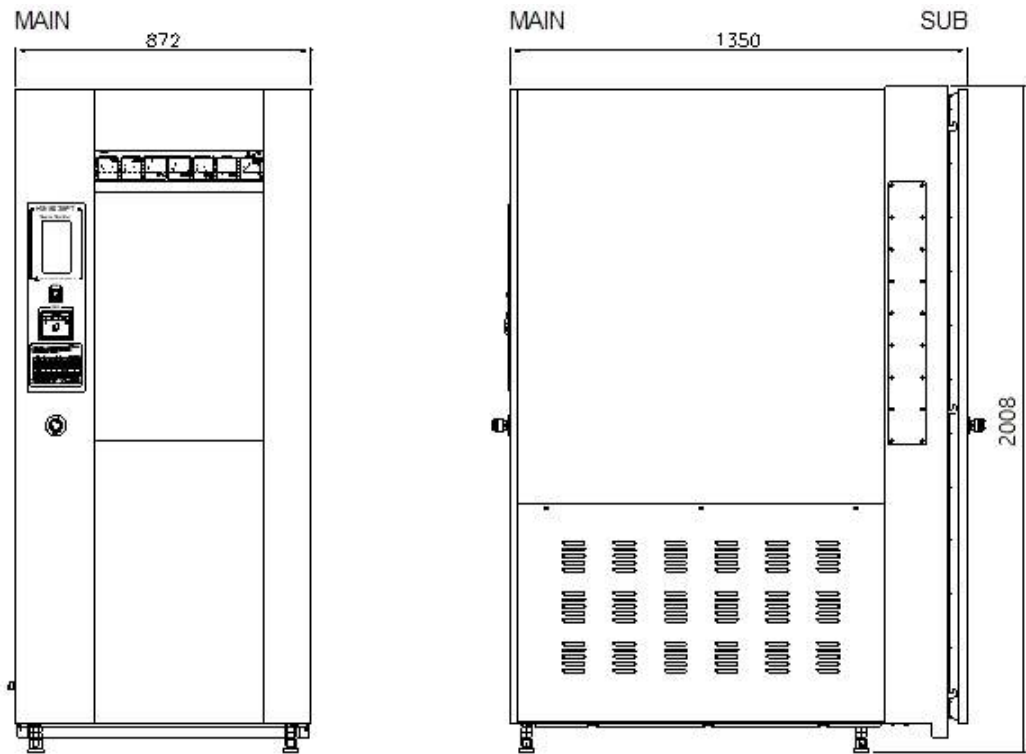


Figure 2-2. Overall Dimension of HS-5035PT Double Door (unit: mm)

3. OPERATION

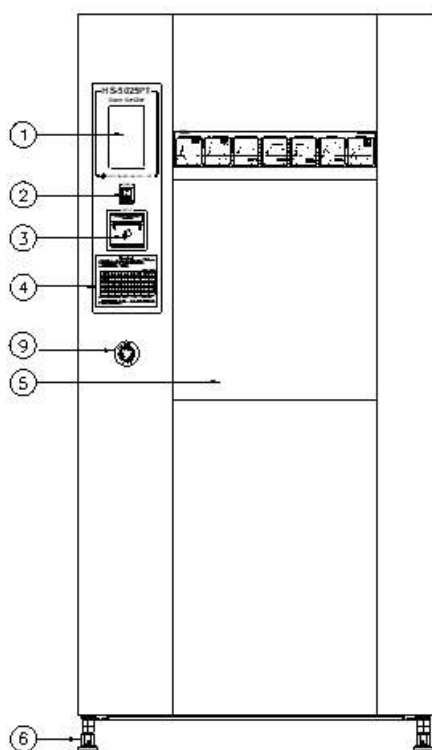


CAUTION

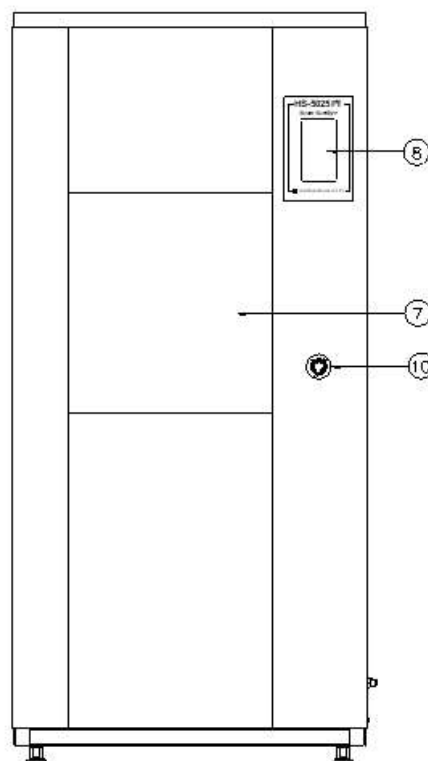
Operate the sterilizer safely only after fully aware of the operating method and matters required attention through this instruction manual.

3.1 Name and Function of the Operational Parts

1) Appearance



(Front Side, Single and Double Door type)



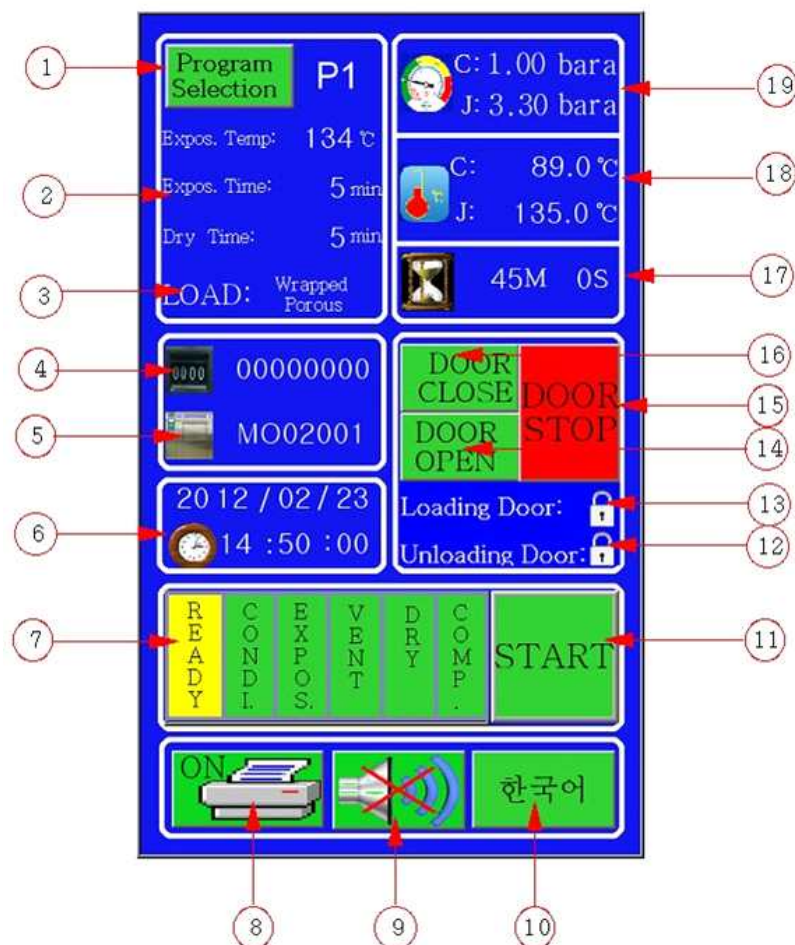
(Rear Side, Double Door type)

No.	Name	Function
1	Touch Screen Control Panel	It allows of operating, controlling the sterilizer and monitoring the situation of cycle progressing in real time.
2	Power Switch	It supplies power source to the sterilizer.
3	Panel Printer	It prints out the cycle performance record after cycle completion.
4	Operating Instruction Plate	The operating procedure of sterilizer is described on this plate.

No.	Name	Function
5	Automatic Vertical Sliding Door	This door is moved upward and downward automatically by driving motor control.
6	Height Adjuster	The installing height of sterilizer can be adjusted with it.
7	Automatic Vertical Sliding Door (Rear Side)	This door is moved upward and downward automatically by driving motor control.
8	Touch Screen Control Panel (Rear Side)	It allows of operating, controlling the sterilizer and monitoring the situation of cycle progressing in real time.
9	Emergency Stop Switch (Front Side)	If an actual or impending danger occurs while operating the front door, pressing this switch quickly allows the operation of front door to shut down for averting the danger.
10	Emergency Stop Switch (Rear Side)	If an actual or impending danger occurs while operating the rear door, pressing this switch quickly allows the operation of rear door to shut down for averting the danger.

Figure 3-1. Name and Function for the Operating Parts

2) Touch Screen Panel



No.	Name	Function
1	<Program Selection> Button	Operator can select one cycle among built-in 5 kinds of sterilization cycle and 2 kinds of test cycle by touching this button.
2	The set parameters of selected cycle program	The set exposure temperature, exposure time and dry time of the selected cycle program are displayed.
3	Load type display	The load and packaging type according to the cycle program are displayed.
4	Total Executed Cycle Times	The accumulated number of cycle times carried out is displayed.
5	Serial Number of the Sterilizer	The serial number of the sterilizer is displayed.
6	Date and Clock	The current date and clock is displayed by year.month.date / hour.minute.second.
7	Cycle Phase Indicator	The each phase of cycle in progress is indicated in yellow color.
8	<Printer Setting> Button	ON and OFF is displayed whenever pressing this button, and the cycle performance record is printed out when it is set ON.
9	<Silence> Button	The audible alarm sounded when an error has occurred during cycle running or cycle has completed is stopped by touching this button.
10	<Language> Button	The display language is changed by English or Korean alternately whenever touching it.
11	<START/STOP> Button	The cycle is started in ready state or stop the ongoing cycle by touching this button.
12	Loading Door state display icon	The current state of front side(loading) door as open or closed is indicated by graphic figure of this icon.
13	Unloading Door state display icon	The current state of rear side(unloading) door as open or closed is indicated by graphic figure of this icon.
14	<DOOR OPEN> Button	The sliding door is opened automatically by touching before cycle executing or after loading chamber.
15	<DOOR STOP> Button	The door is stopped by touching during moving door vertically.
16	<DOOR CLOSE> Button	The sliding door is closed automatically by touching before cycle executing or after loading chamber.
17	Remaining time display	The remainder time of each step of executing cycle is displayed by minute.
18	Actual temperature display	The actual temperature of chamber and jacket are displayed in real time during cycle executing.
19	Actual pressure display	The actual pressure of chamber and jacket are displayed in real time during cycle executing.

Figure 3-2. Graphic Composition and Function of Touch Screen

3) Panel Printer

The panel printer prints the cycle performance record at once when the cycle is completed only in case of setting it [ON]. Operating of the printer is as follows,

- (1) Holding the left and right side of front cover with one hand, pull it forward and the front cover will open downward.
- (2) Loosen the printing paper roll from the top slightly and put it horizontally into the recording paper holder in the panel printer.
- (3) Push up the front cover by hand and snap it closed.
- (4) When printing is completed, set the printed recording paper on the paper cutter and pull it up to be cut.



Figure 3-3. Panel Printer

3.2 Operation Procedure

1) Matters to be Attended before Operating

Carry out the vacuum leak test cycle before operating the sterilizer every day to check the leak of chamber and piping.

CAUTION

1. You should pay attention to a fire to come during operating the sterilizer.
Avoid contact skin directly to the part of the "Hot Surface" label stuck on the sterilizer.
2. Take the loads sterilized out from the chamber wearing the gloves after cooling the sterilizer for about 15 minutes after cycle completion, it prepares for a possible spouting of the hot steam remaining in the chamber.
3. Do not sterilize a toxic substance and the materials which are deteriorated, decolored, deformed or functionally disordered under heat and moisture. The special materials which are not confirmed about the effect under heat and moisture should be decided whether or not to sterilize definitely and the way of sterilization after getting confirmation from their manufacturer.



NOTE

1. The sterilization cycle is preceeded automatically as purge, condition, sterilize, vent, dry, air-in, complete.
2. The cycle is not started unless the door is locked.
3. If an error has occurred during operating, the ongoing cycle is aborted automatically and chamber pressure is recovered atmospheric for safety by the embedded self-diagnosis program.
4. The ongoing cycle is stopped if power failure or you touch <STOP> button during operating, but if the power is recovered automatically within the set time the cycle is restarted and proceeds continually from the stopped step by the resume function of the sterilizer.
5. The situation of cycle progressing and occurred error are displayed on the touch screen during operating and printer prints out the cycle performance record after completing the cycle.

The embedded cycle programs in the sterilizer are as follows,

Items	Basic Cycle					Test Cycle	
Cycle No.	P1	P2	P3	P4	P5 	Vacuum Leak (L.T)	Bowie-Dick (B.D)
Package Type	Wrapped		Un-wrapped		Liquid in the glass bottle	N/A	Test Pack
Air Removal	Vacuum	Gravity				Vacuum	
Exposure Temperature	134.0℃	134.0℃	134.0℃	121.0℃	121.0℃	134.0℃	134.0℃
Exposure Time	5 min	15 min	15 min	30 min	30 min	3 min	3.5 min
Dry Time	5 min	15 min	–	–	–	Dwell: 5 min Test: 10 min	–
Cooling Time	–	–	–	–	30 min		–

NOTE

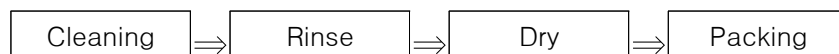
The liquid cycle(P5) has not been verified its compliance with EN 285:2015.

