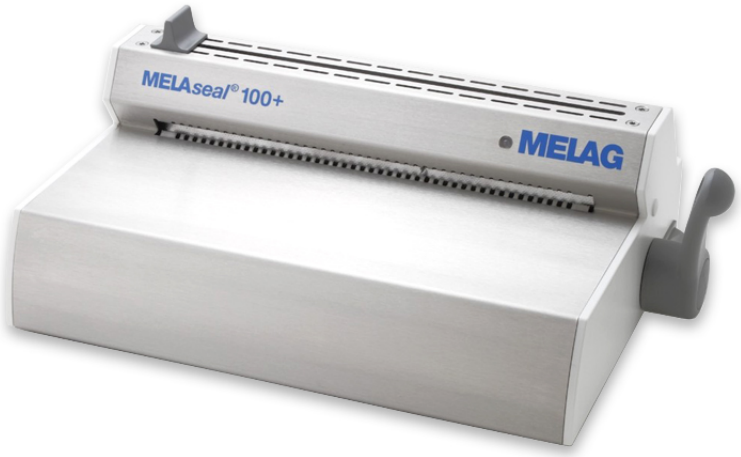
MELAG

Operating Manual

Package sealing device

MELA*seal*® 100+



Dear doctor,

We should like to extend our thanks for the expression of trust in our company which you have displayed through the purchase of this film sealing device.

Since 1951, MELAG, a medium-sized family run company, has specialised in the production of sterilizers and sterilization accessories. During this time, we became one of the leading manufacturers in this area. World sales of more than 450,000 MELAG devices gives testimony to the quality of our devices, which we manufacture exclusively in Germany.

This package sealing device was also manufactured and checked according to strict quality criteria. Please read these operating instructions carefully and thoroughly before commissioning. The functionality and value-retention of this device depends on the care accorded to it.

MELAG – Management and employees

CE

Please read these operating instructions carefully before commissioning the sealing device. The instructions include important safety information. Please store these operating instructions carefully and in close proximity to your sealing device. It represents a component of the product.

Operating Manual MELA*seal*® 100+

Responsible for content: Engineering Department

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Subject to technical changes

Safety Instructions

When operating the sealing device, please ensure that you observe the following safety instructions as well as those contained in following chapters.

- Never open the housing of the sealing device. Incorrect opening and repair can compromise electrical safety and pose a danger to the user.
  The guarantee and warranty are forfeited as soon as the sealing device is opened by anyone other than a member of a MELAG-authorized technical customer service.

Power cable and mains socket

- Only the power cable included in the scope of delivery may be connected to the sealing device.
- Liquids may not be permitted to reach the interior of the sealing device. This could result in an electrical shock or short circuiting.

About these Instructions

Symbol	***Meaning***	***Explanation***
 **Warning**	Observe without fail	Draws your attention to a situation, which if not avoided, could result in damage to the instruments or the device.
	Important information	Draws your attention to important information.
Example of emphasis	***Meaning***	***Explanation***
Chapter 4 - Settings	Cross reference	Reference to another text section within this manual.
Figure 1/(5)	Cross reference	Reference to a detail in a figure – in the example, to part no. 5 in figure 1.

CONTENTS

Chapter 1 – Performance Specifications

Proper use

Application area

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices.
It was developed for the heat sealing of instruments in sterilization packaging.

Suitable materials

It is suitable for the heat sealing of transparent sterilization packaging such as e.g. MELA*fol*®.

Should you wish to use packaging materials other than those specified above, please consult your stockist first or contact MELAG directly.

Unsuitable materials

Tubular film (double-sided film) is not suitable for use in this sealing device as these types tend to become glued together on the sealing rail, thus restricting the functionality of the sealing device.

NOTE

The use of other packaging materials carries the risk of damage to or malfunction of the device.

Please observe the manufacturer information regarding the respective packaging materials as well as the recommended sealing temperatures.

Chapter 2 – Device Description

Scope of delivery

Please check scope of delivery before connecting the MELA*seal*®100+ sealing device.

