

MODEL P30

 **STERIPAK®**

Rotary Sealer

for Pouches and Reels



**OPERATIONS
MANUAL**



Steripak Rotary Sealer P30

Description

- Thank you for purchasing the Steripak Rotary Sealer P30.
- Before using the machine, please read this manual carefully in order to use the product safely.
- Please keep this manual properly so that you can read it whenever you need it.
- Product name: Steripak Rotary Sealer
- Model: P30
- Manufactured for: Progressive Medical Corporation
- Address: 200 C. Raymundo Avenue, Caniogan, Pasig City

Intellectual Property

- The intellectual property rights of this manual and its corresponding products belong to Progressive Medical Corporation
- Without the written consent of Progressive Medical Corporation, any individual or organization shall not copy, modify, translate, and distribute this operational manual and any part thereof in any form.

Declaration

- Progressive Medical Corporation has the final right to interpret this manual.
- Only in the following cases, Progressive Medical Corporation is responsible for the impact on the safety, reliability, and performance of the product:
 - Commissioning, modification or maintenance are all carried out by personnel approved by Progressive Medical Corporation.
 - The electrical facilities in the room meet the relevant requirements.
 - All replacement parts, accessories and consumables used in the repair are original or approved by Progressive Medical Corporation.
 - The equipment should be used in accordance with the requirements of the operational manual.

Maintenance

- The warranty period of the purchased product is subject to the sales contract.
- Consumables: refers to disposable consumables that need to be replaced after each use or consumables that need to be replaced regularly. Consumables are not warranted.
- Please note that the following conditions are not covered by the warranty:
 - Man-made damage.
 - Improper use.
 - The grid voltage exceeds the machine's specified range.

- Grave natural disasters.
 - Replacement or use of parts and accessories not approved by Progressive Medical Corporation.
 - Other failures not caused by the machine itself.
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- If the instrument fails due to the use of consumables not approved by Progressive Medical Corporation, it is not within the scope of Progressive Medical Corporation to provide maintenance service.
 - After the warranty period expires, Progressive Medical Corporation can continue to provide chargeable maintenance services.

After-sale service supplier

Progressive Medical Corporation

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1 Brief Introduction

Name: Steripak Rotary Sealer for Pouches and Reel

Model: P30

1.1 Nomenclature

Steripak P30



1.2 Application scope

Used in CSSD, operating rooms, dental clinics, aesthetic clinics and other areas to seal sterile pouches before sterilization. Paper-plastic pouches, plastic pouches and Tyvek pouches can be sealed using this machine