2) Preparations before Operation

- (1) Check the power, steam, water supplying and open the steam, water valve after placing the power cutoff switch on side.
- (2) The Bowie–Dick test and vacuum leak test is carried out firstly in case of applying pre-vacuum cycle, pre-vacuum cycle can not be applied if these test cycle is failed.

3) Preparation of the Loads to be Sterilized

All the medical devices, instruments and supplies to be sterilized should be cleaned and dried completely before sterilizing. The filth have to be removed from the devices and instruments immediately after using, and an ultrasonic washer and a washer–disinfector is useful for accomplishing this purpose for cleaning the difficult part by manual washing.



- (1) Remove the blood, organism, filth and foreign substances stained on the devices and instruments to be sterilized using a proper quality of water, detergent and method specified by the manufacturer of them. The saline solution must not be used for cleaning.
- (2) Rinse the cleaned devices and instruments with the distilled water or the purifies water by reverse osmosis method(RO water) completely not to remain the residue of detergent and stain on the devices and instruments.
- (3) Remove moisture from all the part of devices and instruments to be sterilized and dry completely (at least for 20 minutes at 60°C).
- (4) The materials of packing should be used the standard materials specified by the manufacturer of items to be sterilized.
- (5) Place the internal chemical indicator(CI) in the package and attach the external CI tape on the surface of package.

4) Chamber Loading and Unloading

Load the items to be sterilized in the chamber as follows by using the exclusive loading equipment.

The loading equipment is consisted of the loading car and carriage. The loading car is put on the rail of carriage and fixed to the carriage by the latch fitted on the rail. The items to be sterilized are loaded in the chamber in a state of putting on the shelf of loading car. The rail height of loading car should be leveled with the height of chamber rail for moving the loading car into the chamber. Adjust the caster height of loading car and level with the chamber rail height if the height between two rails is not leveled. Put on the protective gloves with long-neck for covering arms during loading.

- (1) Loading: In a state of door open, place the carriage loaded loading car in a straight line with the chamber rail and push slightly, then the two hooks placed in front of carriage are fitted to the bottom side of chamber rail and the loading car is fixed to the chamber. Push the loading car slightly lifting up the carriage release knob after checking the level of rail height between the carriage and chamber, then the loading car is slided into the chamber

along the rail. Pull the carriage forward pushing the carriage release knob after that the loading car is placed in the chamber completely and the carriage hooks are released from the bottom side of chamber rail, then the carriage is separated from the sterilizer.

- (2) Unloading: Take out the loads sterilized after cooling the chamber and loading car about 15 minutes for safety. Fix the vacant carriage to the chamber by the same manner of loading in a state of door open, pull the loading car out with a hand-held hook for unloading and put it on the carriage rail. Pull the carriage forward pushing the carriage release knob and is separated from the sterilizer.

CAUTION

1. Load the items to be sterilized in the chamber only using the loading equipment provided by the manufacturer.
2. Leave space between the packs or wrapped instruments when loading for complete air removal and free penetration of steam, and for good dry performance after sterilization phase.
3. Do not overload on the shelves of loading car as this can have adverse affects on the result of sterilization and drying.



WARNING

1. Sterilizer and loading car is hot after completion of cycle, always wear protective gloves, apron and goggle when unloading the sterilized loads.
2. The residual team may be released from the chamber when the door is opened after completion of cycle. Step back from the sterilizer each time the door is opened to minimize contact with steam.
3. The floor of loading and unloading area always should keep dry, wipe up immediately if any liquids or condensation have spilled in the floor, these may lead to injury by slip and fall.

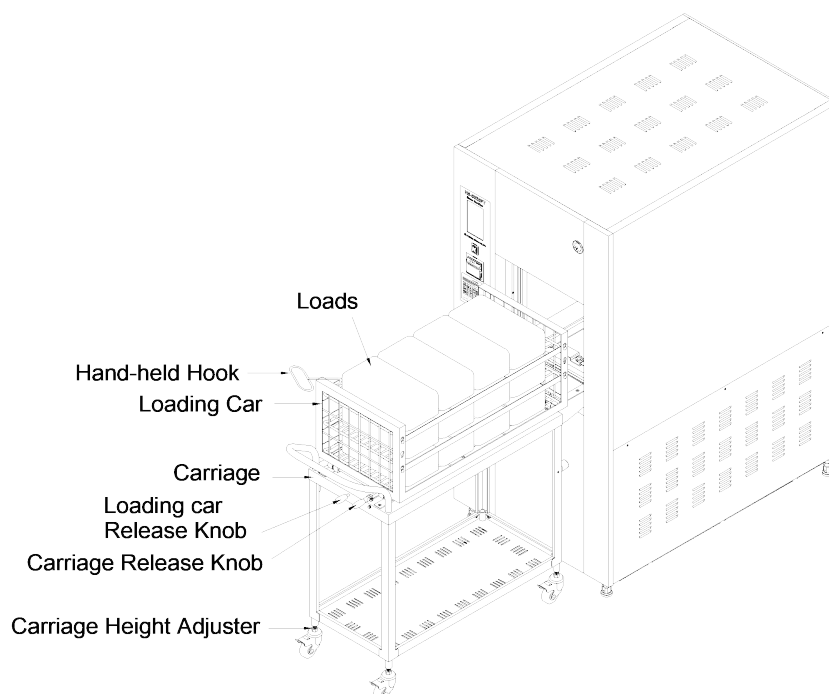


Figure 3-4. Loading Equipment

5) Turning Power On and Preheating

- (1) If you turn <POWER> switch on, the preheating notice is displayed on the touch screen as figure (1).
- (2) The set values(default) of the last cycle executed, the present date and time, the actual temperature and pressure in the chamber, door state[front(loading) door in case of single door type, front and rear(unloading) door in case of double door type] etc. are displayed on the touch screen.
- (3) The display language is able to change into Korean or English.
- (4) When the ready indicator is lit by yellow color after preheating as Figure (2), the selected cycle can be started by touching the <START> button.



Figure 3-5. Screen of Preheating and Ready State

6) Procedures of Performing Cycle

(1) Selecting of a cycle program

Touch <Program Selection> button and select a cycle program intend to carry out in the [Program Selection] screen shown below. The basic cycle programs can be selected automatically by touching <P1>~<P5> buttons, <L.T> button is for the vacuum leak test and <B.D> button is for the Bowie-Dick test.

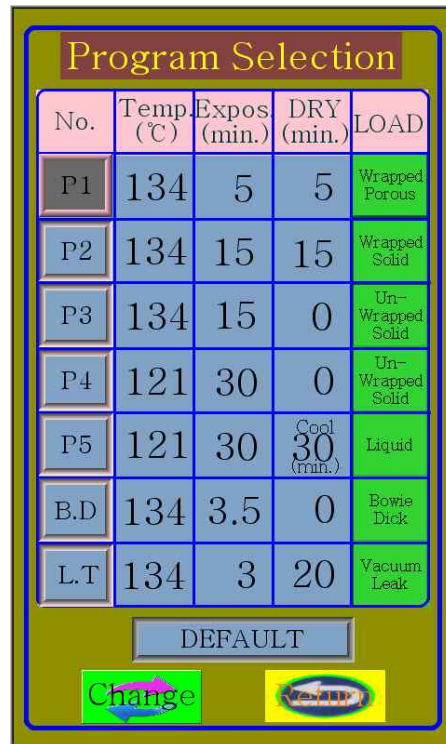


Figure 3-6. Program selection Screen

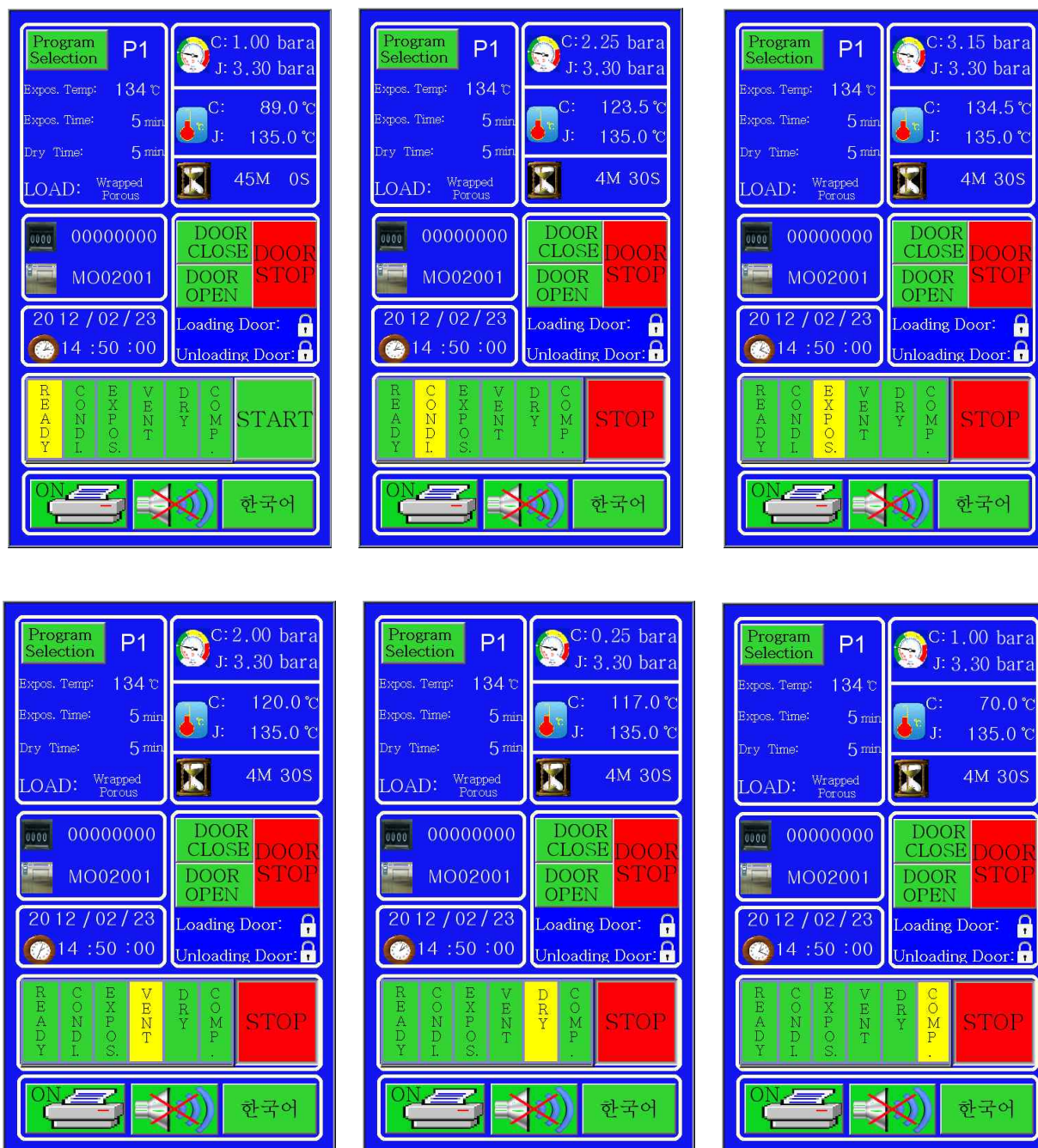
(2) Chamber loading and starting of sterilization cycle

Open the chamber door by touching <DOOR OPEN> button, load the items to be sterilized in the chamber for sterilizing and close door by touching <DOOR CLOSE> button. If you touch <DOOR STOP> button during the door moving, it stops to move. The door open icon on the screen is changed into the closed figure.

Touch <START> button when ready indicator is lit by yellow color after preheating, the cycle is proceeded automatically and each cycle phases are displayed on the screen as ready, condition, sterilization, vent, dry and completion. The operating state and the remaining time are displayed digitally on the screen in real time and the panel printer prints out the cycle performance record after completing the cycle in case of setting printer [ON].



(Single Door type)



(Double Door type)

Figure 3-7. Screens of Cycle Progressing

In case an audible alarm is sounded because of occurring an error during a cycle executing or cycle completion, touch <Silence> button and audible alarm will be stopped immediately.

Take the loads sterilized out after open the chamber door when cycle completion signal is sounded and judge the results of sterilization by checking the state of loads, the change of indicators and cycle performance record. Close the chamber door after unloading if you do not work any more.



(Single Door type)

(Double Door type)

Figure 3-8. Error Displayed Screen

(3) Cycle Cancel

Touch <STOP> button if you need to stop the cycle in progress and the checking window appears as below. Touch <Yes> button and then chamber is exhausted automatically for safety, and the screen is changed to ready state of atmospheric condition after through air-in process.



Figure 3-9. Screens of Cycle Stop Process

7) Changing of the Set Parameters of Cycle Program

The password input window like figure (1) appears if you touch <Change> button located on the bottom side of [Program Selection] screen. Touch the password window and input the password already set and press <ENT>, the [Program Change] screen like figure (2) appears. Select the set parameters intend to change and change them by using the keyboard on the touch screen, the new parameters are saved like figure (3) by touching <SAVE> button. Touch <DEFAULT> button for returning to the default value set initially and the screen is changed to the initial mode if you touch <Return> button.