Standard scope of delivery

- MELA*seal*®100+ package sealing device
- Operating Manual
- Certificate of conformity
- Warranty certificate
- Mains cable
- Lever
- TORX key for housing screws

Views of the device

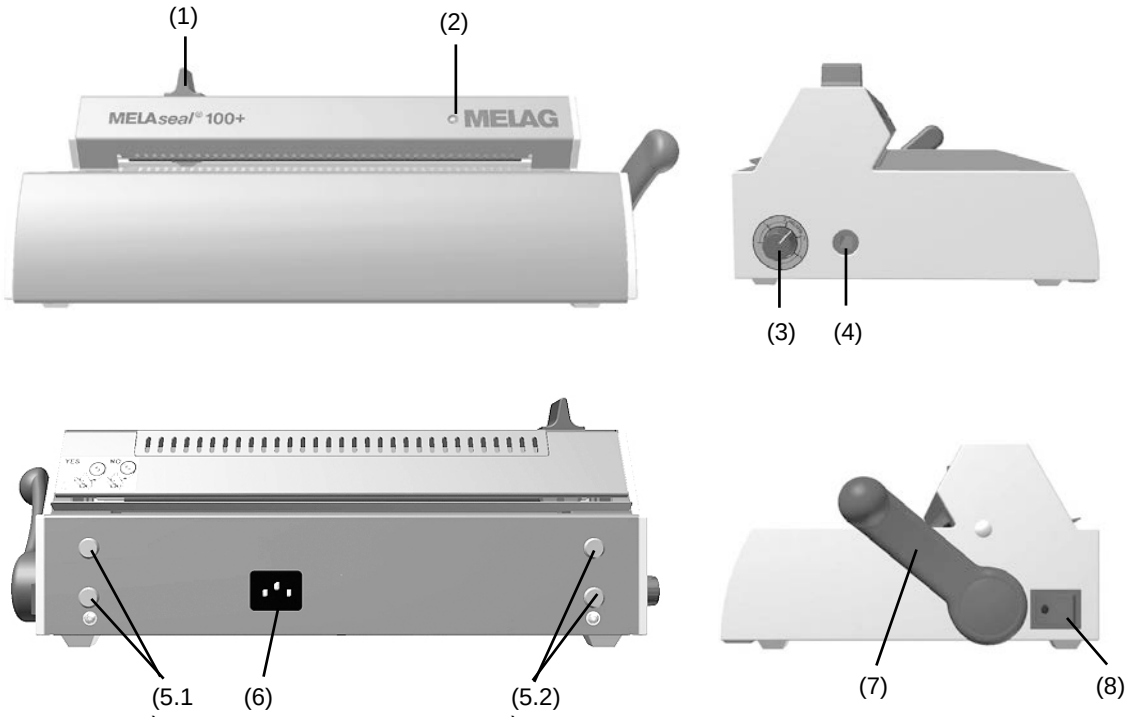


Fig. 1: Views of the device

(1) Knife handle
(2) Control lamp
(3) Rotary knob for temperature adjustment
(4) Square hole for lever (double-sided)
(5.1/5.2) Bracket for roll dispenser
(6) Power cable socket
(7) Lever
(8) Mains switch

Chapter 3 – Initial Commissioning

Transport and storage

Warning

- The MELA*seal*®100+ sealing device should only be transported in its original or otherwise suitable packaging.
- The use of other transport packaging can result in damage to the housing and the device interior.

Storage The device should be stored in such a way to protect against humidity.

Conditions of storage and installation

Warning

- In accordance with current VDE specifications, the sealing device is unsuitable for operation in areas exposed to the danger of explosion.
- The sealing device is conceived for use outside patient surroundings. The device should be located a minimum of 1.5 m radius away from the treatment area.

Failure to comply with these provisions can result in damage to the device and / or human injury.

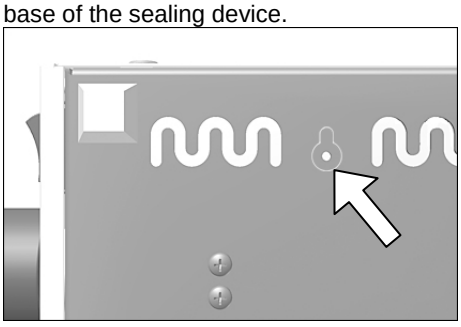
Requirements of the installation location

- Install the sealing device in a dry and dust-protected location.
- Maintain sufficient clearance to the surrounding surfaces in order to ensure sufficient ventilation.
- Ensure that the sealing device is located away from direct sunshine and outside the range of other sources of heat.
- The sealing device must be protected against blows or vibration.