1.3 Structure

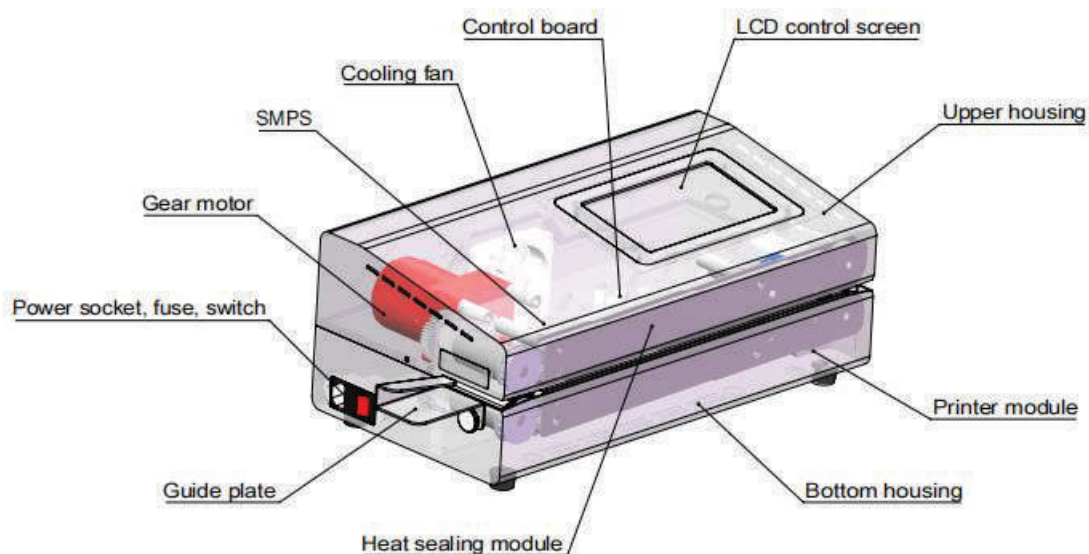


Figure1 schematic structure of sealing machine

1.4 Performance

1.4.1 Specifications

Items		
Model	P30	
Dimension	450×230×170 (mm)	
Weight	11kg	
Power	400W	
Housing	Coated carbon steel	
Seal speed	Adjustable from room temp. to 220°C	
Heating rate	Increase to 180°C/40 seconds	
Seal width	12 mm	
Seal speed	≥10 m/min	
Distance from edge	Adjustable from 0-35 mm	
Control panel	7-inch touchscreen	
Operation system	Built-in	
Pressure monitor	Yes	
Printer	Yes	

Table 1 specifications of Steripak Rotary Sealer P30

1.4.2 Working Conditions

- (1) Temperature: 5-40°C
- (2) Humidity: 15%-95%
- (3) Air pressure: 70kPa-106kPa

2 Attention

- Please read and understand this manual before using the Steripak Rotary Sealer P30.
- This medical sealing machine can only be used for the specified intended purpose, not for other purposes.
- This medical sealing machine can only be disassembled and assembled by an approved personnel of Progressive Medical Corporation.
- The safety instructions, nameplates and labels of this product must be kept complete during installation and use.
- The equipment should work under "1.4.2 working condition".

- Before switching on and using the device, please make sure that there are no safety hazards (such as broken power cord, broken screen, deformed shell).
- During use, please note if there are any abnormalities in the operation of the equipment (such as: abnormal noise, smoke, odor, non-uniform speed), if there are any, stop the operation and cut off the power to check.
- During use, if malfunction prompt appears, please troubleshoot or contact the after-sales service supplier immediately.
- There are high-temperature components and sensors inside the equipment. It is forbidden to install and operate the equipment in areas with potential explosion hazards.
- Be sure to cut off the power before cleaning. Dry or slightly damp soft cloth and neutral cleaning agent are allowed to clean the machine.
- Attention! When feeding the pouch for sealing, make sure that the pouches should entirely cover the item for sterilization.
- Attention! Please make sure that no other items obstruct the path of the sterilization pouch.
- Attention! Please ensure that the cooling fan and vents are not blocked.
- Attention! Any liquid is prohibited from entering the inside of the sealing machine.
- Attention! Please confirm if the seal temperature reached the pre-set before sealing.

3 Ordinary Maintenance

- Keep the power cord away from other frequently moved objects.
- The back of the sealing machine should be kept >5 cm away from the wall or other equipments/objects to avoid blocking of the air outlet.
- Regularly clean the dust from the bottom of the sealing machine or the surface of the placement platform.
- Before moving the sealing machine from one area to another, make sure that the power cord is unplugged.

4 Function

- Fast, automatic, continuous heat sealing technique is used to improve sealing efficiency.
- Equipped with a 7-inch colored touchscreen, which is more in line with daily operating habits.
- Intelligent temperature control. This machine uses microprocessor to accurately control temperature, maintaining temperature stability during sealing process. The temperature is adjustable from room temperature to 220°C and the working temperature accuracy is $\pm 1^{\circ}\text{C}$. When the set temperature is reached, there will be graphic and tone prompts.

- If the upper temperature limit is exceeded, the protection mode will be activated and the device will stop and reveal a prompt tone.
- Temperature standby function, standby time and standby temperature are adjustable.
- Malfunction prompt and alarm function. Monitors the machine running status in real time while the machine is running.
- Seal width $\geq 12\text{mm}$; seal strength meets the requirements of YY/T 0698.5-2009.
- Printing function. English letters, symbols, numbers, and special symbol in accordance with "YY 0466-2003 Symbols Used by Medical Devices for Medical Device Labels, Marks and Information" can be printed, which can reflect the validity period, lot, operator and other requirements required by the Ministry of Health.
- The width of the printed font is adjustable, divided into "narrow", "normal" and "wide". Appropriate width can be selected according to the width of the sterile pouches.
- Printing length prompt. Machine will prompt when there is no content.
- Printing ribbon can be ejected from the side and the ribbon can be replaced without moving the device, which is convenient and quick.
- Using ceramic heating plates, heating is fast, temperature is uniform, dry-heat feasible, imparting long useful life.

