

Medical sealing machine

Instructions

2017 version

Instructions Catalogue

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Summary	2
Application	2
Characteristic	2
Specification	3
Security matters	3
Main characteristics	4
Installation	5
Operation Process	8
Equipment Maintenance	9
Precautions	14
After-sale service	15
Appendix	16

Instructions

Summary

Welcome to use the company's production of MY medical sealing machine. To make it play max performance, you should carefully read the manual before use. Please use strictly according to the requirements of the operation and maintenance manual. Suggest that the manual should be placed in the accessible location for better reference during the operation.

Application

Automatic medical sealing machine, MY101 series, is suitable for packaging of terminally sterilized medical devices, such as paper-plastic bags. The sealing process is continuous and completely meets the requirements of high-temperature steam sterilization, low-temperature ethylene oxide sterilization, hydrogen peroxide plasma sterilization and radiation sterilization.

Sealing 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 foil materials.

Non-sealing materials:

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

Characteristic

The sealing machine is composed of the shell (base+cover+valve), power switch, the direction board, drive mechanism, heated sealing body, monitor, operation panel, print mechanism, main control board and switch power(Figure 1).

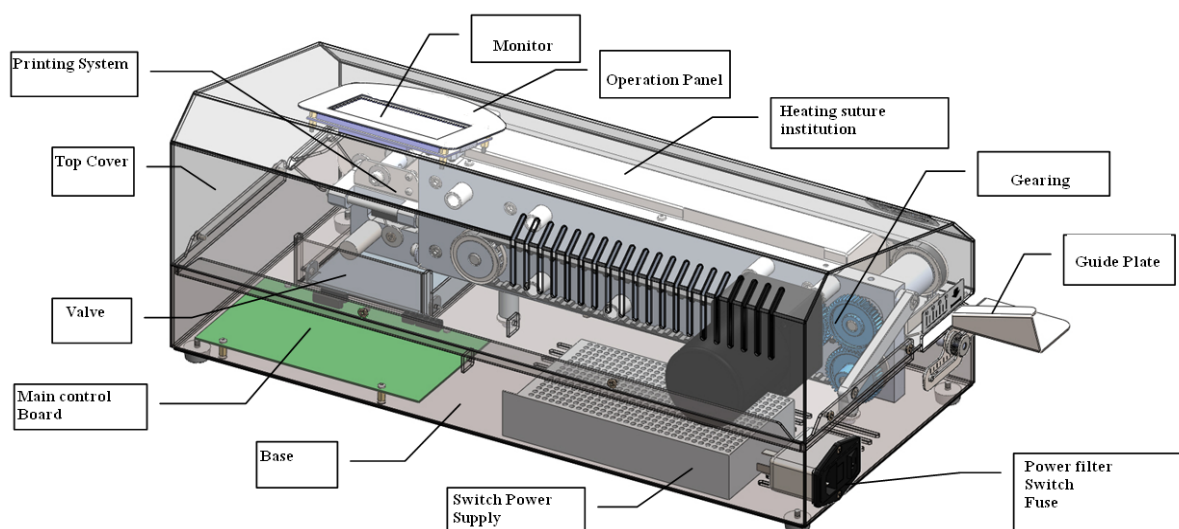


Figure1: Machine diagram

Instructions

Main characteristic: Automatic micro-computer temperature control, easy operation, continuous sealing, large-screen display, high reliability. Sealing temperature, expiry date, pot number and pot batch can be set optionally. The device sets the sealing and print function into one. It is a stylish, compact, lightweight sealing machine.

The device complies with the “BS EN ISO 11607:2006” and “BS EN 868-5:2009” for the sealing machine requirements.

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.

The sealing 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.

