MELAG
competence in hygiene

User manual

MELAseal® 100+

Sealing device

EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument reprocessing and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE

Contents

1 General guidelines

Please read this user manual carefully before commissioning the device. The manual includes important safety instructions. Make sure that you always have access to digital or printed version of the user manual.

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Symbols used

Symbol	Description
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Example	Description
see **Chapter 2**	Reference to another text section within this document.
	Prerequisites for the following handling instruction.
	Reference to the glossary or another text section.
	Information for safe handling.

Disposal

MELAG devices are synonymous for long-term quality. When you eventually need to decommission your MELAG device, the required disposal of the device can take place with MELAG in Berlin. Simply contact your stockist.

Dispose of components, spare parts, accessories, equipment and consumables which you no longer require in the appropriate manner. Comply with all relevant disposal specification in terms of possibly contaminated waste.

The packaging protects the device against transport damage. The packaging materials have been selected for their environmentally-friendly and recycling properties and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials.

2 Safety

When operating the device, comply with the following safety instructions as well as those contained in subsequent chapters. Use the device only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the device.

Qualified personnel

- Only competent and trained personnel may use the device.
- The operator must ensure that the users are regularly trained in the operation and safe handling of the device.

Repair

- Never open the device housing. 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 device is opened by anyone other than a MELAG-authorised technician.

3 Description of the device

Intended use

This device is a bar sealing device for the heat sealing of instruments in sterilization packages, in accordance with ▸EN ISO 11607-2 and ▸DIN 58953-7, in which medical instruments are to be reprocessed by means of steam sterilization. The device is designed for application in a medical context, e.g. clinics and medical and dental practices. The device is not intended for use on patients or in the patient care area.

The bar sealing device MELAseal 100+ is not a medical device as defined by the Medical Device Regulation.

Suitable materials

For the heat sealing of transparent sterilization packages in accordance with ▸EN 868-5 e.g. MELAfol reels and pouches are suitable. Should you wish to use any other packaging materials, please consult your stockist or contact MELAG directly.

Unsuitable materials

Sterilization packages that are not compatible with the requirements of EN 868-5, are incompatible with this device. The following materials are not suitable:

- Pure hose film (double-sided film), as these tends to become adhere to the sealing rail, and can restrict the functionality of the sealing device.
- Polythene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film

NOTICE

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

- Comply with the manufacturer's recommendations for the sealing temperatures suitable for each type of packaging material.

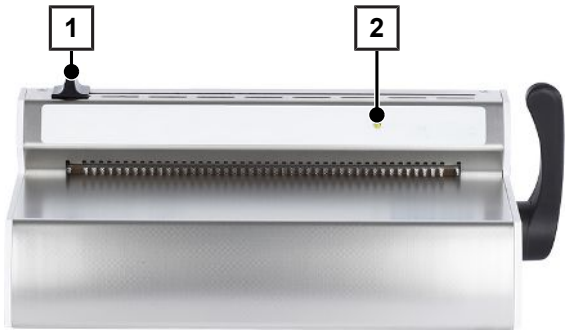
Scope of delivery

Please check the scope of delivery before setting up and connecting the device.

- Sealing device MELAseal 100+
- User manual
- Declaration of conformity
- Warranty certificate
- Power cable
- Sealing lever

