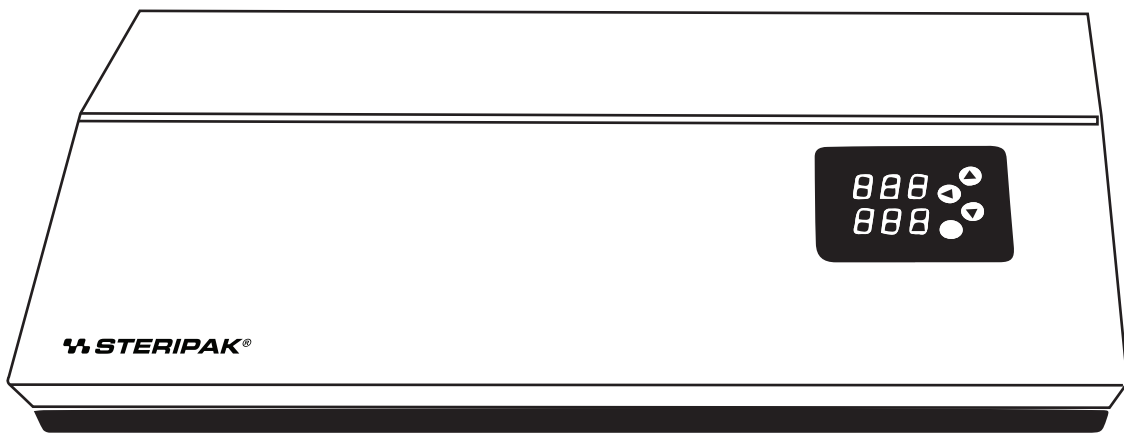


W STERIPAK®

Medical Sealing Machine



OPERATION MANUAL

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I. About

Thank you for choosing Steripak Medical Sealing Machine. To ensure maximum performance, please carefully read this manual and use it accordingly. It is highly recommended to put this manual in accessible locations for quicker reference.

II. Applied Area

Steripak Medical Sealing Machine is capable for continuous sealing of paper -plastic bag, 3D paper-plastic bag and paper-paper bag . The sealing process satisfies the requirements of high-temperature steam sterilization, low-temperature ethylene oxide sterilization, hydrogen peroxide plasma sterilization and radiation sterilization. Seal quality meets corresponding international standards and *GMP* recognition.

Sealable materials:

- Compliance with *EN868-5* and *YY/T 0698-5* bags and volumes;
- Compliance with *EN868-4* and *YY/T0698-4* paper bags;
- High density polyethylene materials (such as *Tyvek*);
- Aluminum foiled materials.

Non-sealable materials:

- Polyethylene film;
- Soft and hard film;
- Nylon membrane;
- OPP film.

III. Features

See the main machine composition in Figure 1.

