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MELAG
competence in hygiene

Operating Manual

MELAseal® 200

Bar sealer

Software version 1.12



Dear Dr.

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

Since 1951 MELAG, a medium-sized family-run enterprise, has specialised in the sector of hygiene for medical practices. In the meantime our company has grown into one of the world's leading producers of sterilization equipment. World sales of more than 450,000 MELAG devices give testimony to the quality of our products, which we manufacture exclusively in Germany.
This device was manufactured and checked according to strict quality criteria.

MELAG – management and employees

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General notes

Please read this operating manual carefully before commissioning the sealing device. The functionality and value-retention of this sealing device depends on the care accorded to it.

The instructions include important safety information. Please read the safety information carefully before using the sealing device.

Please store this operating manual carefully and in close proximity to your sealing device. It represents a component of the product.

About this manual

Symbols used

Symbol	Explanation
	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

Symbol	Explanation
OPEN	Words or phrases appearing on the display of the sealing device are marked as display text.
see **Chapter 2**	Reference to another text section within these instructions.
Fig. 1/(3)	Reference to a detail in a figure – in the example, to part no. 3 in figure 1.

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Table of contents

Chapter 1 – Performance Specifications 5
Intended Use 5
Chapter 2 – Device description 6
Scope of delivery 6
Views of the device 6
Status display and acoustic signals 7
Chapter 3 – Commissioning 8
Transport and storage 8
Conditions of storage and installation 8
Requirements of the installation location 8
Commissioning 9
Simple sealing procedure 10
Sealing procedure for roll stock 11
Seal seam width 13
Chapter 4 – Settings 14
Menu structure 14
Setting the date and time 14
Changing the sealing temperature 15
Switching the signal tones on and off 16
Selecting between up to 10 users 16
Eco Mode and Standby 17
Chapter 5 – Logging 18
Using the USB flash drive as an output medium 18
Using the computer as an output medium 19
File names and ending 19
Reading logs correctly 20
Chapter 6 – Optional Accessories 21
Roll dispenser “standard” 21
Roll dispenser "comfort" and "deluxe" 21
Wall-mounted roll dispenser 22
Chapter 7 – Maintenance 23
Pause times 23
Replacing the blade 23
Cleaning and regular controls 24
Maintenance 24
Validation 24
Software update 24
Chapter 8 – Malfunctions 26
Manufacturer's Recommendation for Routine Operation 28
DIN Specifications 30
Terms 30
General information regarding the packaging and sealing procedure 30
Seal seam width 30
Clearance of the seal seam to the cutting edge 30
Strength of seal seam 30
Storage length for sterile medical products 31
Accessories and Spare Parts 32
Technical Data 32

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Safety Instructions

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

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.

Repair

- 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.

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Chapter 1 – Performance Specifications

Intended Use

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was especially developed for the heat sealing of instruments in sterilization packaging and complies with the standards DIN EN ISO 11607-2 and DIN 58953 part 7.

Suitable materials

It is suitable for the heat sealing of instruments in transparent sterilization packaging in accordance with DIN EN 868-5 e.g. MELA*fol*. Should you wish to use any other packaging materials as those named above, please consult your stockist first or contact MELAG directly.

Unsuitable film and materials

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

PLEASE NOTE

The use of unsuitable 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.

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Chapter 2 – Device description

Scope of delivery

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

Standard scope of delivery

- 1x MELA*seal* 200 bar sealer
- 1x power cable
- 1x lever
- 1x MELAG USB flash drive
- 1x Torx key for the fastening screws of the rear housing cover
- 1x Operating manual
- 1x Declaration of conformity
- 1x Guarantee
- 1x Test and calibration protocol