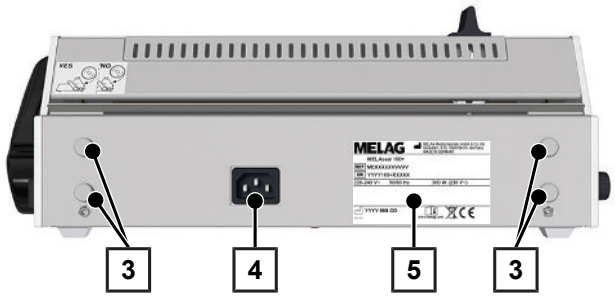
Views of the device

View from the front



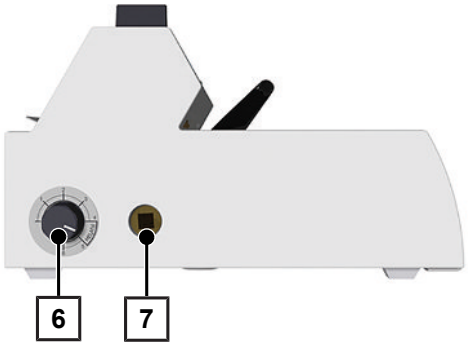
1 Knife handle
2 Control lamp

View from the rear



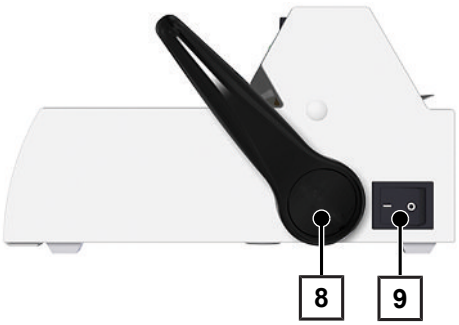
3 Bracket for reel dispenser
4 Power cable connection
5 Type plate

View from left



6 Rotary knob for temperature setting
7 Square hole for sealing lever (on both sides)

Fore right view



8 Sealing lever
9 Power switch (On/Off)

Symbols on the device

Type plate


Manufacturer of the product


Date of manufacture of the product

Article number of the product

Serial number of the product


Observe user manual or electronic user manual


Do not dispose of product in household waste


CE marking


Electrical connection of the product: Alternating current (AC)

Symbols on the power switch

Switching on device


Switching off device

Status display and acoustic signal

Control lamp/acoustic signal		Possible causes	What you can do
	LED illuminates orange	The sealing device is in the heating or cooling phase.	Wait until the pre-set sealing temperature has been reached.
	LED flashes red, warning signal sounds	• The sealing lever is depressed during the heating phase. • The sealing temperature has not yet been reached.	Wait until the LED is continuously illuminated green.
	LED illuminates green	• The sealing device has reached the pre-set sealing temperature and is ready for operation. • The pre-set sealing duration (4 s) has been reached. The sealing procedure has been completed.	Raise the sealing lever and remove the packaging.
	LED flashes green	The sealing procedure runs when the sealing lever is depressed (4 s).	Wait until the LED is continuously illuminated green.
	LED illuminates red, warning signal sounds (malfunction)	The sealing lever has been raised early, despite the required sealing duration not having been reached.	Keep the sealing lever depressed until the green LED is continuously illuminated.
		The sealing lever has not been raised, despite the required sealing duration having been completed.	Raise the sealing lever as soon as the sealing duration has been reached so that the transparent sterilization package is not burnt.
		Device malfunction: The heating phase takes too long (> 5 min). The sealing device does not reach the pre-set sealing temperature.	Upon repeated occurrence, inform an authorised technician.

PLEASE NOTE **If further status displays or acoustic signals occur, contact the authorised technician.**

4 Commissioning

Requirements of the installation location

⚠ CAUTION

Failure to comply with the setup conditions can result in injuries, malfunctions and/or damage to the device.

- Comply with all the specifications of this chapter for initial commissioning.

- Check the device after unpacking for any damage suffered during transport.
- The device is not suitable for operation in explosive atmospheres.
- The device is only intended for use in interior spaces.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
- Install and operate the device in a frost-free environment.
- Install the device in a dry and dust-protected location.
- Ensure that the sealing device is located away from direct sunshine and outside the range of other sources of heat.
- Setup the device protected against blows or vibrations.
- Maintain sufficient clearance to the surrounding surfaces in order to ensure sufficient ventilation.