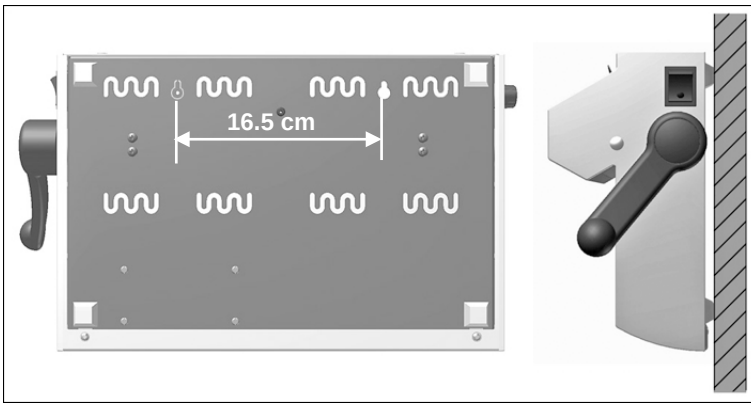
Wall mounting

If the device is not to be placed on a table, it can be mounted on a wall. If this is the case, we recommend using the wall-mounted roll dispenser optionally available. Proceed as follows:

1. Remove the perforated metal wall-mounting metal panels from the base of the sealing device.



2. Drill two Ø 6 mm boreholes in the wall with a clearance of 16.5 mm at the desired mounting height.



3. Insert two rawlplugs (6mm) with round-head screws (Ø3.5 x 45 mm) in the bore holes.
4. Hang the sealing device on the screws.

Connecting the sealing device

Only use the power cable included in the scope of delivery.

NOTE
Ensure that the mains switch is switched off before connection (see Fig. 1/(8) on page 6).

- Connect the one end of the power cable with the port on the rear of the sealing device and the other end with a mains socket with an approved voltage supply (in accordance with the name plate on the rear of the sealing device).
- Insert the lever in the square hole on the left or right-hand side of the device as required (Fig. 1/(4)).

Commissioning

Switching on the sealing device

- Switch on the sealing device at the mains switch. The LED on the mains switch will illuminate green.

The control lamp (Fig. 1/(2)) on the foreside of the sealing device will illuminate yellow after activation.

Sealing device ready to operate

As soon as the control lamp is continuously illuminated green, the pre-set sealing temperature has been reached and the sealing device is ready to operate.

Simple sealing procedure

Danger

The sealing bar is heated continuously after the sealing device has been switched on. The surrounding metal components are hot!

- Never touch the metal surfaces on the cutting bar and on the rear and fore paper guide directly.

Failure to observe this requirement can result in burns.

Simple sealing procedure to seal a film bag

- Introduce the packaging in the paper guide with the paper side facing downwards and push the packaging through the pressure bar and sealing bar.
- Press the lever forwards to its fullest extent until it clicks.

- Leave the lever depressed as long as the control lamp flashes green in short intervals (for 3 seconds).
- When the control lamp is continually illuminated green, return the leaver to its starting position.

The sealing procedure has been completed successfully.

Sealing procedure for rollstock

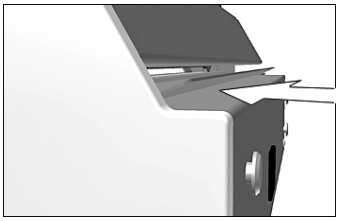
Danger

The sealing bar is heated continuously after the sealing device has been switched on. The surrounding metal components are hot!

- Never touch the metal surface on the cutting bar and on the rear and fore paper guide directly.

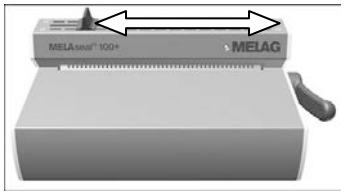
Failure to observe this requirement can result in burns.

If the instruments are packaged from the roll in transparent sterilization packaging bags, proceed as follows:



- Introduce the film in the paper guide from the rear with the paper side facing downwards and push the packaging forward through the pressure bar and sealing bar until reaching the desired length.
- Press the lever forwards to its fullest extent until it clicks.
- Leave the lever depressed as long as the control lamp flashes green in short intervals (for 3 seconds).