Specification

Seal speed: 10m/min

Seal margin: 0-35mm adjustable

Seal width: 12mm

Temperature control precision: $\geq 1\%$

Print model: needle

Environment: 0-40°C

AC power: 220V \pm 10% 60Hz

Power: 500W

Max current: 3.2A

Fuse: 5A \times 2

Outside dimension: 560 \times 260 \times 220(L \times W \times H)mm

Weight: 18Kg

Temperature: -40°C \sim 55°C

Humidity: $\leq 90\%$ (R.H)

Atmospheric pressure: 50KPa \sim 106 KPa

Security matters

1. The device is strictly tested before leaving the factory to ensure each one is both reliably qualified and safe.
2. Safety instruction, nameplates and labels of the product during installation and usage must maintain complete.
3. Please make sure that the device is complete before use. If it has any damage, please contact the manufacturer or authorized agents. Flawed devices are strictly forbidden to continue the installation and usage.
4. Before switch on it, please make sure the device has no signs of any unsafe. If you have any questions, please contact the manufacturer or authorized agents.
5. Do not use the device with the power cord or plug damaged neither the equipment damaged. If the power cable or the device has been damaged, it must be repaired by the manufacturer or an authorized agent.
6. The device power cable must be the original configuration and connected to a reliable grounding outlet with a secure stable voltage.

Instructions

7. The device concludes high temperature and high pressure components. Operation in explosion hazard zone is forbidden.
8. If the device is taken directly from the colder environment into a warmer environment, pay attention to dew condensation. Switch on after making sure the temperature is balanced and dew evaporates. Forced power will cause electric shock and damage to your equipment.
9. Please power off or disconnect the plug when the device is idle.
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.
11. No sharp or flat hard objects can be sent into the sealing machine feed so as to avoid any harm to the equipment.
12. It is forbidden to insert any objects into the thermovent to avoid electric shock or any damage to the equipment.
13. If the equipment is found any unsafe sign, please stop using immediately.
14. The users must be 18 years of age.

Main characteristics

1. 7" colored liquid crystal screen, light-touch keyboard, Chinese operational interface, internally installed clock;
2. Temperature controlled by a microcomputer, accuracy $\pm 1\%$, working temperature range 60~220°C;
3. High rate increase of temperature, 40 seconds required from room temperature to 180°C;
4. Automatic temperature reduction performance by an air removal system which is connected to a temperature control system to reduce the waiting time from high sealing temperature to lower sealing temperature.
5. If the sealing temperature outranges the setting range for more than $\pm 4^\circ\text{C}$, the machine will automatically stop working, which effectively guarantees the seal quality and safety.
6. Sealing speed: 10m/min; automatic seal printing test using light-control technique.
7. Sealing width: 12mm; Seal strength meets *BS EN 868-5:2009* requirements.
8. Sealing margin: 0~35mm adjustable.
9. Adjustable fixed-force system, suitable for sealing 3D paper-plastic bags and any different thickness paper-plastic bags.
10. can be used to print numbers and special symbols which are in the "ISO 15223-1:2007". It meets the requirements from health department such as the sterilization date, validity of expire date, lot number, operator number, pot number/batch, etc.
11. Sterilization date, expiration date, batch code and any other parameters that can be selected to print in symbols .
12. Expiration date can be adjusted automatically according to the effective days. Leap month and long-short month can be adjusted automatically.
13. A printer with 24 needles prints items in order: sterilization date, expiry date, lot number, operator, pot numbers/batch and device numbers.
14. Automatic failure alarm and automatic detection during working.

Instructions

15. Narrow, normal, wide body, three print fonts and symbol print contribute to more content on a relative narrow bag.
16. Print function can be activated partly based on customer demands.
17. Automatic energy-saving standby function. The standby time is adjustable. Intelligent standby recovery system helps return to the working temperature quickly.
18. Advanced flat ceramic heating components, high-temperature stability, long life expectancy and high heat efficiency.

Installation

1. Check the completeness of the packing box. If there is obvious deformation or mechanical damage, please contact our companies or agents promptly to make sure the reason and responsibility.
2. Please carefully remove the machine and the accessories from the packing box. Check the device and the accessories according to the enclosure I, the packing list. Record the missing parts if necessary.
3. Please keep the packing bags, attaching files and other accessories properly.
4. 5cm space around the equipment to ensure the flow of air during the installation.
5. Avoid vibration, dust, corrosive explosive gases, extreme temperatures and moisture, etc.
6. The tester requires a smooth and solid worktable .
7. Guide plate installation: screw nut counterclockwise to adjust plate as Figure 2 and clockwise tighten.