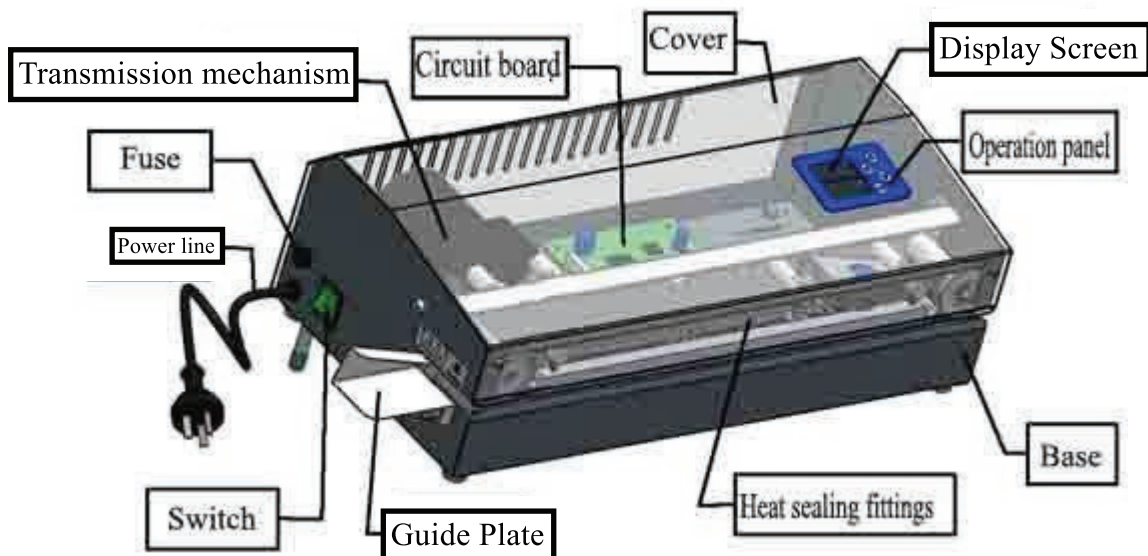


Figure 1

Automatic micro-computer temperature control, easy operation, large-screen display, high-reliability and continuous sealing;

It meets the seal machine standards of *BS EN ISO 11607:2006* and *BS EN 868-5:2009*.

It has Passed the *European Union 2006/42/EC* (machinery command), *2006/95/EC* (electric command) and *2004/108/EC* (EMC Directive) of CE certification.

This seal machine is not on the provisions of *Class I, II, III Medical Device of Supervision and Management of The Medical Devices Regulations (State Council order No.276)*. It is not managed as a medical device.

IV. Technical Parameters

- Seal speed: 10m/min
- Seal margin: 0-35mm adjustable
- Seal width: 12mm
- Work temperature: 60-220°C
- Temperature precision: $\leq 1\%$
- Work environment: 20-40°C
- Power: 500W
- Max current: 3.2A
- Fuse: 5A×2
- Dimension: 490×240×156mm (L×W×H)
- Weight: 11kg
- Store temperature: 0-55°C
- Store humidity: $\leq 90\%$ (R.H)
- Store air pressure: 50-106kPa.

V. Safety

1. All devices are strictly tested before leaving the factory.
2. Machine safety instruction, nameplate and label must maintain complete during installation and use.
3. Please ensure machine's completeness before use; Contact manufacturer or authorized distributor if flawed; Flawed devices are strictly forbidden to use.
4. Before turning on, please make sure the device has no signs of unsafe. Consult manufacturer or authorized distributor for any questions.
5. Do not use the device with damaged power cord or plug. Damaged power cord or plug must be repaired by the manufacturer or an authorized distributor.
6. Must use a factory-original power cable and a reliable grounding outlet with a stable voltage.
7. High temperature and high pressure components inside; Operation in explosive hazard zone is forbidden.
8. Pay attention to dew condensation when travelling the device from cold to warm; Switch on until the temperature balances and dew evaporates; Forced power on may cause electric shock and damage to the device.
9. Please power off or disconnect the plug when off duty.
10. Be sure to cut off the power before cleaning! Only dry or slightly moistened soft cloth and neutral cleaning agent are permitted for cleaning.
Attention! Strictly keep water away from the machine!
11. Must not feed the machine with any sharp or flat hard objects.

12. Do not insert any objects into the thermovent or electric shock or damage to the device may occur.
13. Stop using immediately after any unsafe signs.
14. The users must be 18 year old or above.

VI. Main Characteristics

1. Two-line bright LED display, soft-touch key board;
2. Microcomputer controlled temperature from 60°C to 220°C with accuracy of $\pm 1\%$;
3. High rate increase of temperature, 40 seconds required from room temperature to 180°C; 10 seconds required from 120°C to 180°C;
4. Automatic safe pause when temperature is out of setting more than $\pm 4^\circ\text{C}$;
5. Seal speed: 10m/min; Automatic seal detection by light-control technique;
6. Seal width: 12mm; Seal strength meets YY/T 0698.5-2009 requirements;
7. Seal margin: 0~35mm adjustable;
8. Adjustable fixed-force system; suitable for sealing paper-plastic bags, 3D paper-plastic bags and paper-paper bags;
9. Automatic fault detection and alarm;
10. Advanced flat ceramic heating components, high-temperature stability, long life expectancy and high heat efficiency;
11. Suitable to work with accessories such as multi-functional stainless paper-cutting worktable, axletree worktable, etc.