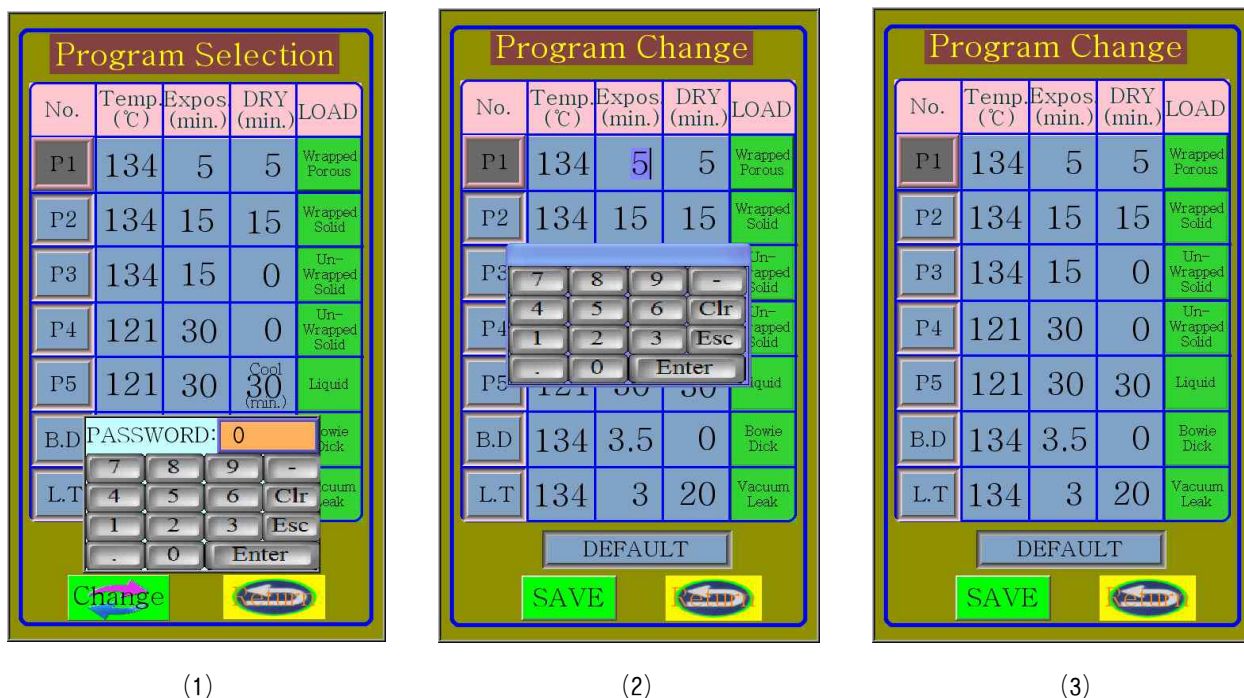


Figure 3-10. Screens of Cycle Parameter Change

8) Printer Setting

[ON] and [OFF] is displayed alternately whenever you touch <Printer Setting> button as below figures. The cycle performance record is printed out after cycle completion in case of setting it [ON].



Figure 3-11. Screen of Printer Setting

9) Adjusting of Date/Time

If the current date and time is not correct, touch the date and clock indicator on the touch screen at the initial mode and a keyboard for input number like figure (1) appears. Input the password already set correctly after touching password window and press <ENT>, then the display is changed to the date/time adjust mode like figure (2). Adjust the date(year/month/date) and time(hour:minute:second) by using keyboard and touch <ENT>, touch <SAVE> button successively, then date/time is displayed correctly and the screen returns to the initial mode. The display is not changed to the date/time adjust mode if a wrong password has been inputted.



Figure 3-12. Screens of Date/Time Adjusting

10) Vacuum Leak Test

Vacuum leak test should be performed before sterilization in condition of empty chamber every day. Close the door, select [L.T] cycle by touching <Program Selection> and touch <Return> button, then the vacuum leak test mode is displayed on the screen as below figure, the cycle starts to run as soon as press <START> button and proceeds to vacuum, dwell, test, air-in step automatically. Error code is displayed on the screen if the vacuum reaching time or leakage rate is out of the set value during cycle processing.

11) Bowie-Dick Test

Bowie-Dick test should be performed after preheating of the chamber and using specified test pack when the vacuum leak test is good. But since specifications such as type of test paper or test pack, size and changing of colour can vary depend on the products, you should follow the instruction or manual of their manufacturer. The test pack made by the user may be used occasionally. Place the test pack contained Bowie-Dick test paper on the most hard position to be sterilized in the chamber just like near drainage, don't load any other materials together with the test pack at this time. Lock the door, select the [B.D] cycle by touching <Program Selection> button and touch <Return> button, then the bowie-dick test mode is displayed on the screen, the cycle starts to run automatically as soon as touch <START> button. When the cycle is completed, take the test pack out and examine immediately. if the colour changing of the Bowie-Dick test paper is dark brown or black evenly, regard the test result as appropriate. There should be no record of "NG", Warning or Caution code on the cycle performance record.



Figure 3-13. Screens of Test Cycle

12) Liquid Cycle (P5)

The progressing of liquid cycle program is basically same with the wrapped and unwrapped cycle programs (P1~P4), but the differences are that the vent phase is performed slowly instead of fast exhaust and cooling phase is performed instead of dry.

NOTE

For the liquid cycle program, the vent is performed slowly after the sterilization phase has been terminated. The chamber is cooled down gradually as vapor would be condensed, and the chamber pressure is dropped. This process could prevent from boiling over or bursting the glass containers caused by the rapid change of pressure.

- (1) Select the liquid cycle program by pressing <P5> button at the [Program Selection] screen.

CAUTION



Do not apply the wrapped or unwrapped cycle program for sterilizing the liquid loads.

- (2) Load the liquid products to be sterilized into the chamber and lock the door.
- (3) Pressing <START>button, the selected cycle starts automatically and progresses in sequence of READY, CONDI., EXPOS., VENT., COOLING, COMP..



WARNING

1. The liquid should not exceed in 70% of the container capacity.
2. Leave the container open or use air vent lid. Don't use screw type or rubber lids.
3. Only borosilicate glass (Type I) should be used. Do not use ordinary glass container which is not suitable for the sterilization process.
4. Pay attention to handling the hot glass. Moving the container filled with boiling liquids may lead to burst.



CAUTION

1. Sterilization of chloride solution must cause corrosion in the chamber.
2. Sterilization time depends on the container capacity. Bigger containers require longer sterilization time(see Table 3-1. Recommended Exposure Time).
3. Putting the bottles with same capacity in the chamber is advantageous to a good result of sterilization.

Table 3-1. Recommended Exposure Time

Material to be Sterilized vs Minimum Time in Minutes	Gravity		Vacuum
	121 °C	132 °C	132 °C
INSTRUMENTS, metal only, in perforated tray, unwrapped	15	3	4
INSTRUMENTS, metal, unwrapped, combined with sutures, tubing or other porous materials	20	10	4
INSTRUMENTS, metal only, in lightly covered or padded tray	20	10	4
INSTRUMENTS, metal, combined with other porous materials, in lightly covered or padded tray	30	15	4
INSTRUMENTS, wrapped in muslin –4 thicknesses– for storage	30	15	4
GLASSWARE, empty, inverted	15	3	4
DRESSINGS, wrapped in paper or muslin	30	15	4
DRESSINGS, loosely packed, in canisters (on sides)	30	15	4
LINEN, packs, maximal size (12"x12"x20") and weight (12 lbs)	30	–	4
SYRINGES and NEEDLES, disassembled, lumen moist, individually packaged in muslin or paper	30	15	4
RUBBER GLOVES, wrapped in muslin or paper	20	–	4
RUBBER CATHETERS, DRAINS, TUBING (lumen moist), unwrapped	20	10	4
RUBBER CATHETERS, DRAINS, TUBING (lumen moist), individually packaged in muslin or paper	30	15	4
TREATMENT TRAYS, wrapped in muslin or paper	30	–	4
SOLUTIONS (square-pak bottles)			
75 ml~250 ml	20	–	–
500 ml~1,000 ml	30	–	–
1,500 ml~2,000 ml	40	–	–
UTENSILS, on edge, unwrapped	15	3	4
UTENSILS, on edge, wrapped in muslin or paper	20	10	4
REFERENCE: Perkins, J. J. : Principles and Methods of Sterilization in Health Sciences, 2nd ed. Springfield, IL., Thomas, 1983, p. 165, 166.			

13) The Way of Storing after Operation

- (1) After sterilizing, clean inside chamber as following the introduction manual if the sterilizer is not used for a long time.
- (2) Turn off the power cutoff switch and keep the steam and water supply valves close.
- (3) The water remained inside chamber and piping etc. should be removed completely beforehand in case the sterilizer is exposed to a sub-zero temperature.

14) Cycle Performance Record

The result of sterilization can be examined with the cycle performance record printed out by the panel printer.

Table 3-2. Cycle Performance Record (Example)				
Record			Description	
HANSHIN MEDICAL CO., LTD. FULL AUTOMATIC STERILIZER MODEL NO : HS-5025PT PROGRAM VER : V1.0.0			The manufacturer of sterilizer. The type of sterilizer. The model name of sterilizer. The version of control program	
STERILIZER NO : MO03001 CYCLE NO: # 1 (WRAPPED)			The serial number of sterilizer Cycle number executed and type of package	
CYCLE START TIME: 16:00:46 DATE: 2012/02/29 CYCLE COUNT: 00000004 EXPOSURE TEMP = 134℃ CONTROL TEMP = 135℃ EXPOSURE TIME = 5 Min. DRY TIME = 5 Min.			The time of a cycle started. The year, month, date of a cycle started. Total number of the cycles performed in this sterilizer. The set sterilizing temperature of the selected cycle. The set controlling temperature of the selected cycle. The set sterilizing time of the selected cycle. The set dry time of the selected cycle.	
	Time	T=℃	P=bar(a)	
P	16:00:46	43.6	1.01	1st column: P; Purge, H; Heat-Up, E; Exhaust, V; Vacuum, S; Sterilize, D; Dry, A; Air-In 2nd column: the start time of each step 3rd column: the temperature of each step 4th column: the pressure of each step
H	16:03:40	106.7	1.04	
E	16:04:07	113.1	2.00	
V	16:04:50	107.6	1.05	
H	16:06:29	96.6	0.30	
E	16:07:15	115.2	2.00	
V	16:07:57	107.3	1.05	
H	16:09:45	94.2	0.20	
E	16:10:30	115.0	2.00	
V	16:11:13	107.0	1.02	
H	16:12:43	97.5	0.20	
S	16:17:14	134.7	3.02	
E	16:22:14	134.8	2.99	
D	16:23:22	103.8	1.02	
A	16:28:22	70.9	0.08	
TEMP MIN:134.5℃		TEMP MAX:135.3℃		
PRES MIN:2.96bar(a)		PRES MAX:3.10bar(a)		
PURGE = 00:02:55 OK CONDITION = 00:13:31 OK STERILIZE = 00:05:00 OK EXHAUST = 00:01:07 OK DRY = 00:05:00 OK AIR IN = 00:00:30 OK TOTAL CYCLE = 00:28:05 ERROR CODE : NO			The time required for each step, total time of a cycle performed and the error code.	
Operate_____Date:				
Check_____ Date:				
Approve_____Date:				

3.3 Audible Signal

- 1) Click sound of touch screen button : Click sound is generated once whenever touching the button.
- 2) Cycle completion sound : An audible signal is sounded for 30 seconds at an interval of 0.1 second after cycle has been completed.
- 3) Warning sound : Warning signal is sounded at an interval of 0.5 second until <Silence> button is pressed in case of occurring an error during operating the sterilizer.

3.4 Error Code

The error code is displayed on the screen accompanying an audible warning signal by the embedded self-diagnosis program if an error has been occurred during operating the sterilizer. Warning signal is stopped by touching <Silence> button.

CODE	CAUSE	CODE	CAUSE
Err 1	Failure of vacuum leak test.	Err 12	Excess of vacuum release time.
Err 2	Overheating of the heater.	Err 13	Air filter expired
Err 3	Door open during cycle executing.	Err 14	Door locking time is delayed in the beginning of cycle start.
Err 4	Excess of temperature deviation	Err 15	Excess of preheating time.
Err 5	Control of atmospheric pressure in chamber is abnormal.	Err 16	Vacuum reaching time is delayed during condition step.
Err 6	Malfunction of the chamber pressure transducer.	Err 17	Heat-Up time is delayed during condition step.
Err 7	Malfunction of the jacket pressure transducer.	Err 18	4th heat-up time is delayed.
Err 8	Malfunction of the chamber temperature transducer.	Err 19	Excess of the exhaust time during exhaust step.
Err 9	Malfunction of the jacket temperature transducer.	Err 20	Door's gasket sealing failure
Err 10	Purge control pressure exceeds at the beginning of condition phase.	Err 22	Delay of front door operation
Err 11	Vacuum reaching time is delayed during dry phase.	Err 23	Delay of rear door operation

3.5 Safety Equipments

1) Safety Valve (RV1, RV2)

If the actual pressure in the jacket or steam generator exceeds the set value of safety valve, the safety valve is opened automatically and the over pressure is released safely.

2) Program for Sensing the Deviation of Sterilizing Temperature

If the actual sterilization temperature is out of the set range, the cycle is aborted automatically and sounds audible alarm signal, "Err 4" code is displayed on the touch screen

by this program.

3) Temperature Sensing and Control System by Temperature Transducer for Chamber (TT1) and Jacket (TT2)

This system senses the actual temperature in the chamber and jacket in real time by a built-in sensor which has the sensing range of 0.0~150.0℃, and also has a temperature limit program which controls the sterilization temperature within the range of 0.0~135.0℃. Transducer sends the temperature data to the controller and displays it on the touch screen by digital type.