Cutting the film



- To cut the film, move the knife handle (Fig. 1/(1)) to the other end of the sealing device quickly. The lever should remain depressed.

Sealing film bags

- Place the instruments to be sterilized in the bag thus produced. Ensure maintenance of the correct clearance between instrument and seal seam (consult the relevant section of the DIN Specifications on page 14).
- Slide the open side of the bag from the front into the paper guide.
- Press the lever forwards to its fullest extent until it clicks.
- Leave the lever depressed as long as the control lamp flashes green in short intervals (for approx. 3 seconds).
- When the control lamp is continually illuminated green again, return the leaver to its starting position.
- The sealing procedure has been completed successfully.

Seal seam width

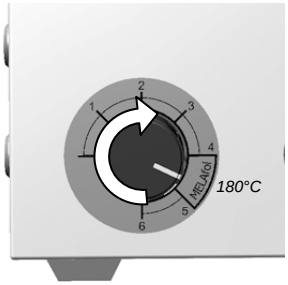
The MELA*seal*® 100+ sealing device produces homogenous 10 mm wide seal seams with every sealing procedure.

The recommended nominal size for the width of the seal seam in the German standard DIN 58953 part 7 is only 8 mm.

NOTE

The German standard DIN 58953 part 7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with transparent bags on the removal edge. This ensures aseptic removal. We recommend a minimum overhang of 10 mm.

Changing the sealing temperature



Continuously variable temperature regulation is performed using the rotary knob (Fig. 1/(3)) on the left-hand side of the sealing device.

The sealing temperature is determined by the type of sterilization packaging.

When using MELA*fol*® transparent sterilization packaging as provided by MELAG, the rotary knob should point to the middle area marked with “MELAFOL”.

To reduce the sealing temperature, turn the knob leftwards in an anti-clockwise direction.

To increase the sealing temperature, turn the rotary knob rightwards in a clockwise direction.

Control lamp status display and acoustic signals

LED/ acoustic signals	***Status***	***Measures***
Illuminated yellow	The sealing device is switched on and is currently warming up.	Please wait until the pre-set sealing temperature has been reached.
Flashes red/ warning signal	The lever is depressed during the heating phase, the sealing temperature has not yet been reached.	Please wait until the LED is constantly illuminated green.
Illuminated green	The sealing device has reached the pre-set sealing temperature and is ready for operation. The pre-set sealing time (3 sec) has been reached and the sealing procedure has been ended.	Raise the lever and remove the packaging.
Flashes green	The sealing procedure is running (3 sec) and the lever has been depressed.	Please wait until the LED is constantly illuminated green.
Illuminated red/ warning signal (malfunction)	The lever has been raised early, despite the required sealing time not having been reached. The lever has not been raised, despite the required sealing time having been completed. The heating phase is taking too long (> 5 min.); the sealing device cannot reach the pre-set sealing temperature.	Please keep the lever depressed until the green LED is constantly illuminated. Lift the lever as soon as the sealing time has been reached so that the film is not burnt.

Chapter 4 – Optional Accessories

Roll dispenser “Standard”

The roll dispenser "Standard“ is placed directly behind the sealing device. The rolls of film are placed into the cavity and held in position using additional spacers located to the left and right. This prevents them from slipping.

The roll dispenser “Standard“ is hooked onto the brackets on the rear of the sealing device.

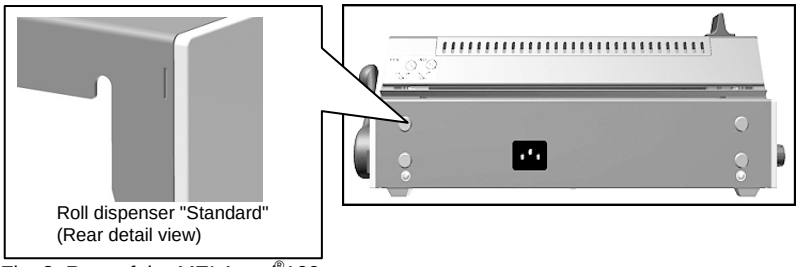


Fig. 2: Rear of the MELA*seal*®100+

Roll dispenser “Comfort”

The roll dispenser “Comfort“ enables space-saving storage of the film rolls over the sealing device.