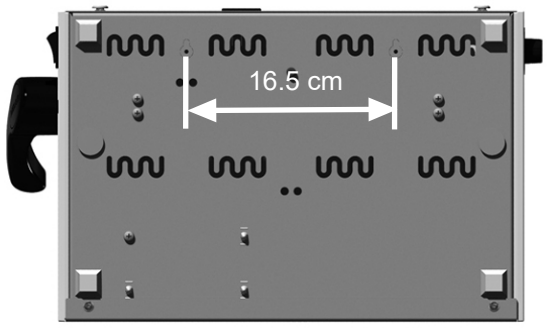
Removing from the packaging

1. Open the transport packaging carefully.
2. Remove the device from the transport packaging.
3. Check the device for any damage suffered during transport.

Wall mounting

If the device is not to be placed on a table, it can be mounted on a wall. MELAG recommends using the optional available wall mounted reel dispenser. Proceed as follows:

1. Remove the perforated 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. Screw two rawl plugs (Ø 6 mm) with roundhead screws (Ø 3.5 x 45 mm) in the drillholes.
4. Hook the sealing device in the roundhead screws.

Connecting the sealing device

Comply with the following for safe handling:

- Only the power cable included in the scope of delivery may be connected to the device.
- The power cable may only be replaced by an original spare part from MELAG.
- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- Never damage or alter the power plug or cable.
- Never bend and twist the power cable.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- Ensure that the power cable does not become jammed in.
- Never place any heavy objects on the power cable.
- Never lead the cable along a source of heat.
- Never fix the power cable with sharp objects.

NOTICE

Warning of material damage due to operation outside the specified ambient temperature.

Operating the device outside the specified ambient temperature (5-40 °C) can lead to damage to individual device components.

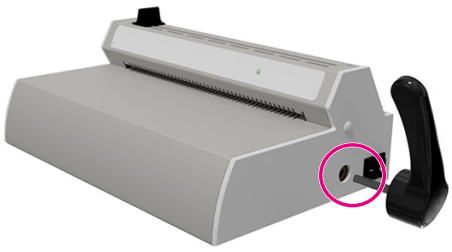
- Allow the device to acclimatise to the required ambient temperature (5-40 °C) before switching it on for the first time.

The following must be fulfilled or present:

✓ The sealing device has been switched off.

✓ The power cable, delivered in the scope of delivery, is present.

1. Connect the power cable to the back of the device.
2. Plug the power plug of the device into the power socket of the practice.
3. Insert the sealing lever in the square hole on the right or left hand side of the device as required.



Switching on the sealing device

✓ The device is connected to the power supply.

▶ Switch on the sealing device at the power switch. The control lamp on the fore side of the sealing device will illuminate yellow after activation.

Operational readiness

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.

5 Sealing

Sealing temperature

Infinitely variable temperature control is performed via the rotary knob on the left-hand side of the sealing device. The sealing temperature is determined by the type of sterilization packaging. The sealing temperature for MELAfol reels and pouches is 170-190 °C. MELAG recommends a sealing temperature of 180 °C. For this turn the rotary knob to point to the middle of the area marked with “MELAfol”. When using transparent sterilization packages from other manufacturers, set the sealing temperature according to the manufacturer’s instructions. The temperature levels correspond approximately to the following sealing temperatures:

Rotary knob at the sealing device

Temperature level	Sealing temperature
0	140°C
1	145°C
2	155°C
3	165°C
4	175°C
5	185°C
6	195°C

Sealing procedure with pre-finished film pouches

⚠ CAUTION

Danger of burns from hot metal parts. The sealing rail is heated continuously when the sealing device is switched on.

- Never touch the metal surfaces on the sealing rail or in the area of the rear and fore paper guide.

NOTICE

Inserting the packaging inverted can result in the adhesion of film residue to the sealing rail.

The film side of the packaging must always face upwards.