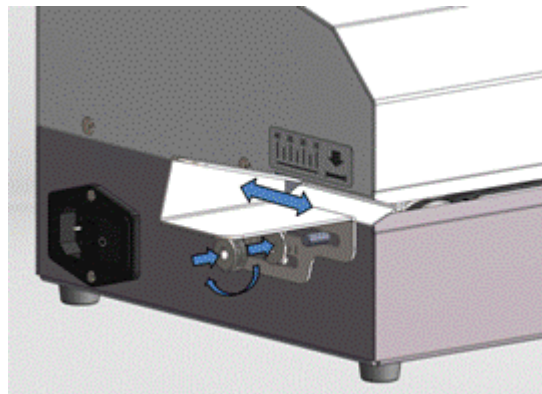


Figure 2

8. Power connection:
 - Make sure the AC power meets the following specializations: 110V 60Hz;
 - Place the original power cord one side inserted into the device power connector and another into the grounded three-prong power plug.

Instructions

Operation Introductions

All the operation process is showed in device operation flow chart in Figure 3:

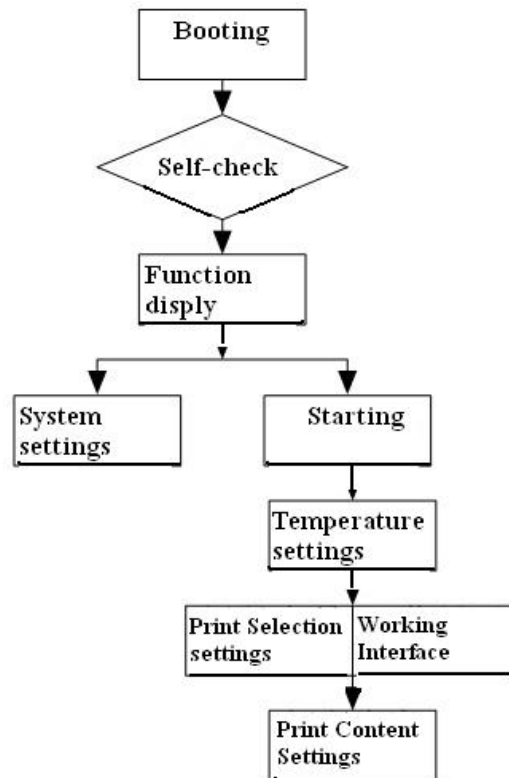


Figure 3

A. Boot:

Connect to the device power cord and turn on the switch on the left side of the machine. After hearing a beep “drop”, representing that the main control panel is good, you will see the welcome display (Figure 4). At the same time, the drive mechanism will run a self-test which lasts for 10 seconds. After that, the device will automatically enter the temperature setting interface (Figure 5).

Instructions

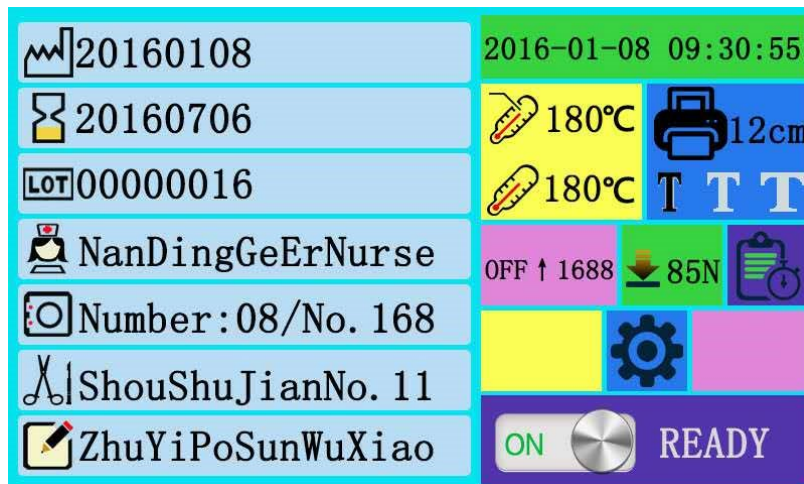


Figure 5

B. Settings:

Working temperature setting interface (60~220°C).