4) Pressure Transducer (PT)

Transducer detects the actual chamber pressure during cycle executing for sending to the controller, the controller displays the actual chamber pressure on the touch screen and also controls the chamber pressure according to the set value.

5) Gasket Pressure Switch (PS4, 5)

The compressed air is introduced to the gasket cavity stucked around the chamber inlet as soon as cycle is started, then the gasket is swelled out and presses the door plate forward to seal the chamber. The gasket pressure switch senses the actual pressure in the gasket cavity and let the controller to keep the set gasket pressure.

6) Chamber Pressure Switch (PS2)

The pressure switch is operated while the chamber pressure is greater than the set value of pressure switch, and it does not allow the chamber door to open under pressure.

7) Main Circuit Breaker

The circuit breaker cuts the power off to protect the control circuits in case of inflow over current to the controller due to short circuit, insulation breakdown of the electrical components or the other caution.

8) 2nd Circuit Breaker

If over current is flown into the power input terminal, heat is generated and the contact point of auto fuse is opened automatically and then power supplying is cutoff immediately, therefore it is a second circuit breaker for protecting the control circuit of sterilizer. Push the buttons sprang out to the original position once, the contact point is connected and power is recovered. The standard product with the capacity specified in the wiring diagram should be used for replacing it.

9) Door Limit Switch

When the vertical sliding door is reached to the limit position of close or open designed mechanically, the door plate presses a limit switch fitted on the upper or lower side and the controller controls the driving motor in order to stop the door at an exact position.

10) Door Safety Bar

The door is equipped with a safety bar at the upper side and two micro switches inside, therefore if any object is touched to the safety bar during moving door upward to close, the door is stopped to move immediately by sensing it.

11) Emergency Stop Switch

If an actual or impending danger occurs while operating the door, pressing this switch quickly allows the operation of door to shut down for averting the danger.

3.6 Information for Access Code

1) Functions Requiring No Access Code ; Available to Operator.

- (1) Execution of the basic cycle program
- (2) Execution of the test cycle program
- (3) Adjusting of the power line voltage and power switch ON/OFF
- (4) Silence of alarm sound
- (5) Manual operation of the automatic sliding door if needed

2) Functions Requiring Access Code: Restricted to Supervisor.

- (1) Change of the cycle program parameters
- (2) Initial reset of the changed parameters
- (3) Setting of the user cycle program
- (4) Setting and changing of the new access code
- (5) Resetting of the Time/Date/Year

3) Maintenance and Troubleshooting of the Sterilizer : Restricted to Trained and Authorized Technician of This Field.

- (1) Adjust temperature and pressure sensor.
- (2) Troubleshooting the sterilizer.
- (3) Maintenance of the sterilizer.

4) Changing of the Control Program; Available only to Manufacturer.

- (1) Initial reset of the cycle counter number
- (2) Default value of the factory access code
- (3) Default function of the all controls
- (4) Default value of the all program (temperature, time, pressure control & display)
- (5) Default printing data of cycle performance record
- (6) Default of the LCD display format
- (7) Default of the self-diagnosis function

3.7 Techniques of Steam Sterilization

The information in this section is intended as a guide to steam sterilization techniques for the most common types of steam sterilizing articles and materials. Prior to sterilization, all materials and articles must be thoroughly cleaned. After sterilization, most goods should be stored for no longer than 30 days, depending on wrapping materials. For sterilization of articles or materials not covered in this section, contact the manufacturer of the article for the recommended procedure.

1) Principles of Steam Sterilization

Steam under pressure is the simplest and most reliable method available for sterilizing medical items in health-care facilities. Steam can be inexpensively produced and rapidly penetrates and heats a wide range of items to provide effective sterilization. Typical steam sterilization temperatures are 121°C and 134°C.

Effective steam sterilization requires the following:

- (1) Presence of saturated steam
- (2) Achievement of proper temperature
- (3) Exposure to steam for proper time

Steam sterilization relies on steam condensing on the item to be sterilized. When steam condenses, moisture and heat are transferred to the item. The presence of saturated steam assures that this transfer of heat and moisture occurs.

Removal of air from the sterilizer and items to be sterilized is absolutely essential for proper sterilization and achievement of saturated steam conditions. Air hinders the penetration of steam and protects microorganisms from the moisture in steam. Sterilizers are equipped with automatic air bleed valves. These valves remain open until air is removed from the sterilizer. Once air is removed, the valve closes to allow pressure to build up so that the set sterilization temperature can be reached.

The importance of moisture and saturated steam is illustrated by the fact that steam sterilization occurs within a few minutes at 134°C, while sterilization requires hours at that same temperature when little or no moisture is present (i.e., dry-heat sterilization).

The presence of saturated steam can be determined by monitoring the sterilizer temperature and pressure during the sterilization phase (i.e., once unit has reached set temperature). When saturated steam conditions exist, there is correlation between temperature and pressure.

Temperature and pressure should be monitored each cycle to assure proper sterilization conditions are present. The recommended amount of water must be placed in the sterilizer and the air vent properly functioning to assure adequate air removal and achievement of saturated steam.

Selection of proper sterilization time and temperature is critical to ensure that the entire contents of the load are exposed to steam long enough to assure sterilization. The time/temperature combinations for particular loads have been thoroughly tested to give sufficient time for steam penetration. These are minimum recommendations and should be

strictly followed.

Items to be wrapped should only be wrapped in appropriate sterilization wraps or pouches. Fabric and hard goods packs should be placed on edge to aid in air removal and facilitate proper drying. Do not overload sterilizer. Items should be placed in the tray so that steam can surround each pack.

As a check on the overall process (i.e., pack preparation, sterilizer loading and sterilizer operation), biological indicators containing *B. stearothermophilus* spores should be run at least weekly.

2) Cleaning of Loads

(1) Instruments: Cleaning the instruments immediately after use is most effective. Disassemble that assembled devices and unlock that locked devices and wash with water. At this time, every debris of dirt should be removed completely. Then, wash out cleanly with warm water and an appropriate detergent and apply water-soluble instrument lubricants, specifically designed for sterilization.

(2) Lumens: Catheter, syringe needle, and tube should be washed cleanly and remove moisture, then soak with distilled water. Pack it with moisture remained in the tube and sterilize immediately (at least within 24 hours) for achieving effective sterilization and prevention of pyrogen generation.

(3) Textiles: Wash out cleanly immediately after use and dry completely before sterilize.

3) Wrapping Fabrics and Hard Goods

Wrapping of packs, instrument sets, and other porous materials provides protection against recontamination when the items are removed from the sterilizer.

The protective wrapping also serves as protection against contact contamination in handling, guards against the entry of insects, etc., and serves as a dust filter for normal storage of sterilized goods. Use steam-sterilization wrappers for surgical supplies to provide protection after sterilization.

NOTE

Muslin of 140 thread count is the present standard for steam sterilization. The manufacturers of other materials should show data that indicates their product is equivalent to or better than the muslin profile in steam sterilization, drying and sterility maintenance.

Use of freshly laundered 140 thread count muslin (or equivalent) helps prevent superheating and provides longer life of the textiles. You may also use non-woven wrap, self-seal and heat-seal pouches.

All fabric packs should be placed on edge, and arranged in chamber to allow for maximum exposure (i.e., minimal resistance for steam passage through the load).

Also place utensils and treatment trays on edge so they will be sterilized and dried properly.

Instrument sets should be placed flat in tray having perforated bottom (or equivalent).

When processing mixed loads combining fabrics and hard goods, place the hard goods on

the lower tray or rack. This prevents wetting of muslin packs from condensate dripping from hard goods load.

Remove any caps from and invert empty jars, canisters and all other nonporous containers to facilitate sterilization and drying.



CAUTION

DO NOT OVERLOAD STERILIZER. Allow for steam penetration between packs. Avoid contact of load components with the walls of the chamber.

4) Avoiding Wet Packs

A major factor governing the sterility of supplies is a "state of dryness." Wet materials may transmit bacteria, therefore a "state of wetness" could compromise the sterility of processed packs and instruments.

No single factor stands out as the primary cause of wet packs, but rather several factors should be considered. Wet pack conditions occur in various:

- (1) types of loads (i.e., instrument sets, utensil sets, textile packs, and steam-sterilized plastic, paper, or all-plastic peel pouches).
- (2) types and sizes of wrappers (i.e., reusable textiles of all thread counts, disposable cellulose-based, and disposable polypropylene-based).
- (3) pack preparation and sterilizer loading techniques.

Following are some guidelines for evaluating packs for acceptable drying.

- (1) External droplets or visible moisture on the exterior of the pack, or on the tape, are unacceptable unless that wrap is completely impermeable to water (e.g., plastic film).
- (2) Water droplets on the interior of a wrap (unless it is completely water impermeable), or on the items within the pack are unacceptable.
- (3) A pack is unacceptable if the pack is damp or wet when opened for use. A general guideline is that the pack be completely dry after cooling at room temperature (i.e., 21°C and 50% relative humidity) for a minimum of one hour following removal from the sterilizer. (If the room temperature and relative humidity vary from these recommendations, a longer drying time and increased cooling time may be necessary before the packs are handled or stored).

These guidelines are not intended to be the final word in establishment of wet pack criteria, but serve as a basis for evaluating sterilized packs to assure an acceptable "state of dryness".

5) Sterilizing of Liquids

This sterilizer is designed to sterilize the liquid load only using borosilicate flask with a poromeric lid. Sterilization of liquid load in any other flask or with the use of non-poromeric lid requires a sterilizer specially designed for that purpose.

Borosilicate glass is recommended because it is a superior glass capable of resisting higher pressure, thermal shock (such as cold air striking the hot glass) and of withstanding repeated

handling. Poromeric lid is required because it will relieve the excessive pressure in the flask.

If other types of glass (such as flint glass) and non-poromeric(sealed) lids are used to sterilize liquid load in the sterilizer, dangerous condition which is capable of causing personal injury and property damage is created. If the liquid load and residual air in a sealed flask is heated and expanded, it's created an internal pressure greater than the external pressure of steam, then the glass becomes weaker and potential of bursting is more greater. After the sterilization exposure, the chamber is exhausted slowly but it still exhausts more rapidly than the pressure in the sealed flask. This pressure will exist until the residual air and the liquid load have cooled down in case of applying non-poromeric lid, the burst potential exists and cause personal injury or property damage.

4. OPERATION THEORY

The following explanation of processing has been accomplished on the basic theory of a cycle operating refer to Figure 4-1~4-7 (Cycle graphs)

4.1 Preheating Phase

- 1) Turning <POWER> switch on, touch screen panel is lit and preheating mode is displayed after a while. In case of using the built-in boiler, boiler is operating.
- 2) In case of the double door type, the compressed air is introduced to the sub door gasket cavity through the gasket air selection valve and the sub door gasket control valve, then the gasket is swelled out and contacted airtightly with the door plate. In this way the sub door remains locking until the sterilization cycle has been completed.
- 3) The jacket steam supply valve and the drain cooling valve starts operating, and the fast exhaust valve and the filtered air valve, the vacuum water valve and the boiler water in 1, 2 valves begin controlling. Steam is introduced into the jacket and pressure and temperature in the jacket is rising.

4.2 Ready Phase

- 1) When temperature in the jacket is reached up to the set value, the ready phase is started by control of the temperature transducer.
- 2) According to control of the jacket temperature transducer, the jacket steam supply valve is controlling to maintain the set jacket temperature.
- 3) The fast exhaust valve, the filtered air valve and the vacuum water valve remain controlling. The drain cooling valve continues to open.
- 4) Boiler operation is changed to control state and the boiler water 1, 2 valves maintains controlling.
- 5) Open the door(the main door in case of the double door type) and loading the articles to be sterilized in the chamber, and then close the door. If the door is locked, door lock icon is displayed on the touch screen.

4.3 Purge Phase

- 1) The purge phase is began as soon as you touch the <START> button.
- 2) The compressed air is introduced to the main door gasket cavity through the gasket air selection valve and the main door gasket control valve, then the gasket is swelled out and presses the door plate forward and the chamber is sealed. Since then, the valves continue to control to maintain the set pressure in the gasket cavity.
- 3) The chamber steam supply valve and the drain cooling valve, the fast exhaust valve and the vacuum water valve are opened and closed three times(four times for a gravity air replacement cycle) alternately for generating the pressure pulse in the chamber.

- 4) This step intends to remove air in the chamber completely, the pulse process is finished and the cycle proceeds to the condition phase automatically when the pressure is reached to the third lower limit value(fourth lower limit value for a gravity air replacement cycle).
- 5) The jacket steam supply valve maintains controlling.
- 6) The boiler water in 1, 2 valves keeps controlling.

4.4 Condition Phase

When the purge process has finished, the cycle proceeds to the condition phase. The vacuum cycle is consisted of the pulse and heat-up process, and the gravity type cycles and liquid cycle have only the heat-up process.

1) Pulsing process :

- (1) According to the control of chamber pressure transducer, the pulsing operation is performed that the chamber steam supply valve and the drain cooling valve, the fast exhaust valve and the vacuum water valve are opened and closed three times alternately.
- (2) This process is designed to remove residual air in the loads and chamber completely, when the third pressure is reached to lower limit and the pulsing is terminated, the step proceeds to heat-up automatically.
- (3) The jacket steam supply valve maintains controlling.
- (4) The boiler continues to control.

2) Heat-up Process :

- (1) The jacket steam supply valve maintains controlling.
- (2) According to the chamber temperature transducer control, the chamber steam supply valve and the drain cooling valve are opened. When the chamber is reached to the set sterilizing temperature, the cycle proceeds to the sterilization phase automatically.