The rolls are slid onto the rod laterally and held in position via additional spacers to the left and right. This prevents the roll from slipping.

The roll dispenser “Comfort“ is hooked onto the brackets on the rear of the sealing device.

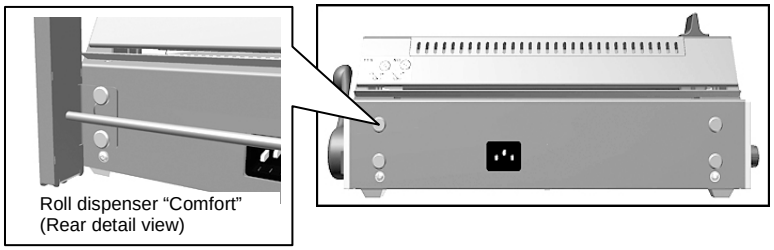


Fig. 3: Rear of the MELA*seal*®100+

Wall-mounted roll dispenser

Mounted on the wall directly over the sealing device, the wall-mounted roll dispenser saves even more space then “Comfort” in storing the film rolls.

Chapter 5 - Maintenance

Replacing the blade

Danger

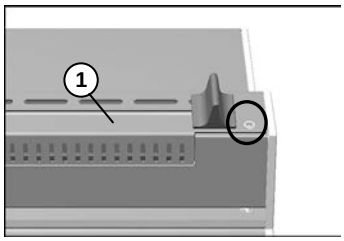
- Switch off the sealing device at the mains and unplug from the mains.

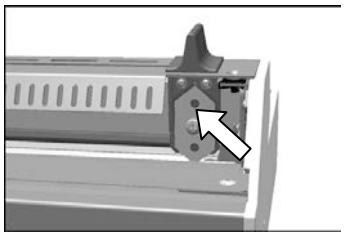
Failure to observe this requirement can result in an electric shock.

Danger

- Allow the sealing device to cool before opening.

Failure to observe this requirement can result in burns.





Proceed as follows to replace the blade:

1. Remove the 2 TORX screws (Torx 20) from the upper side of the sealing device on the cutting bar using the TORX screwdriver included in the scope of delivery.
2. Remove the upper rear housing cover (pos. 1) upwards.
3. Loosen the screws on the blade.
4. Turn the blade in order to use the other side of the blade or replace it entirely.
5. Return the screws.

Replace the unit housing and secure with the Torx screws. Press the fore housing cover against the rear housing cover in order to return the Torx screws.

NOTE

When assembling the sealing device, ensure that the blade is able to move freely from side to side.

Cleaning and regular controls

Cleaning the device after 6 months

The outside of the sealing device should be cleaned at least twice a year. Only use a lint-free damp cloth stainless steel-cleaning agent suitable for use with medical products. It should not deposit any oily residue.

- Switch off the sealing device at the mains and remove the cable before every cleaning run.
- The cleaning cloth may never be allowed to become entirely wet in order to prevent water from entering the interior of the sealing device.

Failure to observe this provision can result in a short circuit and/or an electric shock.

Manufacturers Recommendation for Routine Operation

1. Daily before operation

Making and checking a sample seal seam

Visual check:

- The seal seam should be distinct and even and not contain any creases or defects.
- The colour of the seal seam should be identical with that of a factory-produced seal seam.
  - Should it be too light → The temperature and / or contact pressure is too low;
  - if it is too brown → Too hot

Mechanical check

- Check the tensile strength. The strength required to open the seam must be exactly equal to that required to open the factory-produced seam.
  → Peel test.
- When peeled off, the paper should free itself from the film, leaving almost no residue.

2. Daily after every sterilization

Batch-related check of the seam

- Control the entire packaging for dryness and integrity.
- Clearance after sterilization. Documentation within the framework of process clearance e.g. on MELA*doc* document sheets (Art.-No. 01091).
- Check for dryness and integrity once again, before using the instruments.

3. Weekly routine check

- Visual check with MELAG seal check (Art.-No. 01079) and documentation of the results. The criteria are listed on the MEALG seal check.

4. Annual periodic check

- Check of the seal seam for tear-resistance in accordance with DIN EN 868-5, Appendix D.