VII. Installation

1. Check the completeness of the packing box; Contact the factory or the authorized distributor immediately if damaged.
2. Carefully move the machine and the accessories out from the box; Check the device and the accessories according to the packing list and record the missing parts.
3. Keep the packing bags, attaching files and other accessories properly for future reference.
4. Place the machine with at least 5cm space around to ensure air flow.
5. Avoid vibration, dust, corrosive or explosive gases, extreme temperatures, moisture, etc.
6. Place the machine on a smooth and solid worktable (multi-function worktable is highly recommended).
7. Guide plate installation: screw the nut counterclockwise to adjust, as shown in Figure 2 and clockwise to tighten.
8. Power connection:
 - Make sure the AC power is 110V, 50Hz;
 - Connect the cable with the machine power plug and a reliable grounded tri-core socket.

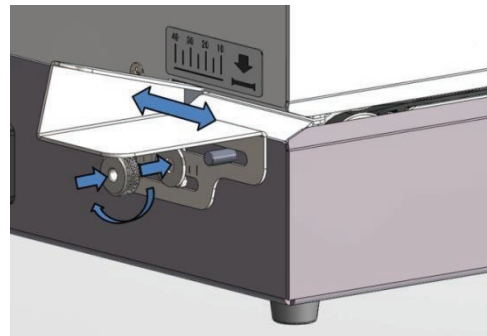


Figure 2



Caution: The earth wire of the socket must be grounded!!

VIII. Installation Qualification (IQ)

ISO11607-2 requires *Installation Qualification (IQ)* by seal test cards. *Installation Qualification* validates seal performance before the machine should be put into use. Seal quality relates to seal temperature, pressure and speed. All these parameters vary on sealed material and must meet the needs of sealing quality. Seal test cards give clear indications if any parameter is deviated.

For best IQ examination and record, please choose seal test cards.

According to *ISO-11607*, the sealing strip should meet the requirements below:

- Continuous and complete.
- No channel or unsealed area.
- No perforation or torn parts.
- No separated layers.

After low temperature and high temperature test card *IQ*, it is necessary to use the seal strength tester to test the strength of the sealing. The test determines whether the paper-plastic bags before and after the sterilization process meet the requirements.

IX. System Operations

Refer to Figure 3 for the whole operating process.

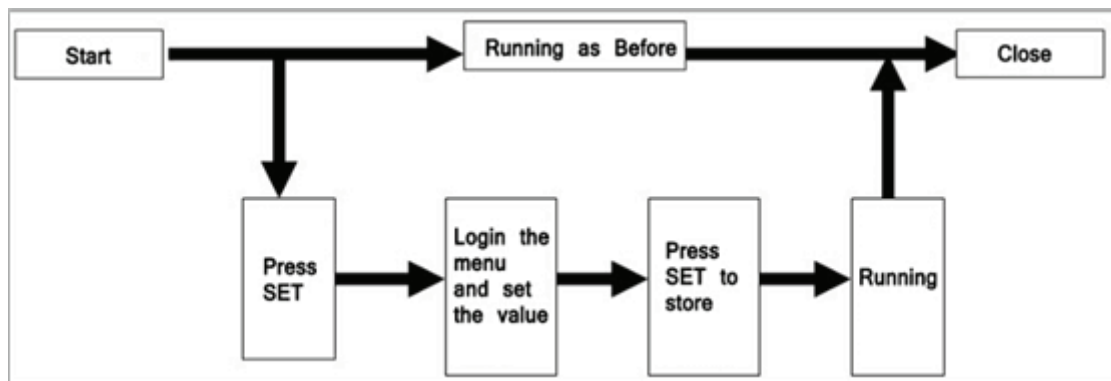


Figure 3

1. Buttons

The button distribution of the device operation panel is shown in Figure 4.