Attention: The sealing temperature depends on materials. Please refer to your supplier, otherwise, refer the following temperature range to set the sealing the temperature.

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

C. Working:

After entering the working interface (Figure 5), the middle bottom of the screen will display the present job status. During the heating process, the bottom of the screen will display “temperature is rising, please wait”; During the cooling process, it will display “temperature is cooling”. When the temperature reaches the setting temperature, it will display “Ready”, meaning the device ready for sealing.

Make sure the contents inside have enough distance from the edge of the bag!

Place the bag with transparent surface faced up and paper faced down to print characters down. (Figure 6)

Make sure the sealing temperature meet the needs of the bags.

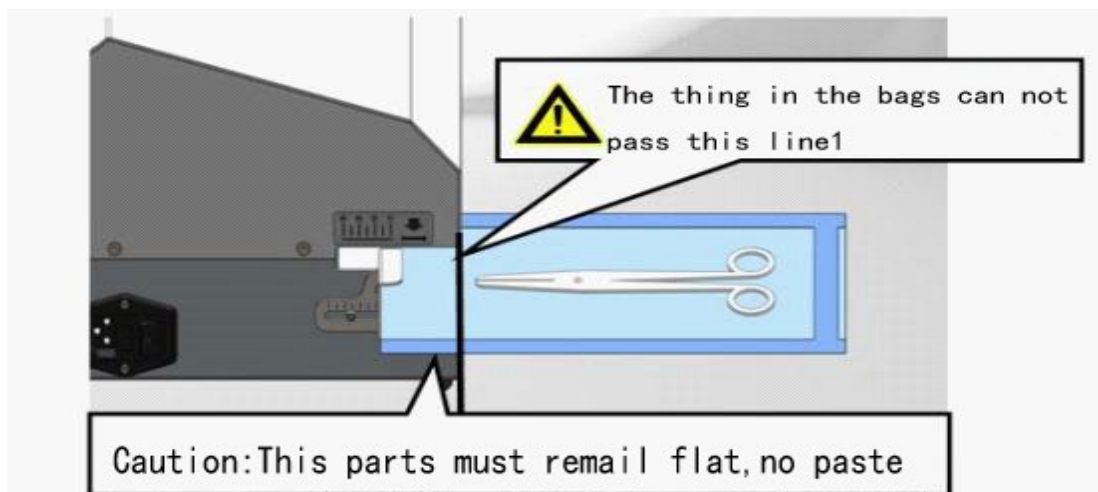



Figure 6

When you place in the bag, the device will automatically turn on the drive mechanism. Without placing in any bags for 10 minutes, the device will stop the drive mechanism to save energy.


D. Print:

Instructions



1) Turn off printing: In the working interface, press , at this time, you will find all the icon turns into grey. That means the print function is shut down, leaving the sealing function only.

2) Turn on printing: Repeat the previous step.

3) Font width adjustment: Press  to switch between three kinds of font including narrow, wide and normal. After selecting the font, the “bag width in need” above will display the demanding shortest length. When the bag length is insufficient, you can adjust the font width appropriately or cancel some of the print options to make sure all the print contents complete. If the paper width is still insufficient with narrow font, please cancel some of the print entries or choose to print symbols.

4) Print content setting: You can set the effective number of days, lot code, operator, pot number and print style content.

a). Valid date setting range: 0~999days;

b). Lot code setting range: 00000000~99999999;

c). Operator setting range: number 0~9, letter A~Z or empty (each loop);

d). Pot number setting range: number 0~9, letter A~Z or empty (each loop);

e). Pot time setting range: number 0~9, letter A~Z or empty (each loop);

Standby temperature setting range: 60~120°C.

No matter the device is turned off or a sudden of power loss occurs, the parameters will be automatically saved.

Operation Process

1. Choose the corresponding bags;
2. Adjust the guide plate location: The specific location depends on the situation (the scale range: 0~35mm).
3. Select the corresponding width and length of sterilization bags depending on the size of the inside content. Turn the print function off and seal one edge of the sterilization bags. After that, put the items into bags. In accordance with the relevant provisions of the “WS310.2-2009”, the sufficient distance between the packaging margin and the inside content should be more than 2.5cm to avoid cracking. (Figure 7)
4. Pay attention to the exceptional and sharp items. Protection for the items is required sometimes for safety.