4.5 Sterilization Phase

- 1) The chamber steam supply valve is controlling by the chamber temperature transducer for maintaining the sterilizing temperature in the chamber. The drain cooling valve continues operation.
- 2) The jacket steam supply valve maintains controlling.
- 3) After the set sterilizing time has completed, the cycle proceeds to the exhaust phase according to the program.

4.6 Exhaust Phase

Exhausting is classified by two types as follows.

1) Fast Exhaust : In case of applying cycles such as P1, P2, P3 and P4.

- (1) The chamber steam valve and the drain cooling valve are closed.

- (2) The steam in the chamber is exhausted quickly when the fast exhaust valve and the vacuum water valve are opened.
 - (3) The jacket steam supply valve maintains controlling.
 - (4) When chamber pressure is dropped to the atmospheric pressure, the exhaust phase is terminated by sensing of the chamber pressure transducer.
- 2) Slow Exhaust : In case of applying the liquid cycle(P5).
- (1) The drain cooling valve continues operating.
 - (2) The chamber steam supply valve and the jacket steam supply valve stop controlling.
 - (3) The fast exhaust valve and the vacuum water valve are closed.
 - (4) Chamber steam is exhausted through the needle valve slowly. The exhaust time is proper between 15 and 30 minutes. As the chamber pressure is dropped to the atmospheric pressure, the exhaust phase is terminated.

4.7 Dry Phase

- 1) The fast exhaust valve and the vacuum water valve are operating continually and exhaust steam remaining in the chamber.
- 2) Chamber pressure maintains the set vacuum level and dry the loads. But this step does not required for the unwrapped instruments and liquid cycle.
- 3) The jacket steam supply valve maintains controlling.

4.8 Air-In Phase

- 1) The fast exhaust valve and the vacuum water valve stop operation.
- 2) The filtered air valve is opened and air flows into the chamber. At the same time, the drain cooling valve operates.
- 3) The jacket steam supply valve maintains controlling.
- 4) The cycle proceeds to the completion phase automatically when the chamber pressure is recovered atmospheric pressure.

4.9 Cooling Phase

The cooling phase is applied only to the liquid cycle program for safety of glass bottles. The cooling phase is continued for 30 minutes.

- 1) The drain cooling valve continues operating
- 2) The chamber steam supply valve and jacket steam supply valve stops controlling.
- 3) The filtered air valve, fast exhaust valve and vacuum water valve is closed.

4.10 Complete Phase

- 1) The sub door gasket release valves operates and the compressed air is removed from the

gasket cavity, then the pressure formed between the door plate and gasket is dropped and the chamber sealing is released, therefore the sub door is able to open for unloading.

- 2) The fast exhaust valve, the jacket steam supply valve maintain controlling and the filtered air valve, the drain cooling valve operate continuously.
- 3) The printer prints out the cycle performance record.
- 4) The buzzer sounds an audible signal for 30 seconds in 0.1 second interval. The audible signal is stopped by touching the <Silence> button.
- 5) Open the door and take out the loads form the chamber. In case of the double door type, unload through the sub door in the clean area because the main door is controlled not be opened at this time. Close the sub door after unloading, then the sub door is locked automatically and the sterilizer is returned to the ready phase for performing the next cycle.

4.11 Ready for Successive Cycle

When the completion phase is finished, screen automatically returns to the ready phase of the selected cycle program lastly. The purpose of this phase is to maintain continuity with the next cycle.

- 1) The fast exhaust valve and the filtered air valve are controlling and the drain cooling valve continues to operate.
- 2) The jacket steam supply valve continues to control.
- 3) In the ready phase, load the articles to be sterilized in the chamber using the loading equipment and close the door. For the double door type, open the main door and load the articles to be sterilized in the chamber, the sub door is controlled not to be opened at this time. If you intend to run the previous cycle program continually, start the cycle by touching the <START> button.

4.12 Cycle Graph and Piping Schematic

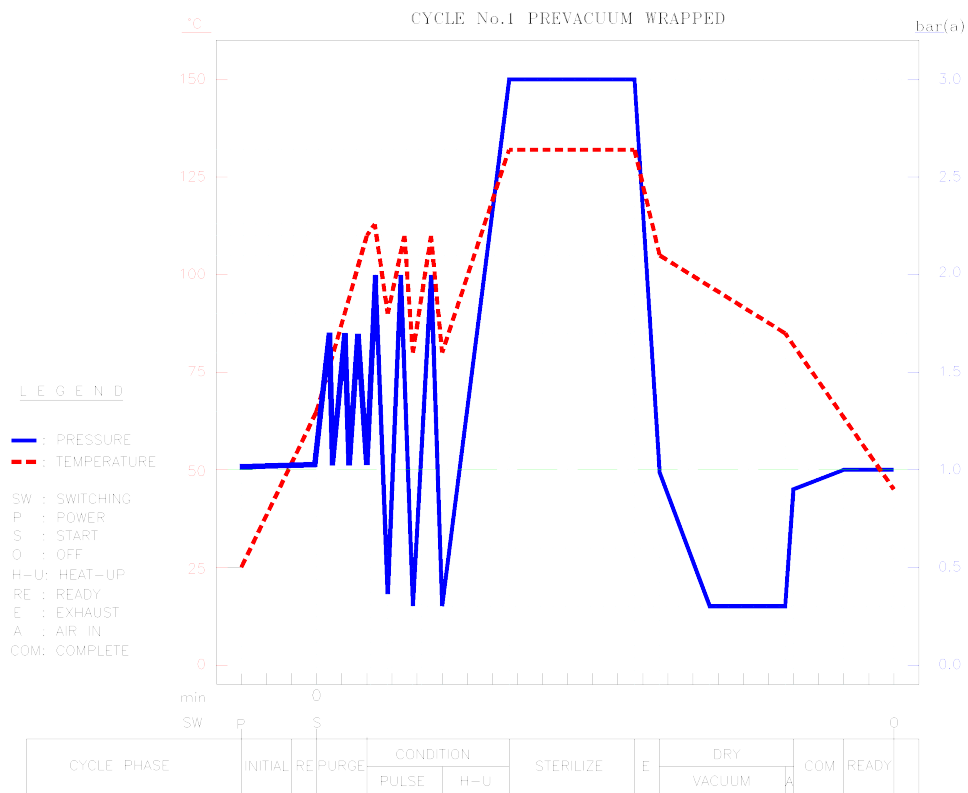


Figure 4-1. Basic Cycle Graph (P1)

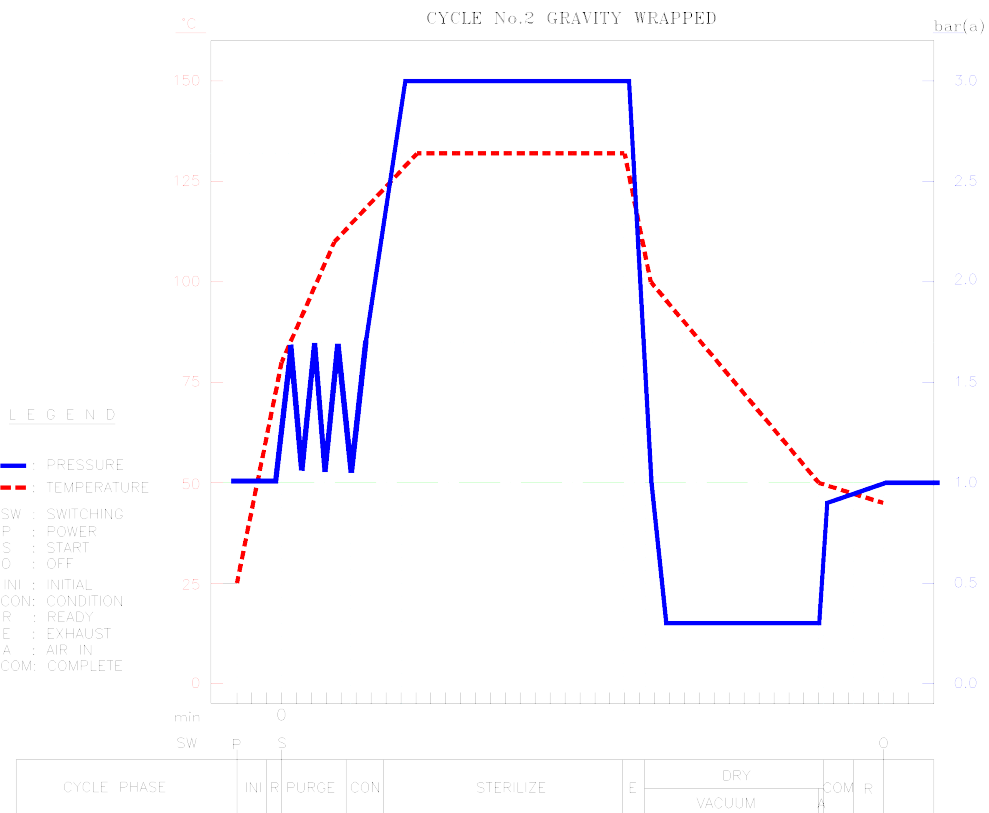


Figure 4-2. Basic Cycle Graph (P2)

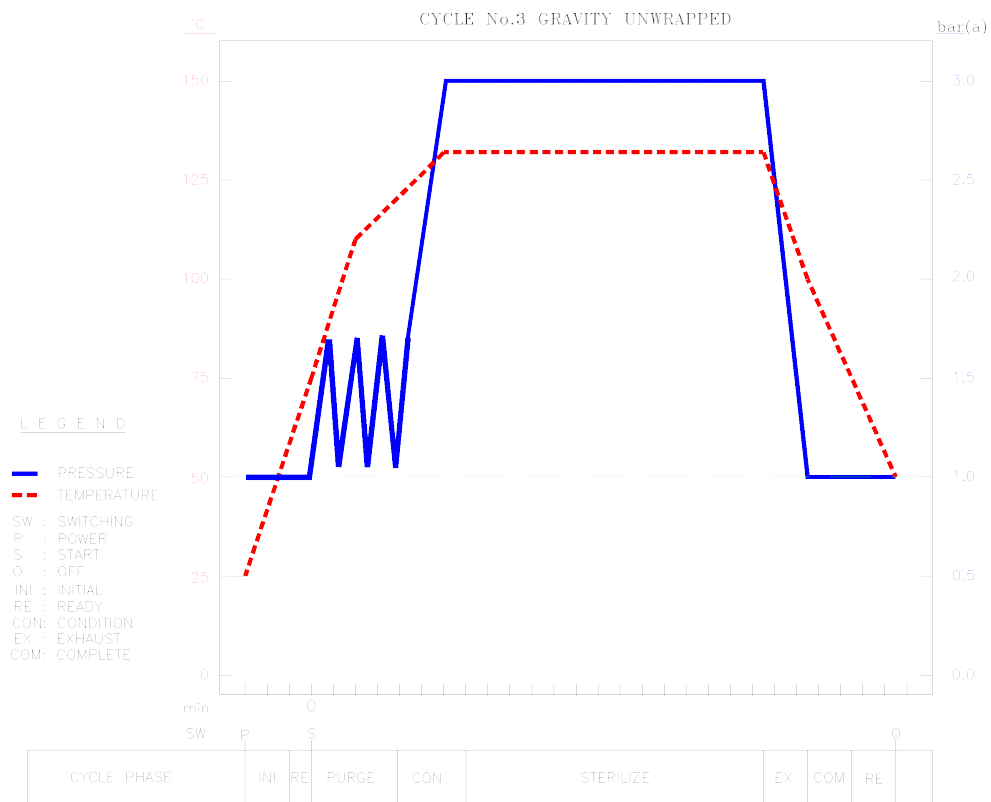


Figure 4-3. Basic Cycle Graph (P3)

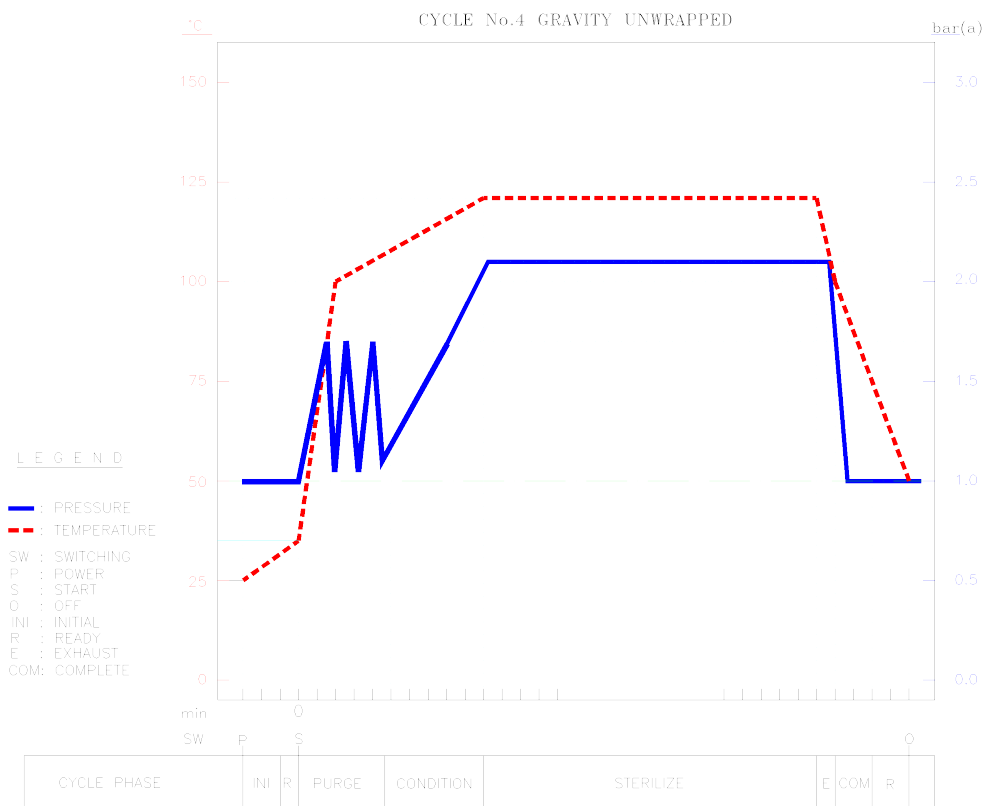


Figure 4-4. Basic Cycle Graph (P4)