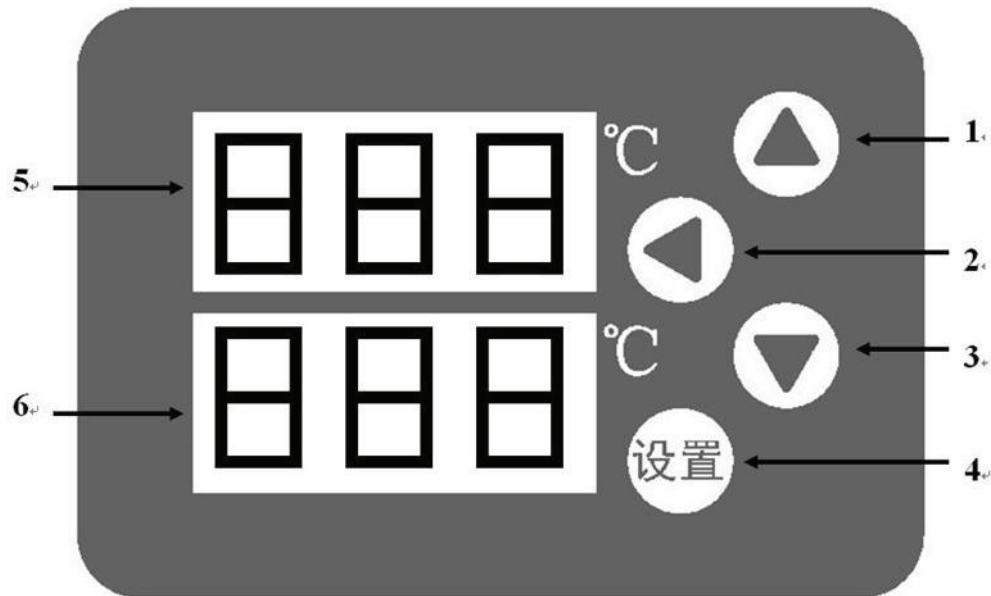


Figure 4

1-Plus button 2-Shift button 3-Minus button 4-Set button 5-Current temperature 6-Set temperature



Caution: No hard object is permitted to be placed on the soft-touch buttons.

2. Start

Power up and turn on the switch. The screen displays *100-L* then *8.8.8. 8.8.8.* with a beep. The machine starts to heat up according to the last set temperature.

3. Temperature setting

Press set button. Current temperature screen displays *SET* and digit on set temperature screen starts blinking. Press plus and minus button to change the number. Press shift button to alter among digits. Press set button once again to confirm changes.

Attention: Seal temperature depends on materials. Please refer to material suppliers for correct seal temperature. Otherwise refer to the following:

- *EN868-5* required for paper-plastic bags: 170-190
- High density polyethylene material(*Tyvek*): 110-130°C



Caution: The right seal temperature has to be determined by seal test results.

4. Work

After reaching set temperature, feed in seal bag from the left side. The transmission mechanic is automatically turned on. After 10 seconds without new fed bags, transmission mechanic stops automatically to save energy.

- Make sure the in-bag content has enough distance from the bag edge (Figure 5);
- Make sure transparent surface of the bag faced upwards and paper surface faced downwards;
- Make sure the seal temperature meets the needs of the bags.