5 Installation

- 1) Check the integrity of the packaging box. If there is any damage, deformation or liquid immersion, please contact our company or agent to confirm the cause and deal with the issue.
- 2) Open the packaging and take out the sealing machine and accessories, check whether the sealing machine and accessories are damaged, and check the accessories table to see if the accessories are complete.
- 3) Place the sealing machine on a flat and stable workbench and keep certain a distance from other equipments/objects to reserve a certain operating space.
- 4) Connect the power cord to the power socket of the sealing machine first and then to the 220V power supply. The power cord should be kept away from frequently moved objects to avoid being pulled.
- 5) Install the guide plate, tighten knurled nut to fix the guide plate, and refer to the ruler near the feeding gap to determine the distance from edge of the sterile pouches.

6 Interface

- 1) Connect to power supply, turn on the sealing machine. The sealing machine will automatically run as per last operation setting; date and time can be saved so date and time can be tracked even after turning off the machine.
- 2) Once the splash screen is over, system enters into "Home" page
- 3) The home page is divided into three parts "Status Display Area", "Parameters Setup Area" and "Printed Content Area"

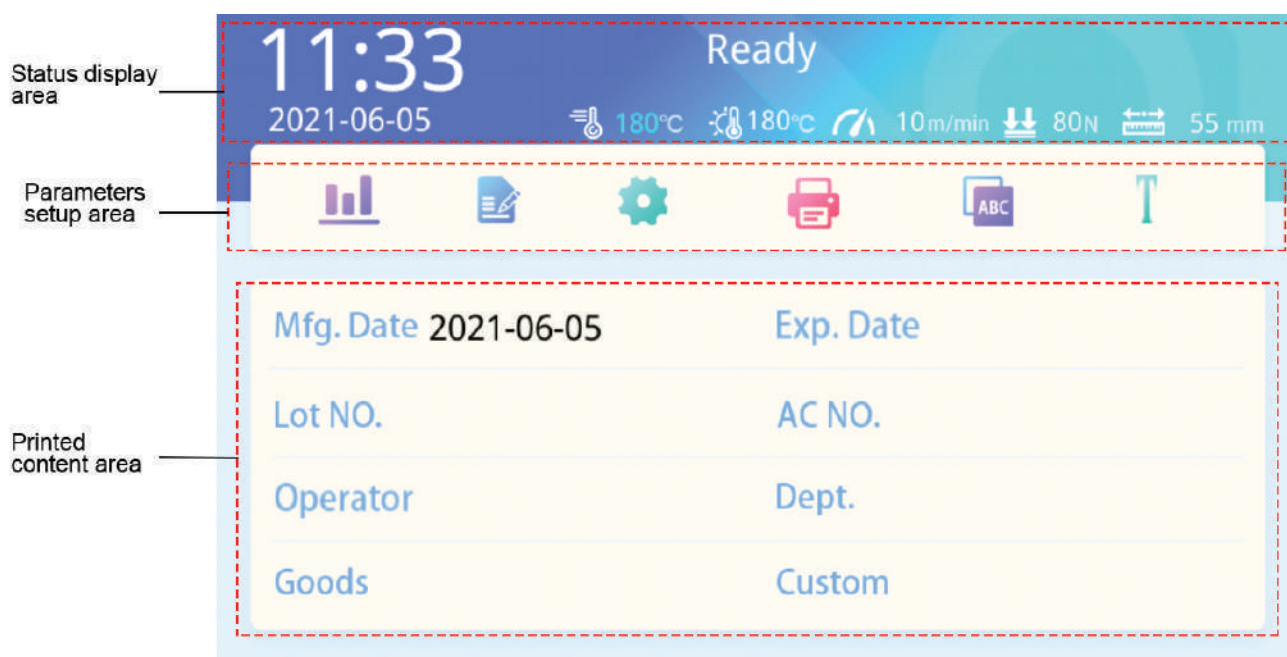


Figure 2 Home page

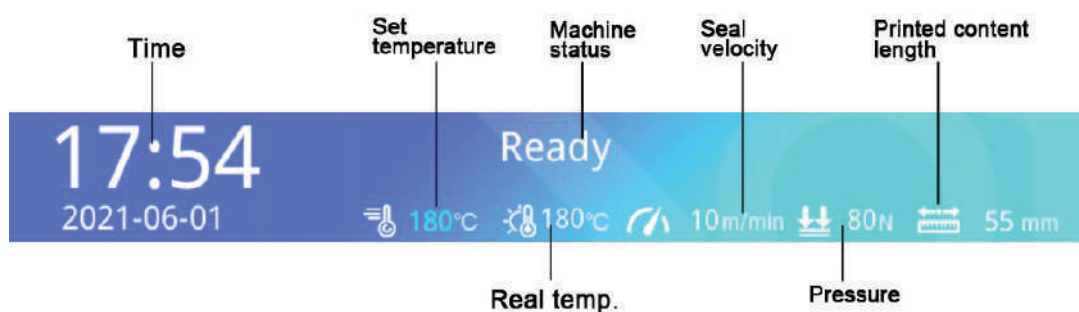


Figure 3 Status Display Area

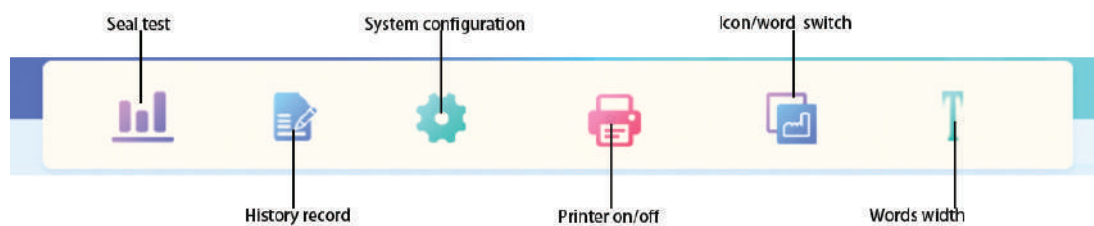


Figure 4 Machine setup area instruction

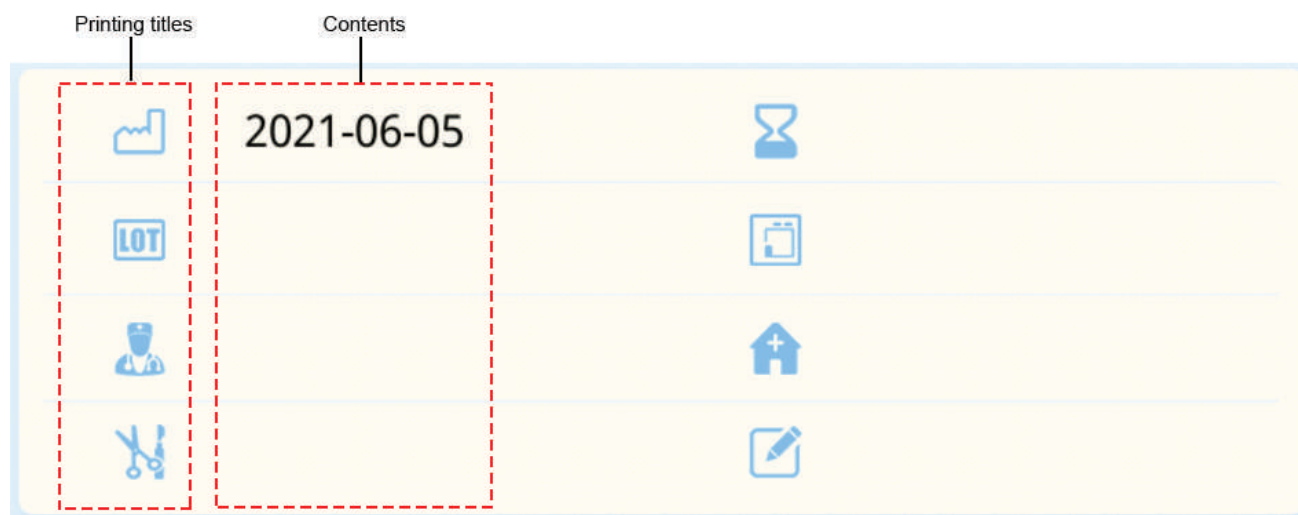


Figure 5 Printing content setup instructions. Click the "Items printed" to control whether or not to print the content on pouch (the light blue color indicates to be printed, and the gray color indicates not to be printed).