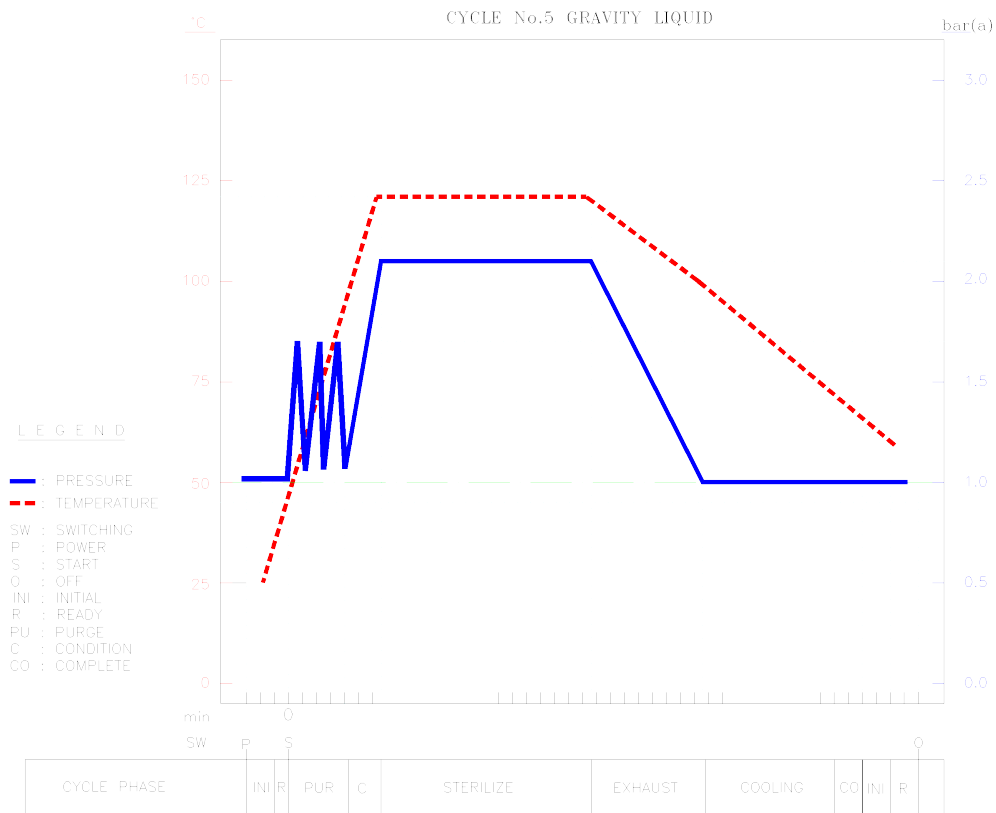


Figure 4-5. Basic Cycle Graph (P5)

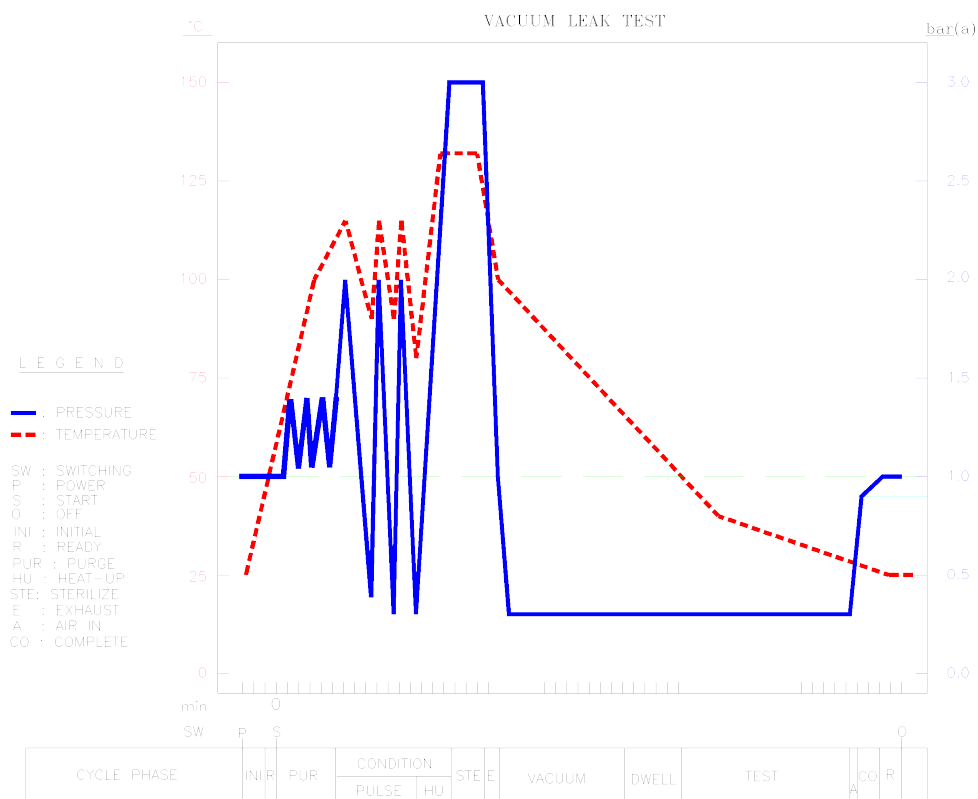


Figure 4-6. Test Cycle Graph (Vacuum Leak Test)

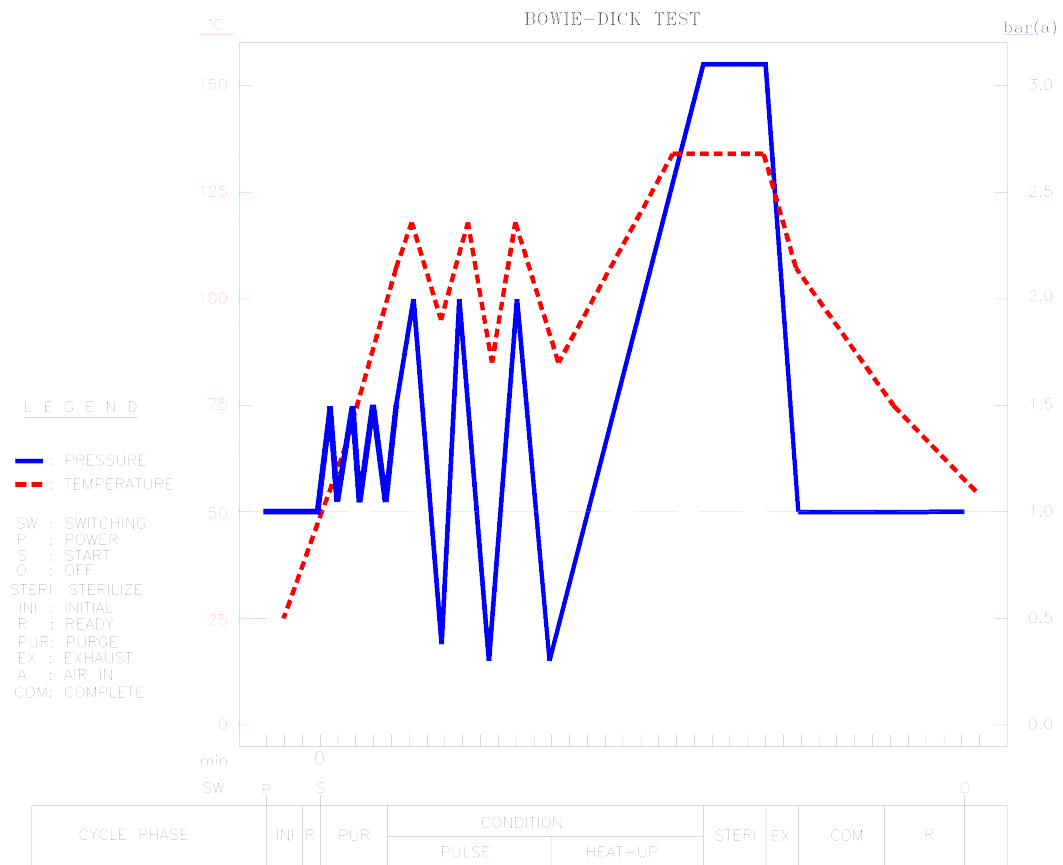


Figure 4-7. Test Cycle Graph (Bowie-Dick)

5. TROUBLESHOOTING

If an error has occurred during operating the sterilizer, it is detected and analysed by the embedded self-diagnosis program, the error code is displayed on the touch screen, an audible alarm is sounded and the cycle in progress is aborted automatically for safety, audible alarm is stopped by touching <SILENCE> button. The cause and proper action for the occurred error is as in table 5-1.

Table 5-1. Error Code			
Error Code	Trouble	Possible Cause	Action
0 1	Vacuum leak test fail ●Standard: within 1.3mbar/min	① Leakage of door gasket. ② Chamber steam supply valve(SV1) open. ③ Filtered air valve(SV3) open. ④ Defective chamber check valve(CV3). ⑤ Defective fast exhaust valve(SV2).	Stop audible alarm and check leak cause, repair. Check item: 1, 6, 7, 8, 17
0 2	Overheating of boiler heater	① Defective control circuit of boiler ② Improper water supply to boiler. ③ Low water level of boiler. ④ Defective water level sensor. ⑤ Defective water supply valves (SV7,8) of boiler. ⑥ Defective water pump of boiler.	Stop audible alarm firstly, cutoff the main power and turn off the power switch of boiler, repair after cooling the boiler. Check item: 12, 20, 21, 24.
0 3	Door unlock during cycle running	① Defective gasket air control valve (SV9, 10, 12) ② Improper steam pressure. ③ Defective door gasket. ④ Defective control circuit. ⑤ Defective driving motor. ⑥ Defective door locking limit switch.	Stop audible alarm and repair. Check item: 1, 2, 22, 29, 30
0 4	Excess of temperature deviation during sterilizing ●Standard: within +3.0℃	① Defective control circuit. ② Improper steam pressure. ③ Improper control of chamber steam supply valve(SV1). ④ Chamber drain filter(DF1) was clogged. ⑤ Defective fast exhaust valve(SV2). ⑥ Leakage of door gasket. ⑦ Defective jacket steam supply valve(SV6).	Stop audible alarm and repair. Check item: 1, 2, 3, 4, 6, 7, 9, 11, 13, 14, 16, 17, 19.

Table 5-1. Error Code			
Error Code	Trouble	Possible Cause	Action
0 5	Malfunction of the atmospheric pressure control	① Defective chamber steam supply valve(SV1). ② Defective fast exhaust valve(SV2). ③ Defective filtered air valve(SV3). ④ Defective vacuum water valve(SV5). ⑤ Chamber drain filter(DF1) was clogged. ⑥ Defective chamber check valve(CV3). ⑦ Defective vacuum water pump(WP1). ⑧ Defective control circuit.	Stop audible alarm and repair. Check item: 4, 5, 6, 7, 8, 9, 17, 18, 25, 26.
0 6	Malfunction of the chamber pressure transducer	① Defective pressure probe. ② Disconnection of probe lead wire. ③ Defective control circuit. ④ Faulty connection of PT1.	Check item: 18.
0 7	Malfunction of the jacket pressure transducer	① Defective pressure probe. ② Disconnection of probe lead wire. ③ Defective control circuit. ④ Faulty connection of PT2.	Check item: 27.
0 8	Malfunction of the chamber temperature transducer	① Defective temperature probe. ② Disconnection of probe lead wire. ③ Defective control circuit. ④ Faulty connection of TT1.	Check item: 19.
0 9	Malfunction of the jacket temperature transducer	① Defective temperature probe. ② Disconnection of probe lead wire. ③ Defective control circuit. ④ Faulty connection of TT2.	Check item: 19.
1 0	Excess of control pressure during purge step	① Defective chamber drain steam trap(TR1), check valve(CV10, 3, 5). ② Defective chamber steam supply valve(SV1). ③ Improper vacuum water pressure. ④ Chamber drain filter(DF1) was clogged. ⑤ Steam input/output strainer(ST1, 4) was clogged. ⑥ Defective control circuit. ⑦ Defective fast exhaust valve(SV2)	Check item: 6, 7, 11, 14, 15, 16, 17
1 1	Excess of vacuum reaching time during dry phase	① Fast exhaust valve(SV2) is not opened. ② Vacuum water valve(SV5) is not opened. ③ Filtered air valve(SV3) is not closed. ④ Leakage of door gasket. ⑤ Chamber drain filter(DF1) was clogged. ⑥ Lack of vacuum water. ⑦ Defective vacuum water pump(WP1).	Check item: 1, 3, 4, 5, 6, 7, 8, 10, 13, 14, 17, 18, 25, 26