PLEASE NOTE

When sealing MELAfol pouches with a side gusset, ensure compliance with the manufacturer’s specifications (e.g. Instructions for handling MELAfol pouches with side gusset) especially when wishing to seal cassettes.

In order to perform a sealing procedure with pre-finished film pouches, proceed as follows:

1. Insert the packaging (film side facing upwards) from the front in the paper guide between the pressure rail and sealing rail. Ensure the correct clearance between instrument and seal seam, see Standard specifications [▸ page 21].

2. Press the sealing lever down until it latches.

3. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).
4. When the control lamp is continuously illuminated green again, raise the sealing lever upwards to its starting position. Remove the film pouch from the sealing device.
5. Perform a visual inspection of the seal seam after every successful sealing procedure.

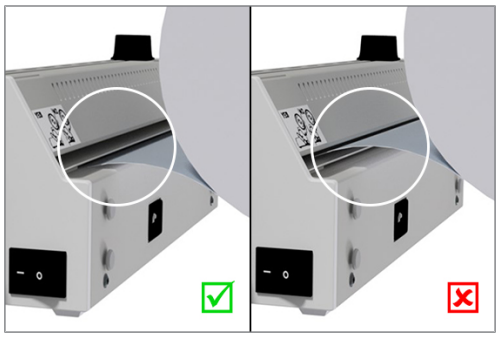
PLEASE NOTE **With pouches with side gussets, perform weekly checks of the seal seam using an ink test (e.g. MELAcontrol Ink Test).**

Sealing procedure for film reels

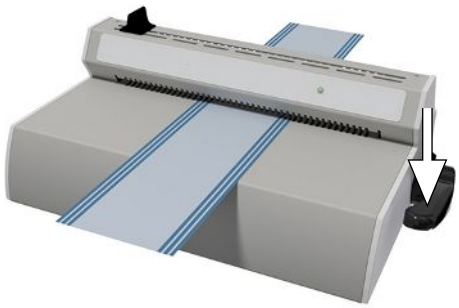
Producing a film pouch

If the instruments are packaged in pouches from the reel in transparent sterilization packaging, proceed as follows:

1. Guide the end of the film reel along the device rear panel into the lower paper guide with the paper side facing downwards (**lower slit**). Slide the film forward between the pressure and sealing rail up to the desired length.

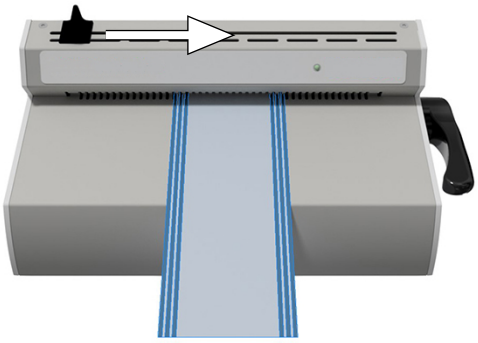


2. Press the sealing lever down until it latches.



3. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).

4. Ideally, the film should be cut off during the sealing procedure: Move the knife handle to the other end of the sealing device quickly; the sealing lever should remain depressed. Do not return the knife handle.



5. When the control lamp is continuously illuminated green, raise the sealing lever upwards to its starting position. Remove the film pouch from the sealing device.

Sealing film pouches

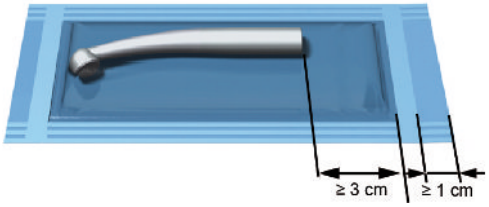
NOTICE

Inserting the packaging inverted can result in the adhesion of film residue to the sealing rail.

The film side of the packaging must always face upwards.

To seal the film pouch cut to the corresponding length, proceed as follows:

1. Place the instruments to be sterilized in the film pouch. Ensure the correct clearance between instrument and seal seam, see Standard specifications [▸ page 21].