Click "Printed Content" corresponding to the items to be printed to edit content shown in Figure 6;

Figure 6 Content editing interface









							
Manufacturing Date	Expiration Date	Lot No.	Autoclave No.	Operator	Department	Goods	Other contents

Figure 7 Icons and corresponding meaning

4) System settings

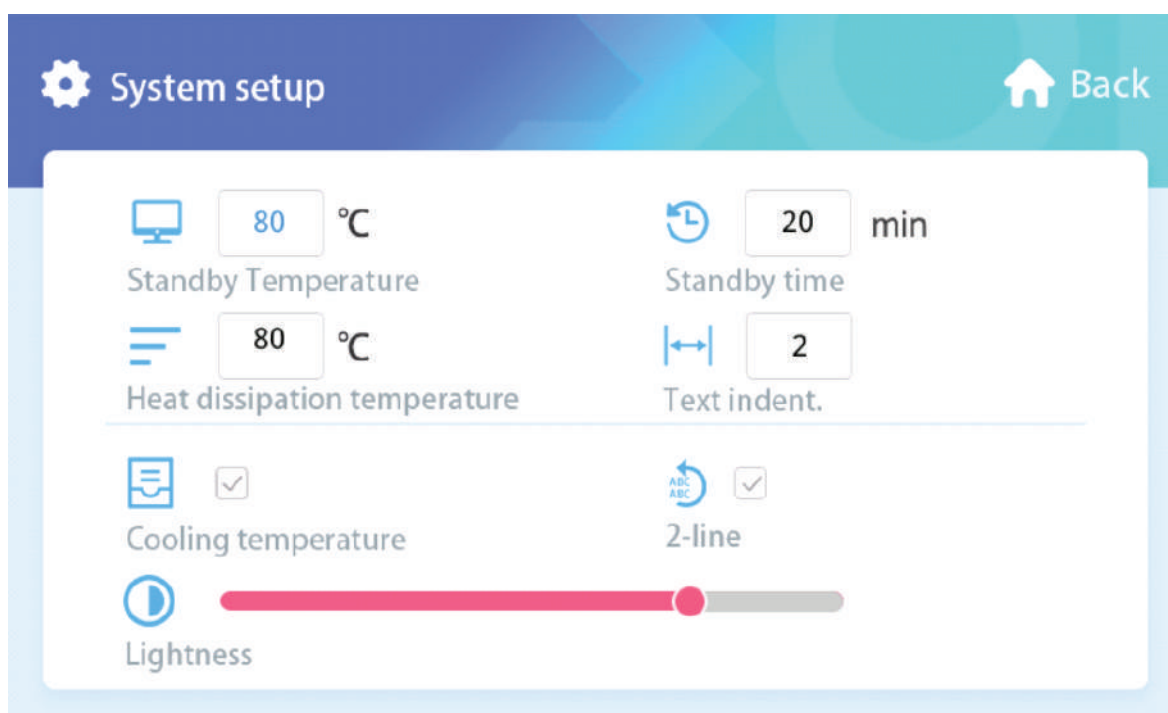


Figure 8 System settings interface

5) "System settings" introduction

- (1) Click "standby temperature" to select the temperature from drop-down menu, "room temperature", "60°C", "80°C" and "120°C";
- (2) Click "standby time" to select from drop-down menu, "10min", "20min" and "30min". If there is no operation for time duration in "standby duration" without operation, the sealing machine maintains at "standby temperature";
- (3) "Cooling temperature" controls the on/off of the cooling fan according to the temperature;
- (4) "Text indent". 1, 2, 3, and 4 character(s) width can be chosen from;
- (5) "Lot No. increment". Automatically increase lot number by one;
- (6) "Motor running constantly" to control whether the motor runs constantly;

7 Sealing Instructions

- (1) According to the WS310.1 (Central Sterile Supply Department Part 1 : Management standard), select qualified pouches made of paper or paper plastic that meets the requirements and check whether markings printed on both sides of the pouches are clear and sufficient before use. Use tester to tests whether the seal strength of both ends of the pouch meets the requirements;
- (2) Position guide plate: Guide plate is installed on the left side of the equipment. Loosen the thumb screw under the guide plate counterclockwise, and adjust the guide plate horizontally according to the distance from the edge. After confirming position, tighten thumb screw. The guide plate is for changing the distance from the edge to the object and for preventing foreign object from entering the heat sealer which may cause damage to the equipment.