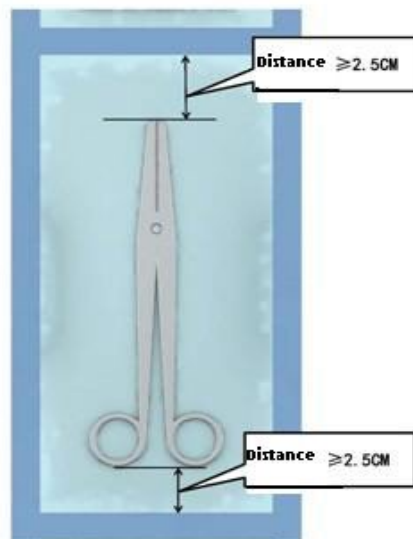


Figure 7

5. Activate the printing function. Feed in the bag in the left side with the paper side down because the printer is placed upward.
6. To make sure the sealing edge unbent and smooth, hold each end of the bags with your hands during sealing.

PS: For better sealing efficiency, please choose our roller worktable.



Warning: No packing items in the sealing trail!

7. Take out sealed bags for a short cooling.

Instructions

Suggestion: Because different manufacturers use different paper-plastic bags (paper bags), Different materials require different sealing temperature.
For better sealing effect, please select the national regulated paper-plastic bags.

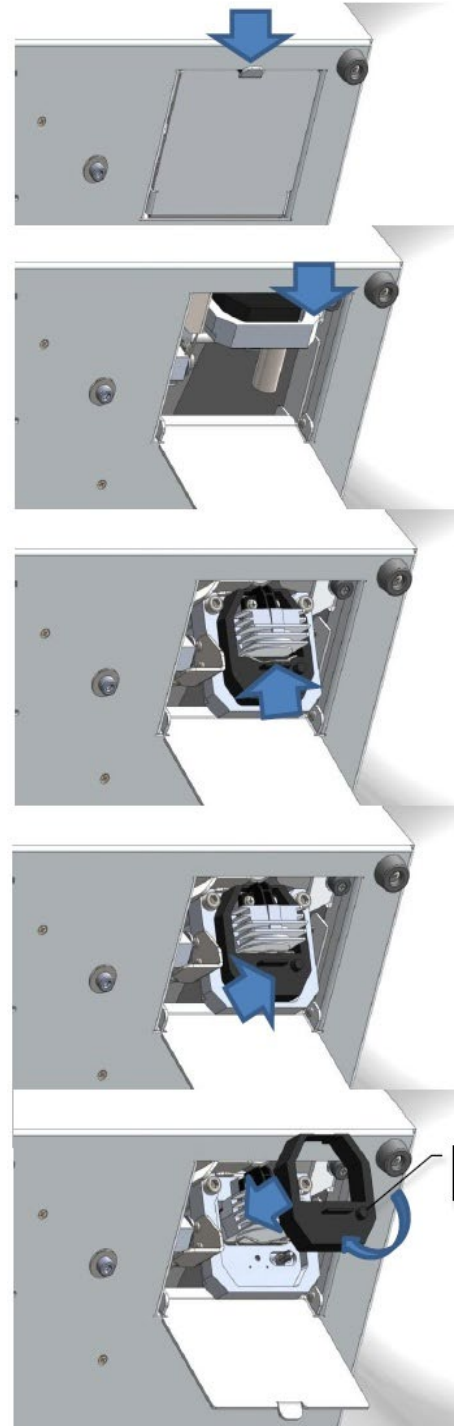
Equipment Maintenance

1.Ribbon replacement: Ribbon is the “ink” of the needle printer. When the print content comes blurred, it indicates that the ribbon needs to be replaced. The steps are shown as in Figure 16:

- 1) Turn over the sealer and open the lid.
- 2) Rotate the print head.
- 3) Take out the ribbon, the black box like a clip, while holding the spring clip.
- 4) Replace the ribbon and restored the stuff to the original.