2. Slide the open side of the film pouch from the front into the paper guide.

3. Press the sealing lever down until it latches.

4. Leave the sealing lever depressed until the control lamp flashes green in short intervals (approx. 4 s).
5. When the control lamp is continuously illuminated green again, raise the sealing lever upwards to its starting position. Remove the film pouch from the sealing device.
6. Perform a visual inspection of the seal seam after every successful sealing procedure.

6 Function checks

Function check with MELAcontrol Seal Check

The MELAcontrol Seal Check serves to check the function of the seal seam produced by your sealing device. MELAG recommends performing this function check once a day during operation.

For further information, see the MELAcontrol Seal Check instructions for use.

Performing a MELAcontrol Ink Test

The MELAcontrol Ink Test is a reliable test for routine control of the seal seam for leaks. The MELAcontrol Ink Test can also be used for bags with a side gusset.

▶ Carry out weekly seal seam checks with a MELAcontrol Ink Test.

For further information, see the MELAcontrol Ink Test instructions for use.

7 Maintenance

Cleaning and regular checks

Comply with the following for safe handling:

- Switch off the sealing device at the mains and remove the cable before cleaning.
- The cleaning cloth may never be allowed to become entirely wet in order to prevent water from entering the interior of the sealing device.
- Liquids may not be permitted to reach the interior of the device. This could result in an electrical shock or short circuiting.

Interval	Measure
When necessary and every 6 months	Clean the exterior of the sealing device with a dry or damp, non-fuzzing cloth and where necessary with a neutral fluid cleaner or spirit. Only at persistent soiling, use a mild stainless steel cleaning agent with a pH value between 5 and 8.

8 Pause times

Pause times

The sealing device can remain switched on over longer operating pauses of many hours. MELAG recommends switching off the device during long operating pauses to save energy.

Transport and storage

NOTICE

Damage to the housing and the device interior as a result of using unsuitable transport packaging.

- Only transport the device in its original packaging or other suitable packaging.

Note the following:

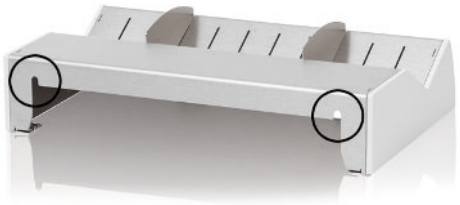
- Store and transport the device frost-free.
- Avoid strong shocks/vibrations.
- Store the device in a fashion protected against moisture.

9 Optional equipment

Reel dispenser Standard

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

- Hook the reel dispenser into the outside brackets to fix it on the rear panel of the sealing device.



Reel dispenser Comfort

The reel dispenser Comfort enables space-saving storage of the film reels above the sealing device. The reels are slid onto the rod laterally and held in position via additional spacers to the left and right. This prevents the reel from slipping.

- Hook the reel dispenser into the outside brackets to fix it on the rear panel of the sealing device.

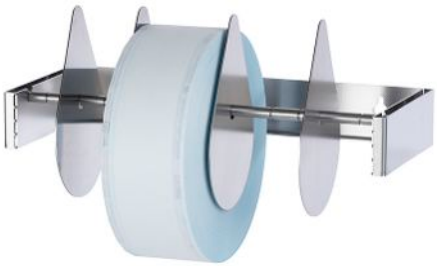
Reel dispenser Deluxe

When using the reel dispenser Deluxe, the film reels are stored above the sealing device, thus saving space. The integrated feeding device enables easy feeding of the film via a hand wheel.

Further information regarding assembly and operation is specified in the appendent user manual.

Wall mounted reel dispenser

Mounted on the wall directly over the sealing device, the wall mounted reel dispenser saves space.



10 Manufacturer's recommendation for routine operation

Video tutorial

See also “Manufacturer’s Recommendation for Routine Operation” (https://www.melag.com/en/service/tutorial).