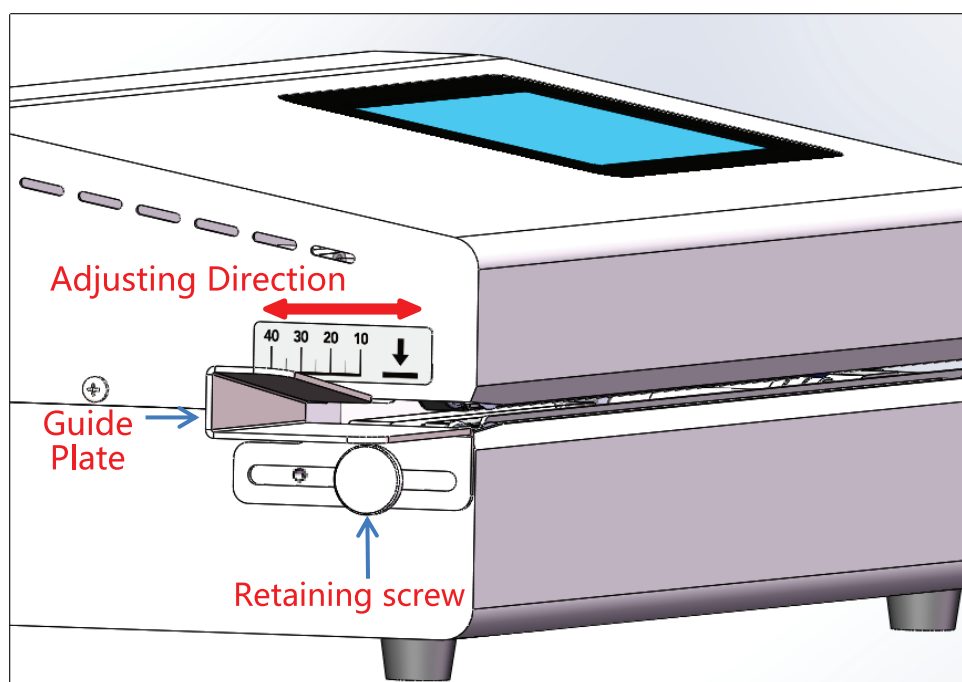


Figure 9 Guide plate installation

- (3) Select sterile pouches of suitable width and length as per items to be sterilized. Disable printer and "Lot No. increment" and seal one end of sterile pouches, and then put the items into the pouch. According to the regulations in WS310. 2-2016 Part 5. 7.10 , the distance between the end of the items and the seal on the sterile pouch should be > 2.5 cm, so ensure enough length on the pouches.



Figure 10 Schematic of distance between the goods and the sealing portion

- (4) If one end of the pouch is sealed already, put the goods into the pouch. It should be noted that the special-shaped and sharp edges of the goods must be placed correctly during placement, the goods must be protected by a sheath; the goods should be placed in pouches of suitable size. Do not fill over-sized goods into the pouch. Goods shall occupy <75% of the space on the pouch to ensure that the pouches will not break during the sterilization and sealing would be flat and smooth;
- (5) Feed the pouches with the paper side faced down and the plastic side faced up on the guide plate of the sealing machine, the machine will automatically convey pouches to the right side of the sealing machine;
- (6) If there is no sliding table, to ensure that the edge of the heat sealing is flat and smooth, please take both ends of the opening with both hands, and fully flatten the opening that enters the sealing machine. The pouch opening should be parallel to the edge of sealing machine. Once the pouch transmission is started, keep the pouch well positioned till the ending of the sealing

8 Sealing Test

- (1) In order to ensure good sealing effect, according to WS310. 2-2016 Central Sterile Supply Department (CSSD) Part 2: Standard for operating procedure of cleaning, disinfection and sterilization issued by Ministry of Health of People's Republic of China, accuracy of the parameters and integrity of the medical sealing machine should be checked before daily use. Standard GB/T19633.2-2015AS011607-2:2006 regulation shall be also referred to through out the use of the sealing test paper.

- (2) Please select sealing test paper according to the type of the pouch (paper-plastic test paper low-temperature seal test paper).
- (3) Please keep as a permanent record of the test paper for the convenience of the machine maintenance.
- (4) Seal test paper analysis:
 - a. Whether the seal edge is straight and smooth.
 - b. Whether there is opening and passage along the seal edge.
 - c. Whether there is wrinkle on the seal.
 - d. Whether over-heated in the seal.

9 Replace dot matrix printer ribbon

When the color of the printed content becomes lighter or grayer, or the text is intermittent and not clear, the ribbon needs to be replaced.

Ribbon removal. The printer module is on the right side of sealing machine. Press the printer module to eject the ribbon. Clamp both sides of the ribbon and press the button on the right side of ribbon. Then the ribbon will be separated from the clip. Move to the right the whole ribbon.