2.Attention :

- 1)Use our dedicated heatproof ribbon to in sure normal use and avoid damage to the print head.
- 2)To avoid scald, replace the ribbon at least 10 minutes later after power off.
- 3)There are two spare ribbons along with the machine.



Attention: Do not rotate the ribbon scroll counterclockwise!

Instructions

3. Replace the fuse: Bad fuse may lead to boot failure. Turn off the power, disconnect the power cable and pry out the fuse mount from the side with a flat blade screwdriver. Replace the fuse if necessary and fix the mount back to the original place.

4. Stuck bags cleaning: when a bag is stuck in the sealing machine and stops moving forward, turn off the power immediately and pull out the bag perpendicularly. Fragments of bag that fall into the machine or stuck in the transmission system will affect the normal operation of equipment. At that time, you should ask professional to clean up and reboot.

5. Machine cleaning

- 1) Turn off the power switch and disconnect the power socket before cleaning the cover of the sealing machine.
- 2) Clean the cover and the screen with soft cloth and no-etching cleaning agent, such as soap. Rugged materials are forbidden (such as steel wool).
- 3) It is forbidden to insert any objects into the thermovent to avoid electric shock or any damage to the equipment when cleaning.
- 4) Prevent any water drop or tiny item into the equipment through the thermovent when you are cleaning around.



Caution: Prohibit any thing with water from contacting with the equipment so as to keep water out of the device.

6. Table of troubleshooting

Failure phenomenon	Failure cause	solution
1. Boot failure	1、improper power on 2、power switch pressed incompletely 3、fuse broken 4、heating plate overheat protection 5、overheat protection component burnout 6、power out of order	1、power on 110V、60Hz 2、continuously press “on—off” switch 3、replace fuse 4、boot after cooling down to room temperature 5、check overheat protection component in room temperature. Replace it if open circuit 6、check the power whether there is nominal voltage and replace it by direct current
2. No printing	1、print function turned off 2、guide plate too close to the front resulting insufficient space in the printer 3、print head failure 4、photoelectric switch out of order	1、enable the print function and check the print entries. 2、move the guide plate backward. 3、check the connection between the printer and the mainboard to exclude the failure of poor conduction. Check and replace the bad printer if necessary 4、check the connection between the photoelectric and the mainboard to

Instructions

	5、the components on mainboard damaged	exclude the failure of poor conduction. Check and replace the bad switch if necessary 5、record the failure phenomenon and call manufactures for maintenance
3. Incomplete printing	1、print needle broken 2、print head broken 3、components on mainboard damaged.	1、replace print needle 2、check the connection between the printer and the mainboard to exclude the failure of poor conduction. Check and replace the bad printer if necessary 3、record the failure phenomenon and call manufactures for maintenance
4. Vague printing	1、ribbon used up 2、loose screws in print head 3、ribbon motor failure 4components on mainboard damaged.	1、replace a new ribbon. 2、tighten the loose screws. 3、check the connection between the ribbon motor and the mainboard to exclude the failure of poor conduction. Check and replace the bad ribbon motor if necessary 4、record the failure phenomenon and call manufactures for maintenance
5. “Print head is overheated” on screen	1、print head overheat protection 2、print head failure 3、the components on mainboard damaged	1、reboot in room temperature 2、check the connection between the print head and the mainboard to exclude the failure of poor conduction. Check and replace the bad print head if necessary 3、record the failure phenomenon and call manufactures for maintenance
6. Running failure after inserting bags at setting temperature	1、motor failure 2、bad input voltage 3、entrance photoelectric switch failure. 4、components on mainboard damaged.	1、check the connection between the motor and the mainboard to exclude the failure of poor conduction. Check and replace the bad motor if necessary 2、power on 110V、60Hz 3、check the connection between the photoelectric switch and the mainboard to exclude the failure of poor conduction. Check and replace the bad switch if necessary 4、record the failure phenomenon and call manufactures for maintenance
7. Heating	1、bad connection	1、check the connection between the