For further information see separate document “Manufacturer's recommendation for routine operation of MELAG sealing devices”.

Performing the peel test

1. Seal a transparent sterilization package in the sealing device.
2. Perform a visual check to verify whether the seal seam extends consistently along the whole width and length of the sterilization package just sterilized. No paper residue bigger than 10 mm is permitted on the seal seam.
3. Process the sealed transparent sterilization package in a sterilization cycle.
4. Working by hand, pull the seal seam apart slowly along the direction of peeling:
   - ↪ The seal seam produced by your sealing device must offer noticeable resistance when opened.
   - ↪ The paper must not tear when opened.
5. Document the results.

MELAG seal seam stability test

Video tutorial

See also “Test for seal seam stability” (https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200).

Each change of a transparent sterilization package has an influence on the result of the sealing process. The optimum sealing temperature, speed and force vary with different transparent sterilization packages. The device is optimised for sealing MELAfol transparent sterilization packages. When using other transparent sterilization packages, observe the manufacturer’s instructions and set the device accordingly.

To ensure that the sealing process complies with all normative specifications, MELAG recommends carrying out a seal seam stability test annually and when the transparent sterilization package is changed.

MELAG offers a seal seam stability test for the validation of your sealing procedures. After testing the film test strips, you will receive a certificate from MELAG stating the conformity of the seal seams with the ▸EN 868-5 standard, Appendix D, if the seal seam stability test is successful. Use the MELAG seal seam stability test application form. Download the application form from the MELAG website (Service/Download Center).

11 Standard specifications

Explanation of terms

Name	Description
Sterile barrier system	▸EN ISO 11607-2 replaces the terms “packaging”, “end packaging” and “primary packaging” with the single term “sterile barrier system”. A sterile barrier system is the minimum level of packaging which prevents the penetration of micro-organisms and permits aseptic provision of the product at the location of use. This includes transparent sterilization packages, a sterilization bag, reusable containers etc.
Protective packaging	The protective packaging is designed to provide the sterile barrier system with protection up until its final application.
Packaging system	The sterile barrier system and protective packaging combine to form the packaging system.
Peel test	A procedure to determine the peeling characteristics of paper-/plastic composite material in accordance with ▸EN 868-5, Appendix E.

General information regarding the packaging and sealing procedure

Comply with the following during wrapping and sealing:

- Choose packaging of a sufficient size.
- Packaging made of porous materials and plastic composite film should be filled to a max. of 3/4 of its volume (▸DIN 58953-7).
- For packaging made of porous materials and plastic composite film, at least 30 mm must remain free between the sterilization material and the seam to be sealed (DIN 58953-7).
- When using transparent sterilization packages from a reel, the removal side must have an overlap of min. 10 mm between the cutting edge and the seal seam, enabling an aseptic removal (DIN 58953-7).
- Press together to remove all air before sealing.

Seal seam width

- The recommended nominal size for the width of the seal seam in DIN 58953-7 is 6 mm. Section 4.3.2 of EN 868-5 requires total seal width of at least 6 mm. Thus for grooved seal seams, the sum of the individual grooved seams should amount to at least 6 mm.

This sealing device produces homogeneous seal seams of 10 mm in width with every sealing procedure.

Clearance of the seal seam to the cutting edge

- Maintain the clearance between seal seam and cutting edge as prescribed in the standard:
  DIN 58953-7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with film pouches on the removal side. This ensures aseptic removal. MELAG recommends a minimum overhang of 10 mm.

Seal seam stability

When using MELAfol transparent sterilization packages, the sealing device guarantees a seal seam stability in accordance with EN 868-5.

Storage duration for sterile medical devices

The maximum storage time is dependent on the packaging and the storage conditions. Please observe the regulatory requirements for the storage period of ▸sterile materials (in Germany e.g. ▸DIN 58953, Part 8 or the ▸DGSV guidelines) as well as the following listed criteria:

- Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterile material in an environment protected against moisture.
- Store the sterile material in an environment protected against excess temperature variations.