MELAG provides this annual check for a cost price of 75.00 € plus V.A.T. (as of 01/2010).
The procedure is as follows

Please send the following test strips to MELAG so that we can check reproducibility: 3 x 10 cm long strips of the smallest packaging format used (e.g. MELA*fol*®) and one 10 cm long test strip from every other larger format. All test strips must have two seal seams separated by a gap of 5 cm.

Before despatching them to MELAG, please sterilize the test strips in the Universal-Program of your autoclave and note in the correspondence the serial number of your sealing device and if known, the sealing temperature and sealing force set on your sealing device.

MELAG will then despatch verification of testing. Should the test be passed successfully MEALG will issue certification of conformity with the standard DIN EN 868-5, Appendix D.

DIN Specifications

Width of seal seam and clearence

Sealed seam width

According to DIN 58953, part 7, the width of the seal seam for transparent sterilization packaging usually amounts to 8 mm, but should not amount to less than 6 mm.

DIN 58953, part 7 specifies that a clearance of a minimum 3 cm should remain between the seal seam and the sterilization material to guarantee a faultless and fold-free seal seam.
This should be ensured when processing both the bags as well as rollstock.

Strength of seal seam

When using MELA*fol*® transparent sterilization packaging, the sealing device MELA*seal*® 100+ guarantees seal strength in accordance with EN 868-5.

General

- Do not select undersized packaging.
- Pressing together should remove all air before sealing.
- When sealing entire standard-tray cassette, the length of the film should be at least double the length of the standard-tray cassette (see DIN 58953, Part 7). This also applies to cases in which standard trays are used to sterilize textiles.

Storage length for sterile medical products

Guidelines for the storage period of sterile medical products according to DIN 58953-8 from October 2003

This standard applies to all medical products delivered in a sterile state and which are to be handled in such a manner so as that their quality is maintained until coming to aseptic application.

Packaging type		***Storage period***	
Sterilized equipment packaging	***Packaging type***	***Unprotected storage*** [1)]	***Protected storage***
Paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bag and tubing of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Sterilization load in primary packaging	Serves supply for immediate use [2)] Should be avoided as a method of storage	6 months Not longer than the expiry date [3)]
	Sterilized equipment storage packaging not opened or opened and then re-sealed	5 years [4)]	

[1)] On shelves in rooms which do not correspond with room class 1 as defined by DIN 1946-4 (Ventilation and air conditioning) 1999-03, table 2.

[2)] Immediate use means application / use of the product within a maximum of 2 days / 48 hours.

[3)] Experience has shown that exceeding the storage period when using this type of package is not to be recommended for both practical and economic reasons.

[4)] The hospital can use its own packaging system as a replacement for original secondary packaging.
The marking of the original packaging must be continued in a suitable fashion.

Primary packaging	The sealed or closed packaging system sealing the medical products from all germs.
Secondary packaging	Packaging containing one or more medical products, each of which enclosed in its own primary packaging (DIN EN 868-1:1997-05).
Storage period	According to DIN 58953-8 section 7.1.1, responsibility for compliance with the specified storage requirements and period is lies with the operator of the institution. According to section 7.4, loss of sterility is dependent less on the length of the storage time as from external influences during storage, as well as transport and handling. An ideal storage time can thus not be generally specified. Specification of a suitable storage time is to be taken from the hygiene plan. Responsibility for the storage conditions and length rests with the practice operator. Primary and secondary packaging may only be opened immediately prior to use. Remove all dust on the packaging before doing so.

Accessories and Replacement Parts

	Article	***Order number:***
Accessories	Roll dispenser “Standard”	00117
	Roll dispenser “Comfort”	00111
	Wall-mounted roll dispenser	00106
	Distance washer for roll dispenser “Comfort” (4 pieces) + wall-mounted roll dispenser	13330
	MELAG seal check	01079
Replacement parts	Knife blade	17780
	Blade mount grey (without blade)	45615
	Knife handle grey	45605
	Handle grey	25201

Technical Data

Model name	MELA*seal*® 100+
Device dimensions (WxDxH)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	220 - 240 V 50/60 Hz 100 - 110 V 50/60 Hz
Power input	300 W
Seal temperature range	160 - 200°C
Seal seam width	10 mm
Length of seal steam	max. 28,5 cm
Sealing time	3.0 sec. (works settings, fix)
Overheating protection	> 240°C