Instructions

plate failure	2、bad input voltage 3、components on mainboard damaged	heating plate and the mainboard to exclude the failure of poor conduction. 2、replace the heating components 3、record the failure phenomenon and call manufactures for maintenance
8. Heating plate cannot reach the setting temperature	1、bad input voltage 2、heating plate failure 3、temperature sensor failure 4、components on mainboard damaged	1、power on 110V、60Hz 2、replace heating components 3、replace temperature sensor 4、record the failure phenomenon and call manufactures for maintenance
9. Temperature out of control	1、temperature sensor failure 2、components on mainboard damaged	1、replace heating components 2、record the failure phenomenon and call manufactures for maintenance
10. "Sensor failure" on screen	1、bad connection 2、temperature sensor damaged 3、components on mainboard damaged	1、check the connection between the temperature sensor and the mainboard to exclude the failure of poor conduction 2、replace the temperature sensor 3、record the failure phenomenon and call manufactures for maintenance
11. Screen out of order	1、program chaos 2、screen failure 3、components on mainboard damaged	1、reboot the device 2、check the connection between the screen and the mainboard to exclude the failure of poor conduction. Check and replace the bad screen if necessary 3、record the failure phenomenon and call manufactures for maintenance
12. Device running with screen inactivated	1、screen failure 2、program chaos 3、components on mainboard damaged	1、check the connection between the screen and the mainboard to exclude the failure of poor conduction. Check and replace the bad screen if necessary 2、reboot the device 3、record the failure phenomenon and call manufactures for maintenance
13. Wrong date	1、wrong date setting 2、clock battery on the mainboard expired 3、components on mainboard damaged	1、reset date 2、replace battery 3、record the failure phenomenon and call manufactures for maintenance
14. Outages	1、program chaos 2、heating plate overheated 3、motor failure	1、reboot the device 2、reboot in room temperature 3、check the connection between the motor and the mainboard to exclude the

Instructions

	4、components on mainboard damaged	failure of poor conduction. Check and replace the bad motor if necessary 4、record the failure phenomenon and call manufactures for maintenance
15. Wrinkled or melting plastic film	1、setting temperature too high 2、inaccurate temperature control	1、lower the setting temperature 2、record the failure phenomenon and call manufactures for maintenance
16. Substandard seal strength	1、setting temperature too high 2、inaccurate temperature control 3、plastic film too thick 4、press wheel short of pressure 5、liquid or smutch in sealing area 6、foreign matter in sealing area 7、smutch on press wheel	1、raise the setting temperature 2、record the failure phenomenon and call manufactures for maintenance 3、raise the setting temperature 4、adjust or replace the spring 5、get a new bag 6、remove the foreign matter 7、clean up
17. Rugged sealing margin	1、setting temperature too high 2、inaccurate temperature control 3、plastic film too thick 4、press wheel short of pressure 5、liquid or smutch in sealing area 6、foreign matter in sealing area 7、smutch on press wheel	1、raise the setting temperature 2、record the failure phenomenon and call manufactures for maintenance 3、raise the setting temperature 4、adjust or replace the spring 5、get a new bag 6、remove the foreign matter 7、clean up

If you still cannot use the equipment, please contact the company or authorized agent