Table 5-1. Error Code			
Error Code	Trouble	Possible Cause	Action
1 2	Excess of vacuum releasing time ●Standard: within 20min	① Air filter(AF1) was clogged. ② Filtered air valve(SV3) is not opened appropriately. ③ Defective air check valve(CV4).	Check item: 5, 8.
1 4	Excess of door lock time at the beginning of cycle starting ●Standard: within 2min	① Defective gasket air control valves (SV9, SV12). ② Defective door driving motor. ③ Improper tension of door driving wire. ④ Defective control circuit.	Check item: 29, 30
1 5	Excess of preheating time ●Standard: within 60min	① Improper jacket steam pressure. ② Defective jacket steam supply valve(SV6). ③ Steam input/output strainer(ST1, 3) was clogged. ④ Defective jacket drain steam trap(TR2) ⑤ Defective control circuit.	Check item: 2, 11, 14, 15, 19.
1 6	Excess of vacuum time ●Standard: within 30min	① Improper vacuum water pressure. ② Leakage of door gasket. ③ Chamber drain filter(DF1) was clogged. ④ Water ejector(WE1) was clogged. ⑤ Chamber steam supply valve(SV1) and filtered air valve(SV3) are open. ⑥ Fast exhaust valve(SV2) and vacuum water valve(SV5) are not opened appropriately.	Check item: 1, 3, 4, 6, 7, 8, 10, 14, 17, 18, 25, 26.
1 7	Excess of heat-up time during heat-up step ●Standard: within 30min	① Improper steam supplying pressure. ② Jacket steam supply valve(SV6) and chamber steam supply valve(SV1) are not opened appropriately. ③ Excessive pressure discharge through the chamber drain steam trap(TR1). ④ Fast exhaust valve(SV2) is not closed.	Check item: 1, 2, 6, 7, 11, 13, 16, 17.
1 8	Excess of reaching time to sterilizing temperature ●Standard: within 30min	① Improper steam supply pressure. ② Chamber steam supply valve(SV1) and jacket steam supply valve(SV6) are not opened appropriately. ③ Fast exhaust valve(SV2) is not closed appropriately. ④ Excessive pressure discharge through the chamber drain steam trap(TR1).	Check item: 1, 2, 6, 7, 11, 13, 14, 16, 17.

Table 5-1. Error Code			
Error Code	Trouble	Possible Cause	Action
1 9	Excess of exhaust time ●Standard: within 60min	① Chamber drain filter(DF1) was clogged. ② Chamber steam supply valve(SV1) is open. ③ Fast exhaust valve(SV2) is close.	Check item: 4, 6, 7, 9, 10, 14, 16, 17, 18, 31, 25, 26.
2 0	Door's gasket sealing failure	① Door's gasket vacuum valve does not open	Check item: 1, 10
2 2	Delay of main door operation ●Standard: within 2min	① Defective door driving motor. ② Malfunction of limit switch for door operation. ③ Defective relevant SSR.	Check item: 22, 23, 30
2 3	Delay of sub door operation ●Standard: within 2min	① Defective door driving motor. ② Malfunction of limit switch for door operation. ③ Defective relevant SSR.	Check item: 33, 34, 35

Table 5-2. Check Item List	
No.	Item Name
1	Door gasket
2	Steam supply ball valve(BV1)
3	Water supply ball valve(BV2)
4	Chamber drain filter(DF1)
5	Air filter(AF1) & Check filter(CV4)
6	Chamber steam supply solenoid valve(SV1)
7	Fast exhaust solenoid valve(SV2)
8	Filtered air solenoid valve(SV3)
9	Drain cooling solenoid valve(SV4)
10	Vacuum water supply solenoid valve(SV5)
11	Jacket steam supply solenoid valve(SV6)
12	Water supply pump to boiler(WP2, WP3)
13	Needle valve for slow exhaust(NV1)
14	Steam input/output strainer(ST1, ST2, ST3, ST4)
15	Steam trap for jacket drain(TR2)
16	Steam trap for chamber drain(TR1)
17	Steam input/output check valve(CV1, CV2, CV3, CV5, CV7, CV10)
18	Chamber pressure transducer(PT1)
19	Chamber and jacket temperature transducer(TT1, TT2)
20	Water supply solenoid valve for boiler(SV7, SV8)
21	Water supply check valve for boiler(CV6)
22	Limit switch for main door close
23	Limit switch for main door open
24	Drain ball valve of boiler(BV3)
25	Water supply pump(WP1)
26	Strainer for water supply line(ST5)
27	Jacket pressure transducer(PT2)
28	Gasket pressure switch(PS4, PS5)
29	Gasket air control solenoid valve(SV9, SV10, SV12)
30	Door driving motor
31	Needle valve for drain cooling(NV3)
32	Needle valve for sensing the jacket temperature sensor(NV2)
33	Limit switch for sub door close (Double door type)
34	Limit switch for sub door open (Double door type)
35	Sub door driving motor (Double door type)

6. MAINTENANCE

Routine checkup and simple preventive maintenance could be done by user, but repair, calibration and adjustments should be accomplished by the qualified service personnel. It is essential that the sterilizer should be checked periodically and maintained in advance for smooth operation.

WARNING



1. The main circuit breaker must be got off and cut off power supplying to the sterilizer for preventing human injury by an electric shock during carrying out preventive maintenance or repair.
2. The whole operation should be started when the sterilizer has been cooled down to ambient temperature.

CAUTION



1. The preventive maintenance, calibration, adjustment and repair should be carried out by the qualified service personnel.
2. The standard parts approved by the manufacturer of sterilizer should be used when replacing the parts.
3. The damaged sterilizer resulted from being ignorant of observing the caution is not guaranteed the free repair service even though it is under warranty.
4. The manufacturer or supplier have not any responsibilities for the human injuries or property damages resulted from being ignorant of observing the warning and cautions.

6.1 Routine Checkup and Actions by Operator

Operator should check the sterilizer everyday before sterilizing and act as follows,

- 1) Check the cleanness of exterior, inside chamber, door and clean them if needed.
- 2) Check the gasket for chamber sealing and replace it if deformed or damaged, clean it if incrustated with a foreign substance.
- 3) Check if the door moving is smooth and, if not, contact the manufacturer or supplier for proper service.
- 4) Contact the manufacturer or supplier in case the vacuum leak test is failed.
- 5) Check the remainder of printing paper roll and replace it with a new one if shorted.

6.2 Preventive Maintenance

User should perform inspection periodically and action as Table 6-1.

Table 6-1. Preventive Maintenance Plan		
Check Item	Period	Procedure
1. Chamber drain filter cleaning	Daily	①Separate the drain filter placed the front bottom side of chamber. ②Remove the foreign matters from the hole of filter and clean completely. ③Execute one cycle without any load in the chamber after cleaning.
2. Inside chamber cleaning	Weekly	①Clean inside chamber, inside door and gasket with a cotton soaked in detergent completely, and remove moisture with a dry cloth after rinsing with clean water. ②Execute one cycle without any load in the chamber after cleaning.
3. Automatic sliding door unit Inspection and cleaning	Weekly	①Inspect and clean the each part of the door. ②Check door locking and unlocking status. ③Inspect automatic operating state of the door. ④Inspect the operating state of driving motor. ⑤Consult with the manufacturer or supplier if there is problem after checking.
4. Door gasket Inspection and replacement	Weekly	①Inspect if the gasket was deformed, damaged and its elasticity. ②Replace the defective gasket immediately after inspecting and replace at least every 1 year.
5. Safety valve Inspection	Every 3 Months	①Pull the release pin of the safety valve in a state of existing pressure. ②The release pin should be returned when pressure has been released. WARNING  Wear the personal protective equipments(PPE) to prevent an accidental burns when giving off steam. ③Check the crack or steam leaked part, and remove foreign substances, dust. ④Consult the manufacturer or supplier if the problems are not solved and persisted.
6. Air filter (HEPA filter) inspection and replacement	As required	①Inspect whether the air filter has a problem if the vacuum release time is exceeded in the set time when executing the vacuum leak test cycle. ②Replace the defective air filter immediately if it has a problem. ③Replace the air filter every 1,500 cycles run.

1) Cleaning of Chamber

- (1) Chamber should be cleaned periodically, remove the fragments of foreign matter, cloth patches and any debris from the chamber. The chamber drain screen should be inspected and cleaned after lifting it up.
- (2) It must clean immediately to prevent solidifying and corroding when the solution was spilled on the chamber floor. Wash all interior surfaces with a mild detergent solution and rinse with water. Clean the shelves and loading car in the same manner.

CAUTION



1. Cleaning shall be carried out safely after the sterilizer is cooled down enough.
2. Do not use the steel wire brush, steel wool, abrasives for cleaning inside chamber.
3. Remove moisture completely inside chamber with a dried cloth after cleaning.

- (3) Check and clean the drain pipe system once a week. Lift out the chamber drain screen and insert a suitable funnel into the draining hole and pour one liter of hot trisodium phosphate(Na_3PO_4) solution(containing about 28 gram of trisodium phosphate) into the pipe, and flush the pipe with one liter of hot tap water again.

2) Cleaning of Chamber Drain Filter

Filter is located at drain of the chamber. Filter should be disassembled and cleaned once a week to prevent blocking of drain hole. To clean filter, lift the filter with hand to remove dirt completely with wire brush and insert the filter again.



Figure 6-1. DRAIN FILTER

3) Change of Door Gasket

The gasket should be cleaned as frequently as possible because it has to keep airtight of the chamber. It must be inserted correctly in the gasket groove and checked the elasticity, deformed or not.

Remove the damaged gasket with a suitable tool and clean the gasket groove up. Begin inserting the new gasket by pressing it into the middle of the upper part of the groove. Insert the gasket into the groove in the middle of each side(top, bottom, left and right) and in each corner. Continue to insert the gasket into the groove in the middle of each loose part. The

gasket shall be put evenly without strain or contraction partially.

4) Change of Air Filter(HEPA Filter)

The air filter should be replaced every 1,500 cycles run for preventing loads in the chamber from recontamination by supplying the fresh air filtered completely into the chamber.

- (1) Pick out the air filter intended to change by force grasping the bottom side of it from the air in line.
- (2) Insert a new air filter to the holder of air in line.
- (3) Discard the separated air filter according to the legitimate procedure.

5) Inspecting of Sliding Door

- (1) The sliding door is consisted of the door plate, insulation cover, door cover and equipped with the safety bar including two micro-switches in the upper side. If any object is touched to the safety bar during the door moving upward, these micro-switches sense and the door is moved down to the bottom automatically. These switches should be replaced immediately if they do not sense any touch.
- (2) The door is linked to the wire and fixing device, and open or close the chamber moving vertically by the driving motor. When the door is reached to the upper or lower position already designed to open or close the chamber completely, the door presses the limit switch fitted in the upper and lower side respectively and the controller stops the door moving at that position by stopping the driving motor.

6) Main Circuit Breaker

As a safety device disconnecting electric power automatically in case overload occurs in electrical system, circuit breaker is installed at the rear side of main control box and marked on [POWER CUT-OFF] switch. In case of disconnecting circuit due to the overload, you should check cause of overload to recover, and then turn the switch on. In case the sterilizer is not used for a long period, turn the switch off.

7) 2nd Circuit Breaker

Two auto fuses are installed in connection with <POWER> switch by the circuit breaker at the rear side of main control box. In case of overload, the knob will be sprang up to disconnect current flow. Pushing the knob to the original position, the function will be recovered(reset). The cause of overload must be inspected before operating.

8) Inspecting of Safety Valve

- (1) The safety valve should be checked whether the valve moves smoothly when you operate it up and down test lever, and whether there is any sign of leakage (rust or scale).
- (2) The safety valve is set to 40psi(g)[2.76bar(g)] for RV1, 87psi(g)[6.0bar(g)] for RV2 and sealed so as to prevent repair or adjustment. Therefore the safety valve should be replaced if it is not operated properly.
- (3) The replacing procedures is as follows,
 - ① Firstly cut off electric power and cool the chamber enough to touch,

- ② Remove the fluid exhaustion pipe linked with the safety valve outlet by turning counterclockwise using a proper sized spanner.
- ③ Separate the old safety valve from the nipple installed on the jacket by turning counterclockwise using a proper sized spanner.
- ④ Assemble the new safety valve tightly to the nipple installed on the jacket by turning clockwise using a proper sized spanner.
- ⑤ Reattach the fluid exhaustion pipe to the safety valve outlet by turning clockwise using a proper sized spanner.

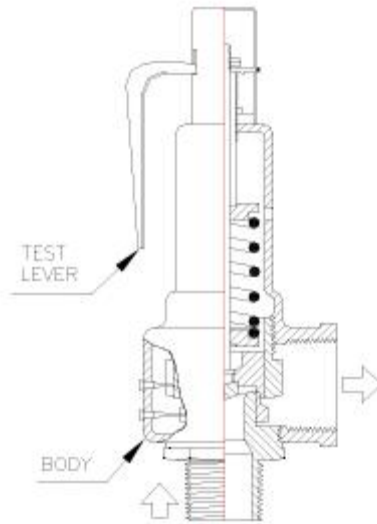


Figure 6-2. SAFETY VALVE

9) Strainer

The strainer should be checked and cleaned twice a year at least because the accumulated deposits in the strainer reduce the flow of steam or water.

- (1) Remove the cap and gasket.
- (2) Pull out the filter from body.
- (3) Remove all the rust and residue from the filter and body.
- (4) Insert the filter into strainer body, replace the filter if damaged, rusted or corroded.
- (5) Insert the gasket and tighten the cap, change the gasket if necessary.
- (6) Check if all the pipe connecting is tight after reassembling.