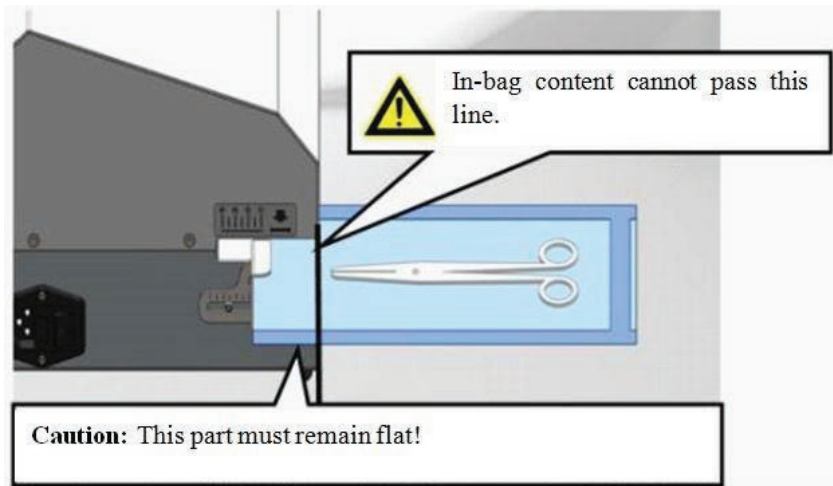


Figure 5

5. Temperature calibration

Attention: Current temperature screen displays *HHH* when it exceeds 230°C.

 **Parameters are all saved automatically before power off even on sudden power loss.**

X. Seal Operations

1. Adjust the guide plate: The specific location depends (0~35mm).
2. Select matching sterilization bags for the contents. Turn print off and seal one edge of the bags. Then put items into the bags. In accordance with *WS310.2-2009*, the sufficient distance between the seal edge and the inside content must be not less than 2.5cm (Figure 6).
3. Pay attention to exceptional and sharp items. Protection may be necessary.
4. Activate printing. Feed in the bag at the left side with the paper side down.
5. To ensure straight and flat seals, hold the external end of the bags with hands throughout sealing.
6. Take the sealed bags out for a short cooling.

Notice: For efficiency, roll-able worktable is highly recommended.

Notice: Sterilization bag materials differs between manufacturers, so does the seal temperature. Use test cards and seal strength tester to find the best seal temperature.

For better seals, please choose national regulated paper-plastic bags. Paper-plastic bag produced is recommended.

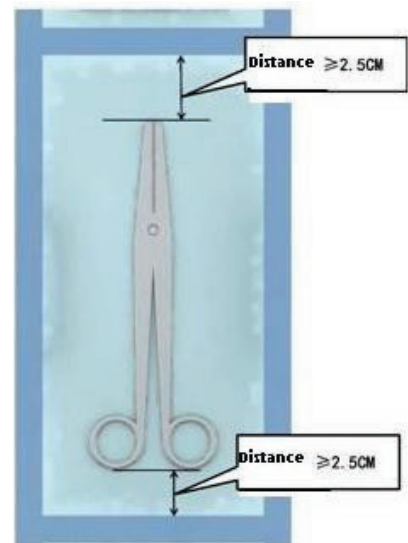


Figure 6

 **Warning: Inside contents are strictly prohibited in the trail!**

XI. Operation Qualification (OQ)

According to *part II of the ISO-11607 and WS310.2-2009*, user is obligated to test the seal quality with test cards before daily use.

- Whether channels or unsealed areas exist;

- Whether the pressure is too high or too low;
- Whether the temperature is too high or too low;
- Whether the sealing strip is continuous.

For better seals, a routine operation qualification before and after daily use is highly suggested.

Test card and *Tyvek* test card are highly recommended.

A seal strength tester also improves the seal validation.

XII. Testing Method

1. Seal test card:

As the effect of validation of sealing, seal test paper detects and records the comprehensive technical sealing parameters according to the requirements of *OQ* in *ISO 11607-2:2006* (Figure 22). Seal test paper directly displays the seal flaws and provides reference for temperature and pressure adjustment. Manufactures have two types of seal test card: test card for high temperature (180°C) paper-plastic bag seal and *Tyvek* cards for low Temperature (120°C) seal.



Figure 7

2. Seal strength tester

Seal strength tester tests the joint tension of sealed materials before and after sterilization based on the requirements of 5th part of *YY/T 0698.5-2009 Breathable Material with Plastic Film Sealing Bag Requirements and Test Methods*. Data output includes embedded micro printer printing or computer connection through specific application (optional).