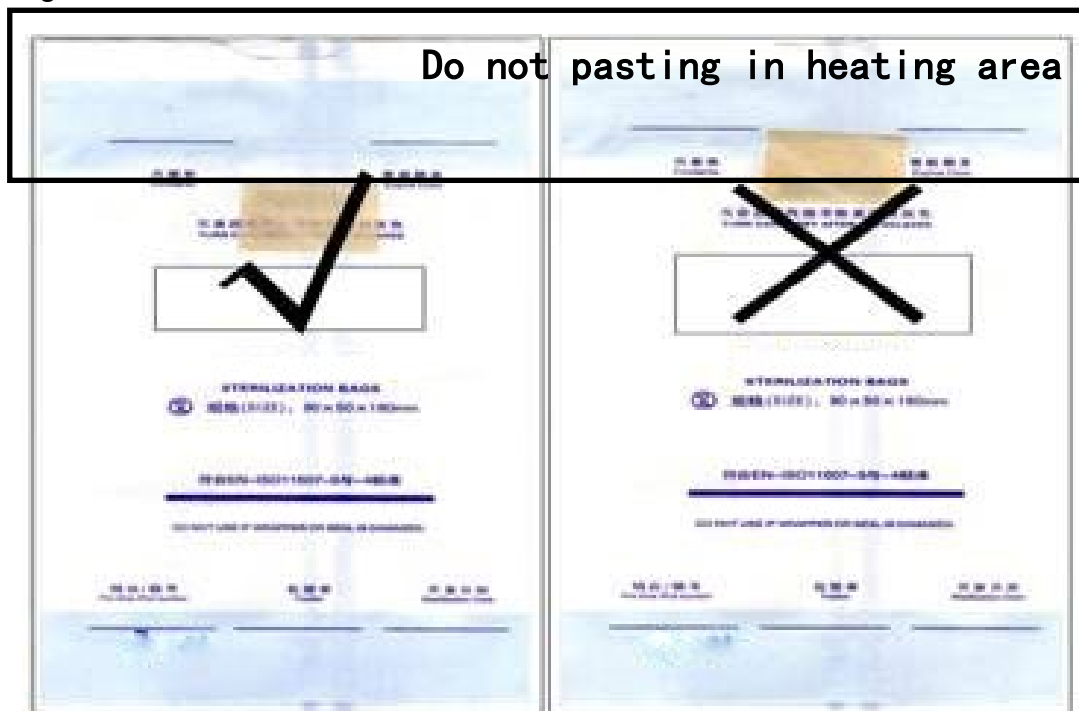
Instructions

Precautions



Do not open the enclosure in order to prevent the electric shock or scald. All the reparation and upgrade must be done by specialized and authorized person. Please power off the device when it is in idle.

- When failures occur, power off the device immediately. Troubleshoot the problems before use.
- **Prohibit sealing Tyvek (120°C low temperature bag) in high temperature (higher than 150°C) .**
- Prohibit running the machine when failures exist. Only after the check by specialized and authorized person can the machine be used.
- **Static holds great damage to mainboard. Please ensure a good grounding.**
- Avoid adhesive tapes rolled into the transmission mechanism and sticking on pressing wheels.



The correct position to paste the indicator tape The wrong position to paste the indicator tape
PS: Do not paste the indicator tape near the sealing line, it is hard to clean and will affect the sealing result if it is taped on the wheel of the sealer.

Conclusion: The purpose of all the sealing device tests, seal strength tests and sealing regulations is to insure the content highly germ-free since sterilization, also, to help improve the sealing quality.

Instructions

After-sale service

1. Scope of free service:

medical treatment offers 1 year after-sale service, from the date of the invoice (or one month after the date of production if no invoice).

We offer free maintenance, renewal parts and device exchange in guarantee period (power cable is out free maintenance due to its vulnerability).

Please contact the manufacture and distributor :

2. Scope of service charged:

- 1) We charge for the service beyond the guarantee period.
- 2) In guarantee period, we charge for maintenance if the cause is not one of the followings:
 - a). Body parts damaged by artificial force;
 - b). Dust accumulation, machine corrosion, moldiness, biological violation and wet of liquid due to bad environment;
 - c). Heat sensitive materials attached to mechanical parts because of improper usage;
 - d). Use of improper sealing materials not mentioned in instructions;
 - e). No guaranteed ground connection;
 - f). Voltage used beyond the voltage rating;
 - g). Irresistible natural disasters;
 - h). Use of unoriginal parts;
 - i). Not follow the service manual;
 - j). Unauthorized modification, dismantle or maintenance;

3. Maintenance procedures:

Maintenance from a licensed agent or MY requires following steps:

Caution: Users must provide the factory number and service number or we will not offer the after-sale service.

- a) Contact with our sales department or sales agent and provide us the factory number and service number at the right side of the product. We will find the detailed production and maintenance files according to the information you provide.
- b) Provide certified acquisition date;
- c) State failure phenomenon;
- d) Offer telephone number and address;

Instructions

Appendix

Enclosure 1: packing list

Enclosure 2: wiring diagram

Enclosure 1:

Packing list of

Serial number	Name	Standard	Quantity	Remark
1	Machine		1	
2	Cable		1	
3	Guide plate		1	
4	Manual		1	
5	Fuse	5A 5×20	2	
6				
7				
8				

Instructions

Enclosure 2:

wiring diagram

