

***MY100-A***

# **Medical Seal Machine**

## **Manual**

AnQing YIPAK Packaging Material Co.,Ltd

**2021 version**

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## I.About

Thank you for choosing *YIPAK* series of medical seal machine. To ensure max performance, please carefully read the manual and use strict accordingly. It is highly recommended to put this manual in accessible locations for quicker reference.

## II.Applied Area

Automatic medical seal machine, *MY100-A* series, is capable for continuous paper-plastic bag, 3D paper-plastic bag and paper-paper bag sealing. 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.

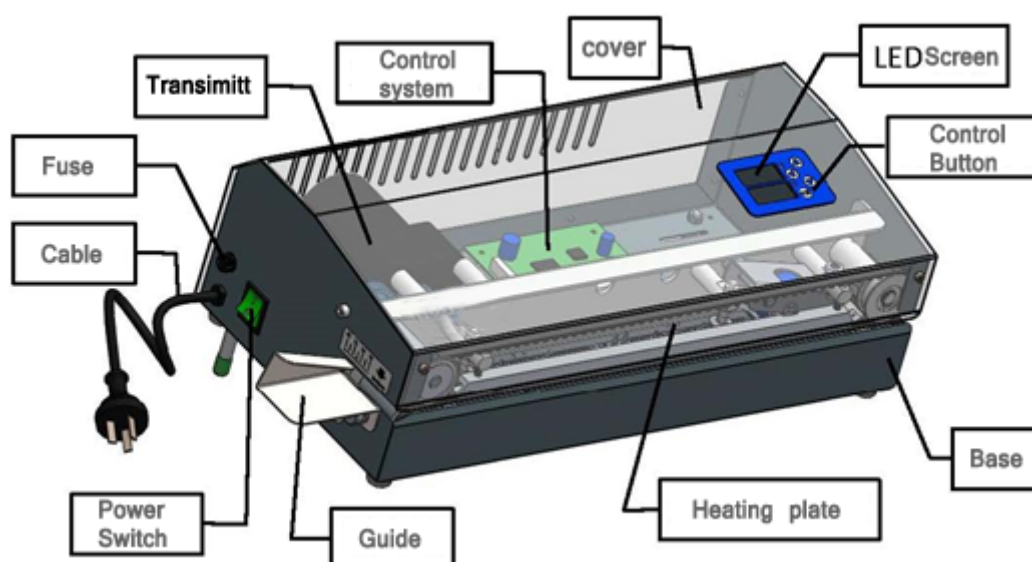


Figure 1

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

It meets the seal machine part 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.

The 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;
- AC power: 220V $\pm 10\%$  50Hz;
- Power: 500W;
- Max current: 3.2A;
- Fuse: 5A $\times 2$ ;
- Dimension: 490 $\times$ 240 $\times$ 156mm (L $\times$ W $\times$ 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 agent 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 agent for any question.
5. Do not use the device with damaged power cord or plug. Damaged power cord or plug must be repaired by manufacturer or an authorized agent.
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 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!**

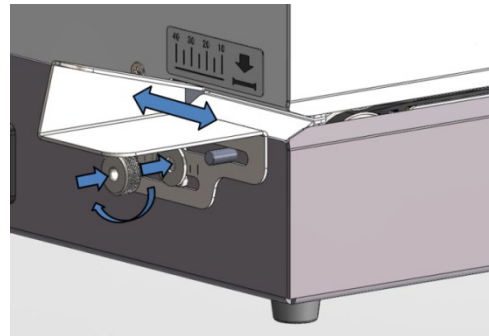
11. Must not feed the machine with any sharp or flat hard objects.
12. Do not insert any objects into the thermovent or electric shock or damage to device may happen.
13. Stop using immediately after any sign of unsafe.
14. The users must be 18 or older.

## VI. Main Characteristics

1. Two-line bright LED display, light-touch keyboard;
2. Microcomputer controlled temperature from 60°C to 220°C with accuracy  $\pm 1\%$ ;
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 connect 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 authorized agents 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 (*YIPAK* multi-function worktable is highly recommended).
7. Guide plate installation: screw the nut counterclockwise to adjust as in Figure 2 and clockwise to tighten.
8. Power connection:
  - Make sure the AC power is 220V, 50Hz;
  - Connect the cable with the machine power plug and a reliable grounded tri-core socket.





**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 machine 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 YIPAK 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 (YIPAK patent) 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.