Figure 8

Notice: This test should be done after the sterilization.

According to *ISO11607*, recommends daily tests with seal test card and seal strength tester to ensure seal quality, especially after change of seal materials and device maintenance.

User can choose to contact for a test visit or send the test sample (seal machine if necessary)

back to the factory for an analytic report (service charges).

XIII. Equipment Maintenance

1. Fuse replacement

Bad fuse leads to startup fail. To replace fuse, turn off the power, disconnect the power cable and pry out the fuse mount from the side with a flat screwdriver. Replace the fuse if necessary and fix the mount back to the original place.

2. Stuck bags

Turn off the power immediately and pull out the stuck bag perpendicularly. Restart the machine only if the stuck bag remains whole. Do not start the machine if bag fragments fall into the machine or got stuck in the transmission system. Ask professional personnel for cleaning.

3. Machine cleaning

- 1) Turn off the power switch and disconnect the power socket before any cleaning;
- 2) Clean the cover and the screen only with soft cloth and non-erosive cleaning agent like soap; Hard materials are forbidden (such as steel wool);
- 3) Object in thermovent is prohibited to avoid electric shock and device damage;
- 4) Prevent any water drop or tiny item into the equipment through the thermovent when cleaning.



Caution: Liquid contact with the machine is strictly prohibited to keep water out!

4. Troubleshoot table

Situation	Cause	Solution
Startup Fail	<ul style="list-style-type: none"> • improper power connection • power switch improperly pressed • broken fuse • heat plate overheat protection • burned overheat protection component 	<ul style="list-style-type: none"> • power on with 110v 50Hz • press switch repeatedly • replace fuse • reboot after cooled down to room temperature • check overheat protection component in room temperature and replace it if open circuit • check the source power and replace it by direct current if not standard
Vend fail	<ul style="list-style-type: none"> • bad gear engagement • bad input voltage • entrance photoelectric switch fail • motor fail 	<ul style="list-style-type: none"> • power on with 110v 50Hz • check the photoelectric- mainboard connection and replace the bad switch if necessary • check the motor-mainboard connection and replace the bad motor if necessary • reconnect the motor

	<ul style="list-style-type: none"> connection mainboard components damaged 	<ul style="list-style-type: none"> record and call manufacturer for maintenance
Incomplete LED display	<ul style="list-style-type: none"> bad display connection mainboard components damaged 	<ul style="list-style-type: none"> check screen-mainboard connection and replace the bad screen if necessary record and call manufacturer for maintenance
<i>HHH</i> on screen	<ul style="list-style-type: none"> sensor fail overheat protection mainboard components damaged 	<ul style="list-style-type: none"> check the ground connection and restart restart until cooling down to room temperature record and call manufacturer for maintenance
Display out of order	<ul style="list-style-type: none"> program crash screen fail mainboard components damaged 	<ul style="list-style-type: none"> reboot the device check screen-mainboard connection and replace the bad screen if necessary record and call manufacturer for maintenance
Buttons without reflection	<ul style="list-style-type: none"> bad button connection bad button mainboard components damaged 	<ul style="list-style-type: none"> check the button-mainboard connection replace the membrane switch record and call manufacturer for maintenance
Heat plate fail	<ul style="list-style-type: none"> bad connection bad heat plate mainboard components damaged 	<ul style="list-style-type: none"> check the heat plate-mainboard connection replace the heat components record and call manufacturer for maintenance
Heat plate does not reach the setting temperature	<ul style="list-style-type: none"> bad input voltage heat plate fail temperature sensor fail mainboard components damaged 	<ul style="list-style-type: none"> power on with 110v 50Hz replace heating components replace temperature sensor record and call manufacturer for maintenance
Temperature out of control	<ul style="list-style-type: none"> temperature sensor fail mainboard components damaged 	<ul style="list-style-type: none"> replace heat components record and call manufacturer for maintenance