Ribbon installation. Incline the ribbon inside to the left side and then right side to clip. If there is resistance, turn the knob on the ribbon. Make sure the ribbon is visible, the ribbon is not folded and the printer head is covered. Move the ribbon slightly to ensure firmness. Finally, push the small plate near the printer wholly into the machine to lock the printer.

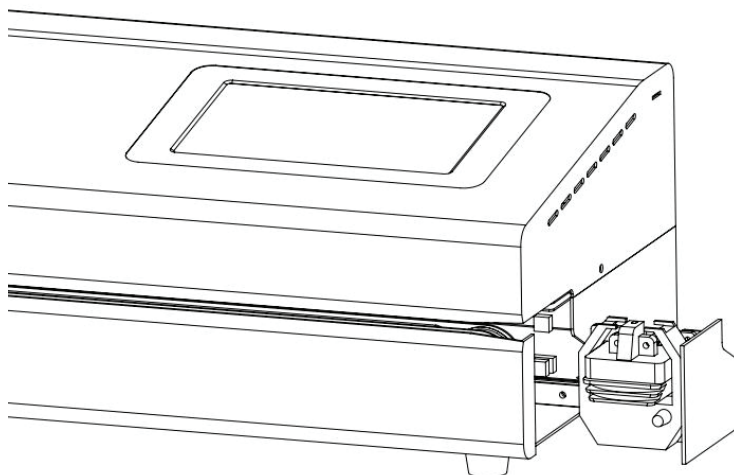
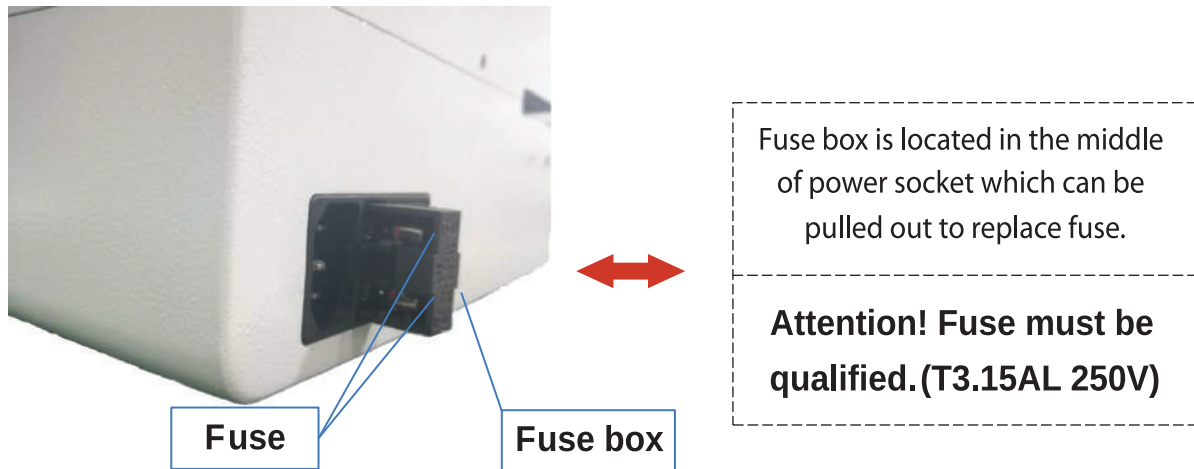


Figure 11 Schematic of disassembling the ribbon

10 Replace Fuse



Double fuses (model: T3.15AL, 250V) are employed in the machine power socket. If the equipment cannot be started, please turn it off, disconnect the power source and check whether the fuses are intact. If fuse is brown, replace fuse of specified model.

11 Troubleshooting

There are sensors and high-temperature elements in this equipment. To disassemble the machine without guidance is strictly prohibited.

If malfunction appears, please contact the after-sales service provider.

Please keep the equipment packaging carton and packaging sponge properly, in case of needed to be returned to the factory.

Appendix: Scope of delivery

No.	Items	Qty.	Specification	Remarks
1	Steripak Rotary Sealer	1	Model P30	
2	Power cable (type F)	1	PSB-10-3× 0.75	Widely used in Europe
3	Guide plate	1		
4	Retaining screw	1		
5	Fuse	2	T3.15AL 250V	
6	Operation manual	1		
7	Certificate	1		