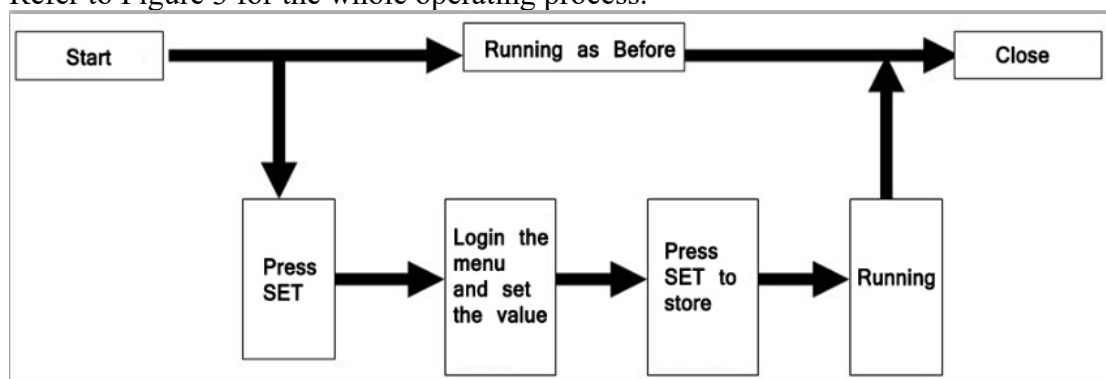


Figure 3

## 1. Buttons

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

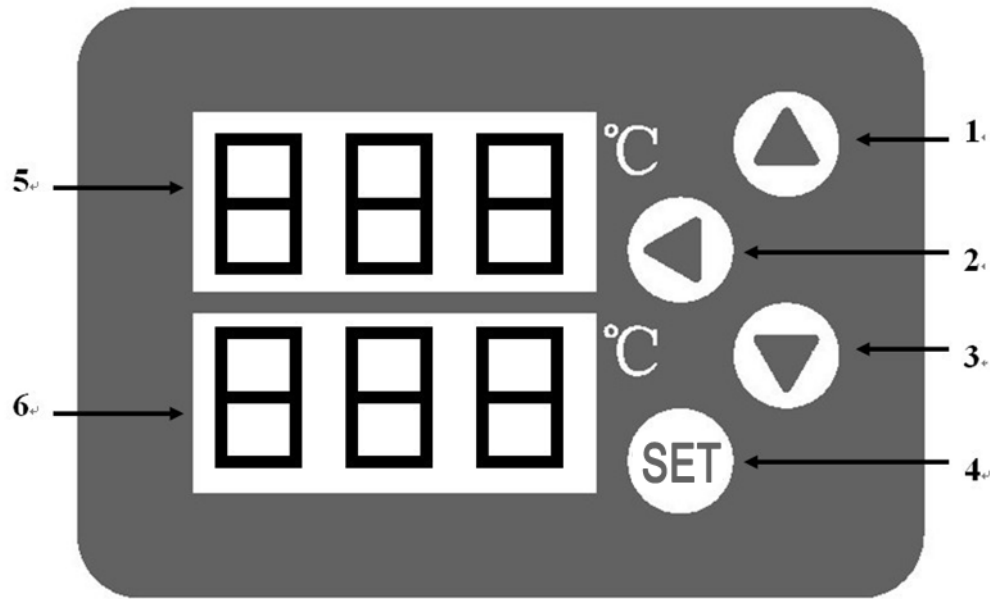


Figure 4

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 replace soft touch on the buttons.**

## 2. Start

Power up and turn on the switch. The screen displays *NJ- 100* 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 paper-plastic bags: 170-190°C
- 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.