Display out of order	<ul style="list-style-type: none"> • program crash • screen fail • mainboard components damaged 	<ul style="list-style-type: none"> • reboot the device • check screen-mainboard connection and replace the bad screen if necessary • record and call manufacturer for maintenance
Outage	<ul style="list-style-type: none"> • program crash • heat plate overheated • motor fail • mainboard components damaged 	<ul style="list-style-type: none"> • reboot the device • reboot in room temperature • check motor-mainboard connection and replace the bad motor if necessary • record and call manufacturer for maintenance
Wrinkled or melted plastic film	<ul style="list-style-type: none"> • setting temperature too high • biased current temperature • inaccurate temperature control 	<ul style="list-style-type: none"> • lower the setting temperature • Refer to chapter IX for temperature calibration • record and call manufacturer for maintenance
Loose seal	<ul style="list-style-type: none"> • setting temperature too low • inaccurate temperature control • plastic film too thick • pressure wheel short of pressure • liquid or smutch in seal area • foreign matter in a seal area • smutch on press wheel 	<ul style="list-style-type: none"> • raise the setting temperature • record and call manufacturer for maintenance • raise the setting temperature • adjust or replace the spring • get a new bag • remove the foreign matter • clean up
Rugged seal	<ul style="list-style-type: none"> • setting temperature too low • inaccurate temperature control • plastic film too thick • pressure wheel short of pressure • liquid or smutch in seal area • foreign matter in 	<ul style="list-style-type: none"> • raise the setting temperature • record and call manufacturer for maintenance • raise the setting temperature • adjust or replace the spring • get a new bag • remove the foreign matter • clean up

	seal area • smutch on press wheel	
Lack of accessories	• unable to cut paper-plastic bags • low seal efficiency • inconvenient bag placement • unable to test seal strength • unable to test seal results	• choose single-deck or double-deck roll bag cutting machine • choose roller table or flat table • choose specific stainless steel multifunctional table • choose seal strength tester • choose test card and magnifier

Parts of maintenance above are restricted to authorized personnel. If problem still remains, please contact the company or authorized distributor.

XIV. Precautions



Unauthorized personnel must not open the device shell in order to prevent possible electric shock and scald. Any repair and upgrade must be done by a specialist or an authorized personnel.

- Please turn off the device when it is in idle.
 - When fail happens, power off immediately; Troubleshoot before next use.
 - Seal operations of Tyvek bags (120°C low temperature bag) at high temperature (higher than 150°C) are strictly prohibited.
 - Forced start-up with fail occurring is strictly prohibited; Machine can only be used after maintenance by a specialist or an authorized person.
 - **Static cause great damage to the mainboard; User must ensure a good grounding.**
 - Avoid adhesive tapes in transmission mechanism and sticking on pressure wheels.
- Conclusion: All the sealing device tests, seal strength tests and sealing regulations are to ensure that the content are germ-free after sterilization, as well as to ensure that the machine is working normally.