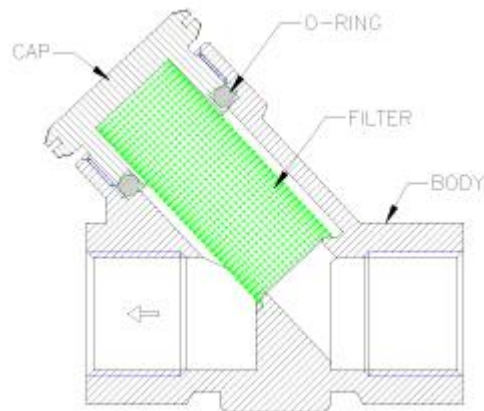


Figure 6-3. Strainer

10) Steam Trap

Steam trap is installed to drain line for discharging condensates. If the trap does not operate normally, condensates will not be drained or steam will be leaked causing troubles. In this case you should disassemble the trap and clean at first. The trap should be disassembled and cleaned once a month regularly. The method of cleaning is as the followings;

- (1) Remove the cover from the main body.
- (2) Remove the bellows to clean, and check for damaged part.
- (3) Clean inside of the main body and check for damaged part.
- (4) In replacing damaged parts, correct parts shall be used.
- (5) Assembling should be done in reverse order of dismantling.

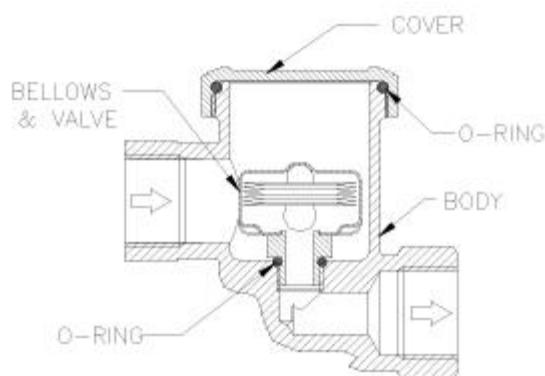


Figure 6-4. Steam Trap

11) Check Valve

Check valve is installed to prevent counterflow of water, steam and air in pipe line. Failure of normal operation of check valve is mostly caused by the insertion of foreign matter which interferes attachment of ball cone to the seat. In this case you should disassemble check valve to clean. Even you finish cleaning, check valve shall be replaced with new valve if it is not operated properly.

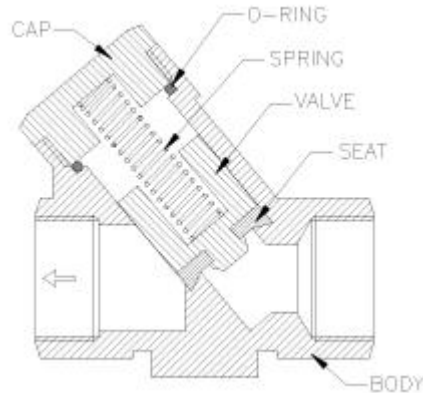


Figure 6-5. Check Valve

12) Solenoid Valve

- (1) In general, when the rating voltage is given to the coil, sluggish valve operation, excessive leakage or noise will indicate that cleaning is required. The strainer also should be cleaned when clean the solenoid valve, replace the part worn or damaged.
- (2) Check the valve as follows if it's operation is not normal,
 - ① Faulty control circuit : It indicates the loss of electrical power that a metallic click signal is not caught when the solenoid valve is energized. Check the ground of coil and short of input line.
 - ② Coil opened : Check if coil is opened. Replace coil if necessary.
 - ③ Low voltage : Check the voltage given across the coil leads. It must be given at least 85% of the rating voltage specified in the nameplate.
 - ④ Incorrect pressure : Check the pressure added to the valve, it must maintain within the range specified in the nameplate.
 - ⑤ Excessive leakage : Disassemble the valve and clean all the parts, replace the valve if worn or damaged.
- (3) Changing coil
 - ① Turn off electrical power and disconnect the lead wires of coil.
 - ② Remove nut and separate the nameplate.
 - ③ Remove the old coil from the tube, insert new one.
 - ④ Reassembling is in reverse order of disassembling.

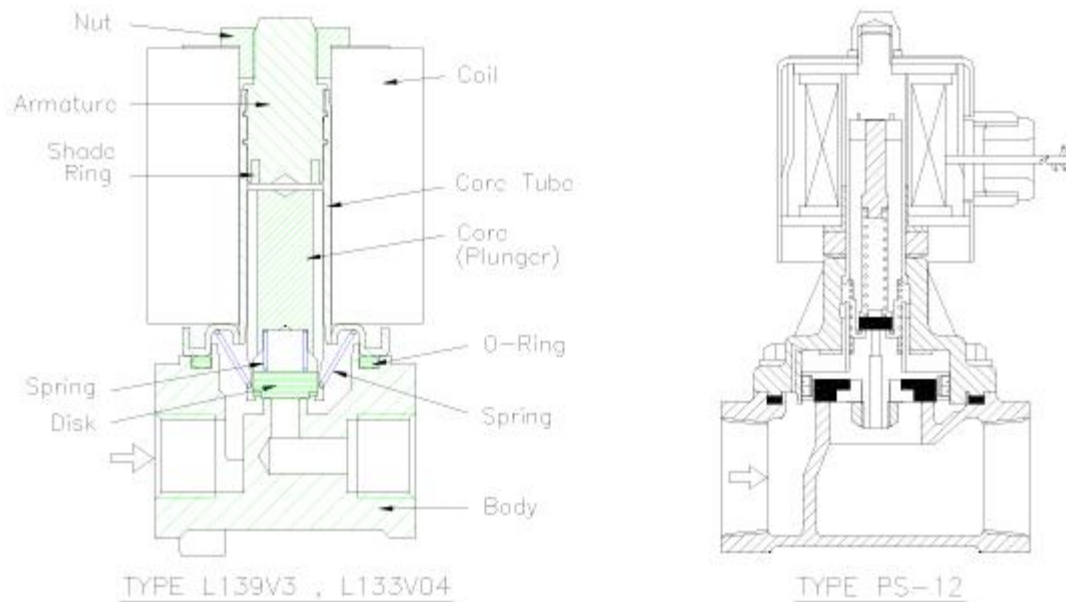


Figure 6-6. Solenoid Valve

13) Water Pump

- (1) Priming Water : Never operate the pump without priming water. Before using the centrifugal pump, you should fill casing and inlet tube with ample water and operate the pump. In case that water supply level is at the center line of the pump, if you remove priming plug and open the water supplying valve a little, the pump will be vented and filled with water.

If water overflows at the priming hole, seal the hole with a plug and open the water supplying valve fully. In case that the water supplying level is lower than the level of pump center, remove the priming plug and fill the pump and inlet pipe with water through the priming hole, and then seal the hole with a plug.

- (2) Operation: During pump operating, check the condition such as leakage, water pressure of the pipe and current for the pump motor, and confirm if there is any trouble.
- (3) Prevent Freezing : There is a risk of breakdown by freezing if the pump is stored at the temperature below 0°C without operation, so you should remove drain plug, priming plug and drain water. Plugs should be removed until reuse the pump.

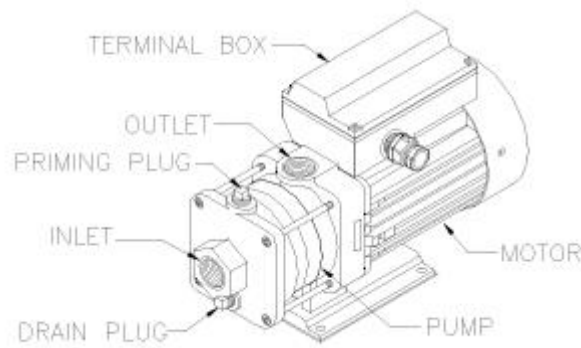


Figure 6-7. Water Pump

14) Control Box

It is very convenient to operate, maintain and repair the sterilizer because the power supply, cycle control system, display and panel printer are all assembled in the control box. If the control box is malfunction, you should request the technical service to the supplier or manufacturer in principle. Otherwise the control box is designed to be separated by the lump easily from the sterilizer, therefore it's simple to send quickly to the supplier side or manufacturer's factory for repairing.

15) Steam Generator (Boiler)

(1) Blowdown

Blowdown is the best preventive maintenance for the boiler and will prolong the life of boiler. Make sure a blowdown schedule is established and followed regularly. Blowdown will elevate the heat efficiency by removing the scale accumulated in water and from the heater surface. In case of using hard water, blowdown should be performed once a day, but once a week for soft water.

- ① Turn off the power switch of the sterilizer and the boiler, and close water supplying valve.
- ② Open the drain valve of boiler and then blow down.
- ③ When blowdown is completed :
 - a. Close the drain valve.
 - b. Open the water supplying valve.
 - c. Turn on the sterilizer power switch.
 - d. When turned on the boiler power switch, the pump will operate automatically and supply water to the boiler.
- ④ When refilling is completed, turn off the boiler power switch if would not operate.

(2) Water level control system

The water supply system is controled by two sensors(high and low level) which are detecting the electrical resistance of the water and installed in the chamber of the steam generator. When power is supplied to the empty steam generator, the water pump starts

operating and the valve is opened and water is supplied to chamber. The heater will be activated only when the water level is above the low-level sensor. When the water level reaches the high-level sensor, the pump will stop its operation and the valve will be closed. If water is used and its level falls below the high-level sensor, 10 seconds later, the pump will automatically operate and so does the valve. This process will repeat so that the water level is always maintained above the low-level sensor. If, for any reason, the water level falls below the low-level sensor while the sterilizer is operating, the power will be automatically cut off to the heater.

(3) Inspections



CAUTION

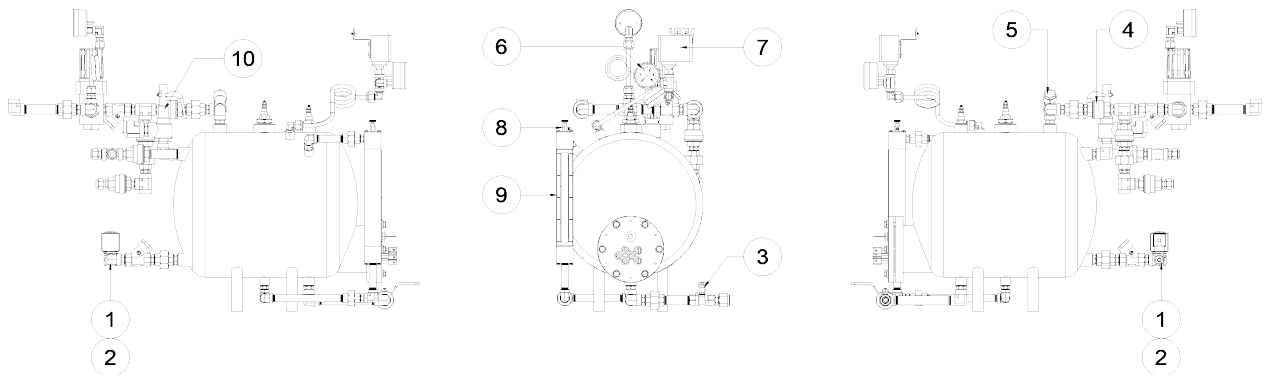
Cut all electrical power off before working on boiler to prevent electricity shock.

- ① A monthly inspection should be made to ensure that all electrical connections are tight.
- ② When steam or water leaks are observed, fittings should be tightened immediately.
- ③ Every four months, the water level sensor should be checked for deposits and cleaned, if necessary. Remove deposits from sensor. Care should be taken during the removal and reinstallation of the sensor so the porcelain insulator is not damaged.
- ④ At the same time, remove the heating element and inspect for scale formation. If scale has begun to form, clean element and also flush boiler.

(4) Troubleshooting

- ① Boiler does not work when main switch is turned on :
 - a. Check if main power is on.
 - b. Check circuit breaker.
 - c. Check all electrical connections for their tightness.
 - d. Check water level
 - e. Check water level sensors and clean off scale.
- ② Overflow
 - a. Check water level sensors and clean off scale.
 - b. Check electrical connection at sensor and water level control part.
- ③ The heater continuously burns out or the water level is not controlled.
 - a. Check whether water supplying to the boiler is smooth.
 - b. Check whether there are scale or a foreign substance on the sensor.
 - c. Check whether the sensor function is normal.
 - d. If the voltage specified does not detected even though the sensors are cleaned and the function is normal, the control circuit may be defective.
 - e. The boiler should be tested continuously draining water until the heaters are exposed in the air.

- ④ Sight Glass Corrosion : Hard water makes sight glass corroded.



No.	DESCRIPTION	REMARKS
1	SOLENOID VALVE(SV7, 8)	BOILER WATER IN
2	CHECK VALVE(CV6)	BOILER WATER IN
3	BALL VALVE(BV3)	BOILER DRAIN
4	CHECK VALVE(CV7)	BOILER STEAM OUT(Jacket Steam In)
5	STRAINER(ST6)	BOILER STEAM OUT(Jacket Steam In)
6	PRESSURE GAUGE(PC2)	BOILER STEAM PRESSURE
7	PRESSURE SWITCH(PS1)	BOILER STEAM PRESSURE
8	AIR VENT(AV)	
9	WATER LEVEL GAUGE(SC)	
10	SAFETY VALVE(RV2)	

Figure 6-8. Steam Generator (Built-in Boiler)

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