12 Technical Data

Device type	MELAseal 100+
Device dimensions (W x D x H)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	
Power supply	220-240 V, 50/60 Hz | 100-110 V, 50/60 Hz[1)]
Max. voltage range	198-264 V
Electrical power	max. 300 W, average 100 W
Overvoltage category	transient overvoltages up to the values of overvoltage category II
Air pollution degree (in accordance with EN 61010-1)	Category 2
Overheat protection	> 240 °C
Length of the power cable	2 m
Ambient conditions	
Installation location	interior of a building
Max. altitude	2000 m
Ambient temperature	5-40 °C (ideal range 16-26 °C)
Relative humidity	max. 80 % at 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)
Degree of protection (in accordance with IEC 60529)	IP20
Sealing characteristics	
Sealing temperature range	140-195 °C
Sealing force	factory settings, fix
Heating duration (from 25 °C to 180 °C)	approx. 200 s
Sealing duration	min. 4 s (factory settings, fix)
Seal seam width	10 mm
Seal seam length	max. 27.5 cm

[1)] see type plate

13 Components, accessories and spare parts

You can obtain the specified articles and an overview of further accessories from your stockist.

Accessories

Category	Article	Art. no.
Films	MELAfol 501 (pouch, 5 x 25 cm, 1000 pcs.)	ME00501
	MELAfol 502 (roll, 5 cm x 200 m)	ME00502
	MELAfol 751 (pouch, 7.5 x 25 cm, 1000 pcs.)	ME00751
	MELAfol 752 (roll, 7.5 cm x 200 m)	ME00752
	MELAfol 1001 (pouch, 10 x 25 cm, 1000 pcs.)	ME01001
	MELAfol 1002 (roll, 10 cm x 200 m)	ME01002
	MELAfol 1502 (roll, 15 cm x 200 m)	ME01502
	MELAfol 2002 (roll, 20 cm x 200 m)	ME02002
	MELAfol 2051 (side gusset bag, 20 x 50 cm, 100 pcs.)	ME02051
	MELAfol 2502 (roll, 25 cm x 200 m)	ME02502

Other equipment

Category	Article	Art. no.
Optional equipment	Reel dispenser Standard	ME10117
	Reel dispenser Comfort	ME10111
	Reel dispenser Deluxe	ME10108
	Wall mounted reel dispenser	ME00106
	Spacer washer for wall mounted reel dispenser	ME13330
	Spacer washer reel dispenser Comfort/Deluxe (white)	ME89740
	Separating plate for reel dispenser Standard (2 pcs.)	ME72335
Testing equipment	MELAcontrol Seal Check	ME01079
	MELAcontrol Ink Test	ME01089

Spare parts

Article	Art. no.
Sealing lever (black) for MELAseal 100+/200	ME77000

Glossary

DGSV

DGSV is the abbreviation for “Deutsche Gesellschaft für Sterilgutversorgung” [German Society for Sterile Supply]. The training guidelines of the DGSV are listed in DIN 58946, Part 6 as requirements for personnel.

DIN 58953

Standard for “Sterilization – Sterile supply”

DIN 58953-7

Standard for “Sterilization – Sterile supply – Part 7: Application technology for sterilization paper, nonwovens, paper bags and sealable transparent bags and tubes”

EN 868-5

Standard for “Packaging for medical devices to be sterilized in the final packaging – Part 5: Sealable transparent bags and tubes made of porous materials and plastic composite film - Requirements and test methods”

EN ISO 11607-2

Standard for “Packaging for medical devices to be sterilized in the final packaging – Part 2: Validation requirements for forming, sealing and assembly processes”

Sterile material

Sterile goods are successfully sterilized (i.e. sterile) goods. Sterile goods are also referred to as batches.

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Email: info@melag.com
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Original instructions
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