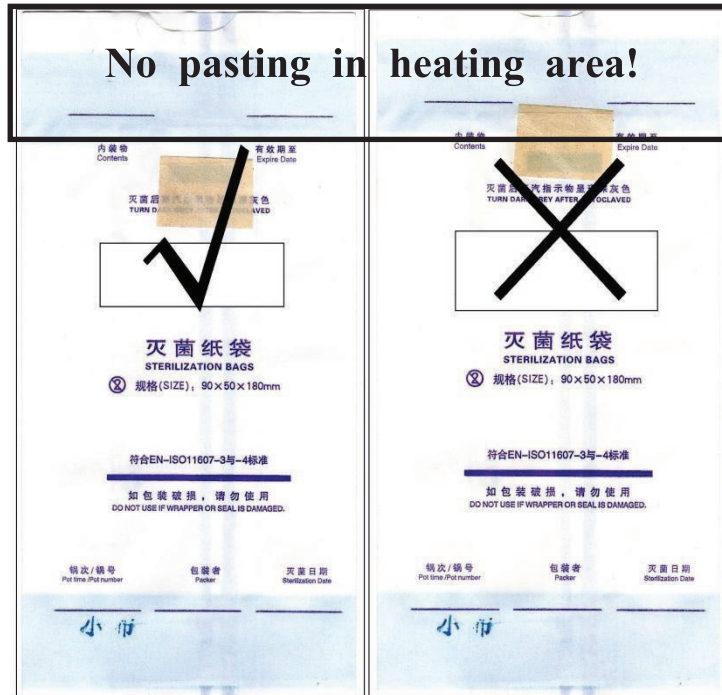


Figure 9

X. After-sales service

1. Scope of free service:
 - promises 1 year after-sale service, from the date of the invoice (or one month after the date of production without invoice).
 - offers free maintenance including renewal parts and device exchange in guarantee period (except power cable being vulnerable and color ribbon being expendable).
 - Contract provisions comes first.
2. Scope of charged service:
 - 1) charges for the service beyond the guarantee period.
 - 2) In guarantee period, charges for maintenance if the cause is one of the followings:
 - a) Body parts damaged by artificial force;
 - b) Dust accumulation, machine corrosion, moldiness, biological violation and inside liquid due to bad environment;
 - c) Melted materials attached to mechanical parts due to improper use;
 - d) Use of improper seal materials not mentioned in the instructions;
 - e) No reliable ground connection;
 - f) Voltage used beyond rating;
 - g) Natural disasters;
 - h) Use of unoriginal parts;
 - i) Not following this manual;
 - j) Unauthorized modification, dismantle or maintenance;
 - k) Unable to prove that the device is under guarantee period.
3. Maintenance procedure:
 - Maintenance from a licensed agent requires the following steps:



Caution: Users must provide the device number and service number to receive after-sales service.

- 1) Contact with the sales department or authorized sales agent. Provided device number and service number at the right side of the product, allows tracing of the detailed production and maintenance file accordingly;
 - 2) Provide certified acquisition date;
 - 3) State the fails and faults;
 - 4) Offer contact information;
 - 5) If back-factory maintenance is necessary, please send the device by *Debon* or other manufacturer specific logistics to the manufacturer. Customer must afford the transport expense after warranty period expires.
4. If you have any problem with the unit, please refer to the warranty at the back of this manual

XV. Intellectual Property

Our company is the copyright owner of this service manual and it is not open to be published, we have the right to consider it restricted. This manual is only a reference to operate and maintain the product.

This manual and all intellectual property (including copyright) belong to us. It is forbidden for anyone unauthorized to use, disclose, or help others get information from this from this manual by any means. It is forbidden for any one to take pictures, copy, duplicate and translate part of or all the information to any other languages without written authorization from *us*.

Our company owns the right of final explanation;

Our company keeps the right to modify the manual without prior notice.

Our company keeps the right to adjust the equipment technical parameters without prior notice.

XVI. Pack List

Number	Name	Standard	Quantity	Remark
1	Seal machine	100-L	1	
2	Guide plate		1	
3	Manual		1	
4	Certificate of quality		1	
5	Fuse	5A 5×20	2	
6	Operating procedure	Plastic sealed	1	
7	Sample sterilization bag		1	
8	Seal test card	351, 361	10	
9	Test card instruction		1	
10	Auxiliary leg		2	



Product Warranty Card

Name: _____

Address: _____

Date of Purchase: _____

Purchase from: _____

Product: _____

Model: _____

S/N:

0000000000

Progressive Medical Corporation warrants this product to be free from defects in material or workmanship within 1 year from date of purchase under normal use. If fault is found, please return the equipment, freight prepaid, in its original packaging along with the purchase receipt to the address below. Progressive Medical Corporation will repair or replace any defective parts free of charge subject to the terms and conditions stated herein.

For service, the unit is to be returned freight prepaid to:

Progressive Medical Corporation
200 C. Raymundo Avenue Caniogan, Pasig City 1606 Philippines.
Tel: +63 (2) 8656 6888 | www.pmc.ph

Please register your unit online at pmc.ph/warranty/

Registration Date: _____