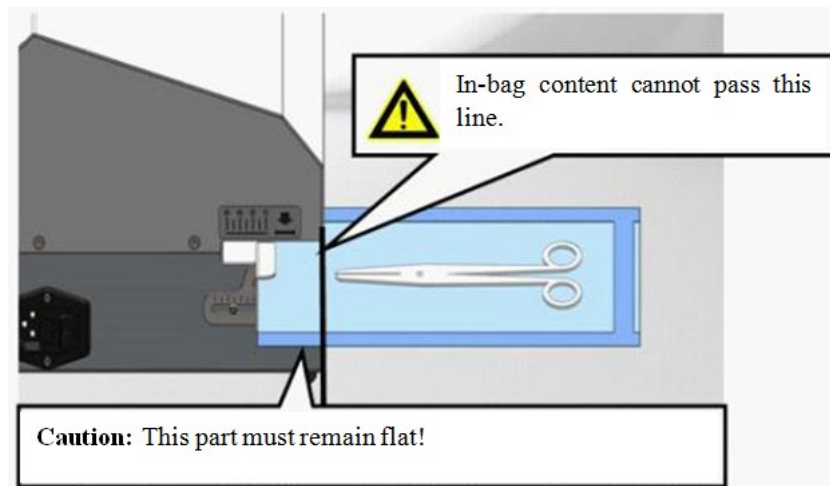


Figure 5

#### 5. Temperature calibration

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



**Parameters are all saved automatically before power off even 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 bags. In accordance with *WS310.2-2009*, the sufficient distance between the seal edge and the inside content must be no 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 bags with hands throughout sealing.

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

6. Take the sealed bags out for a short cooling.

**Notice:** Sterilization bag materials differ 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 by us is recommended.

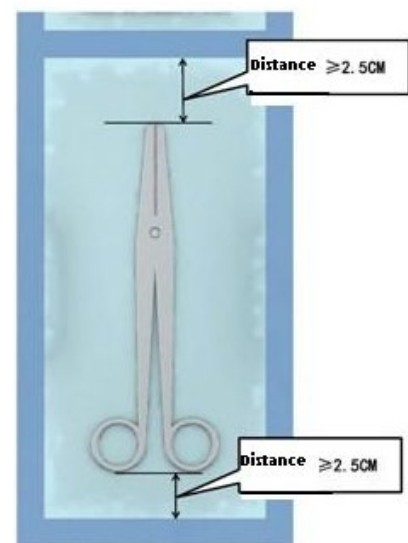


Figure 6



**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.

*YIPAK* 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 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. *YIPAK* manufactures 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*, *YIPAK* 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 *YIPAK* for a test visit or send the test sample (seal machine if necessary) back to 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 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"><li>• improper power connection</li><li>• power switch improperly pressed</li><li>• broken fuse</li><li>• heat plate overheat protection</li><li>• burned overheat protection component</li><li>• source power out of order</li></ul>	<ul style="list-style-type: none"><li>• power on with 220V 50Hz</li><li>• press switch repeatedly</li><li>• replace fuse</li><li>• reboot after cooled down to room temperature</li><li>• check overheat protection component in room temperature and replace it if open circuit</li><li>• check the source power and replace it by direct current if not standard</li></ul>
Vend fail	<ul style="list-style-type: none"><li>• bad gear engagement</li><li>• bad input voltage</li><li>• entrance photoelectric switch fail</li><li>• motor fail</li><li>• bad motor connection</li></ul>	<ul style="list-style-type: none"><li>• power on with 220V 50Hz</li><li>• check the photoelectric- mainboard connection and replace the bad switch if necessary</li><li>• check the motor-mainboard connection and replace the bad motor if necessary</li><li>• Reconnect the motor</li><li>• record and call manufacturer for</li></ul>

	<ul style="list-style-type: none"> <li>• mainboard components damaged</li> </ul>	maintenance
Incomplete LED display	<ul style="list-style-type: none"> <li>• bad display connection</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• check screen-mainboard connection and replace the bad screen if necessary</li> <li>• record and call manufacturer for maintenance</li> </ul>
<i>HHH</i> on screen	<ul style="list-style-type: none"> <li>• sensor fail</li> <li>• overheat protection</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• check the ground connection and restart</li> <li>• restart until cooling down to room temperature</li> <li>• record and call manufacturer for maintenance</li> </ul>
Display out of order	<ul style="list-style-type: none"> <li>• program crash</li> <li>• screen fail</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• reboot the device</li> <li>• check screen-mainboard connection and replace the bad screen if necessary</li> <li>• record and call manufacturer for maintenance</li> </ul>
Buttons without reflection	<ul style="list-style-type: none"> <li>• bad button connection</li> <li>• bad button</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• check the button-mainboard connection</li> <li>• replace the membrane switch</li> <li>• record and call manufacturer for maintenance</li> </ul>
Heat plate fail	<ul style="list-style-type: none"> <li>• bad connection</li> <li>• bad heat plate</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• check the heat plate-mainboard connection</li> <li>• replace the heat components</li> <li>• record and call manufacturer for maintenance</li> </ul>
Heat plate does not reach the setting temperature	<ul style="list-style-type: none"> <li>• bad input voltage</li> <li>• heat plate fail</li> <li>• temperature sensor fail</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• power on with 220V 50Hz</li> <li>• replace heating components</li> <li>• replace temperature sensor</li> <li>• record and call manufacturer for maintenance</li> </ul>
Temperature out of control	<ul style="list-style-type: none"> <li>• temperature sensor fail</li> <li>• mainboard components damaged</li> </ul>	<ul style="list-style-type: none"> <li>• replace heat components</li> <li>• record and call manufacturer for maintenance</li> </ul>

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

	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 agent.

#### XIV.Precautions



**Unprofessional personnel must not open the device shell in order to prevent possible electric shock and scald. Any reparation and upgrade must be done by specialist and authorized person.**

- Please power 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 startup with fail occurring is strictly prohibited; Machine can only be used after maintenance by specialist and authorized person.
  - **Static cause great damage to 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 insure the content highly germ-free since sterilization, as well as to insure the machine working normally.

Figure 9

## X.After-sale

1. Scope of *YIPAK* year service, date of (or one the date without *YIPAK*

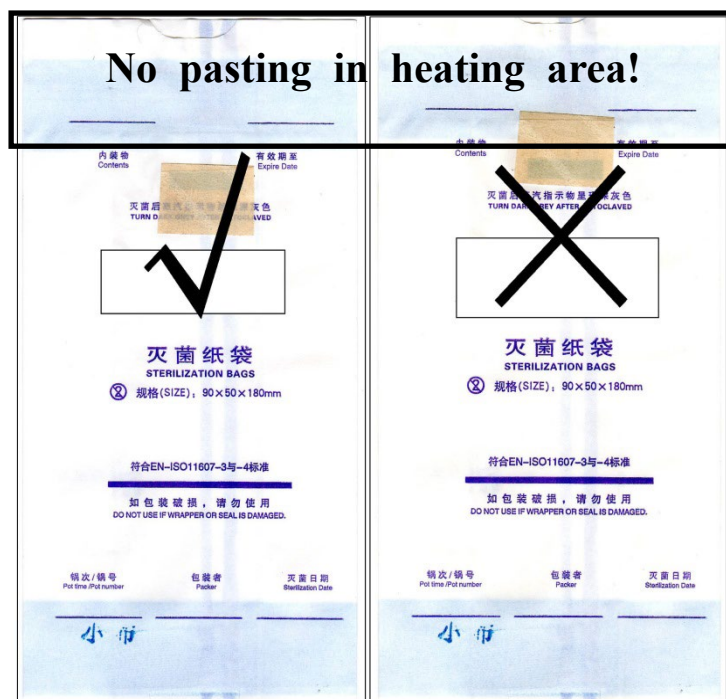


Figure 9

maintenance including renewal parts and device exchange in guarantee period (except power cable being vulnerable and color ribbon being expendable). Contract provisions come first.

2. Scope of charged service:
  - 1) *YIPAK* charges for the service beyond the guarantee period.
  - 2) In guarantee period, *YIPAK* 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 instructions;
    - e) No reliable ground connection;
    - f) Voltage used beyond rating;
    - g) Irresistible natural disasters;
    - h) Use of unoriginal parts;
    - i) Not following this manual;
    - j) Unauthorized modification, dismantle or maintenance;
    - k) Unable to prove the device is in guarantee period or the device is a *YIPAK* product.
3. Maintenance procedure:  
Maintenance from a licensed agent or *YIPAK* requires following steps:



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

- 1) Contact with *YIPAK* sale department or authorized sale agent. Provide device number and service number at the right side of the product. *YIPAK* will find the detailed production and maintenance file accordingly;
- 2) Provide certified acquisition date;
- 3) State the fails and faults;

service

free service: promises 1 after-sale from the the invoice month after of production invoice). offers free

- 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. Contacts:
- If you have any problem, please don't hesitate to contact our company or sales agent.
- Contact information of sales agent: (filled by agent or users)
- Name:
- Address:
- Tel.:
- Tax:
- E-mail:
- Website:

## Appendix

### Enclosure 1: Pack list

#### Enclosure 1:

#### Pack List of *MY100-A*

Number	Name	Standard	Quantity	Remark
1	Seal machine	<i>MY100-A</i>	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	Auxiliary leg		2	