Views of the device

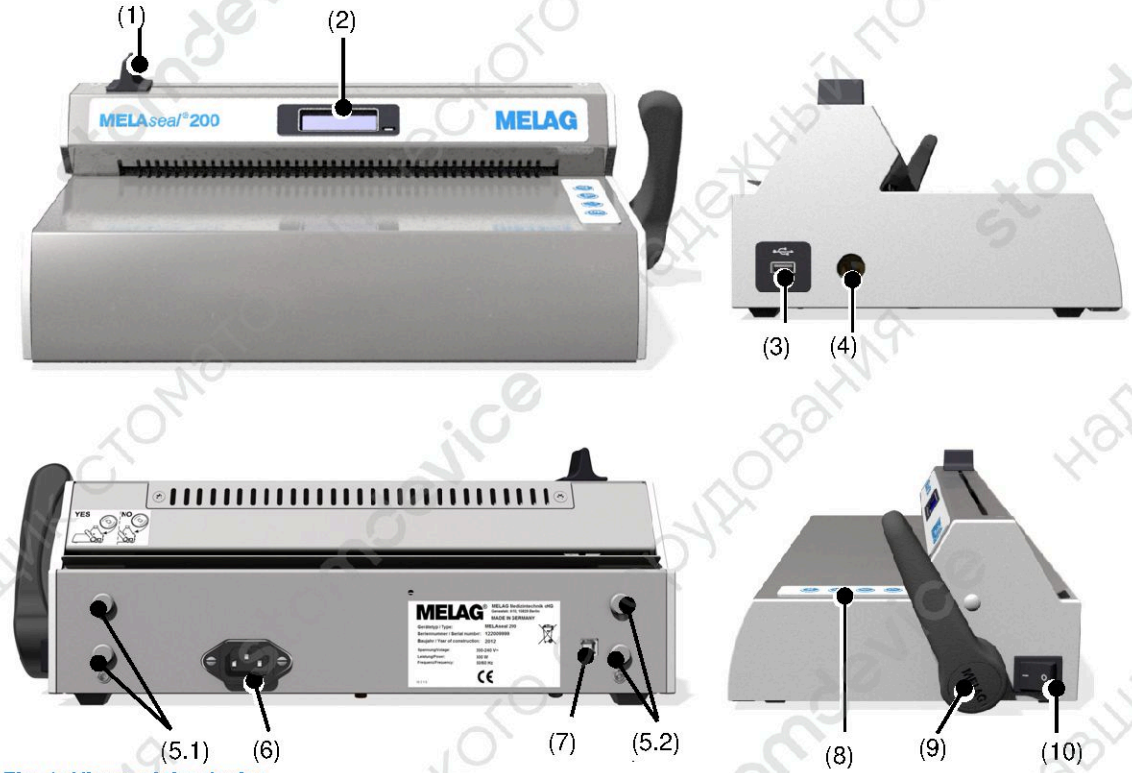


Fig. 1: Views of the device

(1) Knife handle
(2) Display with control lamp
(3) USB interface for the USB flash drive
(4) Square hole for lever (double-sided)
(5.1/5.2) Bracket for roll dispenser
(6) Socket for power cable
(7) USB interface (type B) for connection to the computer
(8) 4 Softkeys
(9) Lever
(10) Power switch

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Status display and acoustic signals

Table 1: The meaning of the control lamps and signal tones

Control lamp/ acoustic signals	Possible cause	Measure
LED illuminates orange	Sealing device is in the heating-up or cooling down phase	Please wait until the pre-set sealing temperature has been reached.
LED flashes red Warning signal sounds	The lever is depressed during the heating phase, the sealing temperature has not yet been reached.	Clear the display message with OK and wait until the LED control lamp illuminates green permanently.
	The lever has been raised early, despite the required sealing time not having been reached.	Clear the display message with OK. Leave the lever depressed until the message **Open** is issued.
	The lever has not been raised, despite the required sealing time having been completed.	Raise the lever as soon as the display message **Open** is issued. Otherwise, the sealing procedure will not be completed successfully. Failure to observe these provisions can result in the melting of the film and damage to the sealing device.
LED illuminates green	The sealing device has reached the pre-set sealing temperature and is ready for operation.	
	The pre-set sealing time (c. 3 sec) has been reached and the sealing procedure has been ended.	Raise the lever and remove the packaging.
LED flashes green	The sealing procedure runs when the lever is depressed (3 secs). The progress bar will be displayed.	Wait until the green LED control lamp is constantly illuminated / the display outputs **Open**.
LED illuminates red, Warn signal sounds (malfunction)	Device fault: The heating phase is taking too long (> 5 min.); the sealing device cannot reach the pre-set sealing temperature.	Switch off the sealing device and then back on again. Upon repeated occurrence, inform your stockist / MELAG customer services.

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Chapter 3 – Commissioning

Transport and storage

WARNING

The use of unsuitable packaging can result in damage to the housing and the device interior.

- The sealing device should only be transported in its original or otherwise suitable packaging.

Storage

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

Conditions of storage and installation

- 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.
- Observe all the information contained in this chapter during commissioning.

DANGER!

Failure to comply with the set-up conditions can result in malfunctions or damage to the sealing 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.

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Commissioning

Connecting the sealing device

Check the following points before connecting:

- ✓ *The device power switch is on.*
- ✓ *Use only the network cable included in the scope of delivery.*
- ✓ *The USB flash drive included in the scope of delivery is plugged into the sealing device.*

1. Connect the low-heat power socket of the power cable to the rear side of the sealing device and connect the power plug in the power socket.
2. Insert the lever in the square hole on the left or right hand side of the device as required.



Switching on the sealing device

1. Switch on the sealing device at the mains switch



After activation, the display issues system information e.g. the user set, confirmation as to whether the USB flash drive is connected correctly and the current temperature. The control lamp on the front of the sealing device illuminates orange and the sealing device is heated to the pre-set temperature.

The sealing device is ready for operation as soon as the pre-set sealing temperature has been reached and the display changes between **Ready** and an output of the current temperature and time. The control lamp must also illuminate continuously green.



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Simple sealing procedure

DANGER

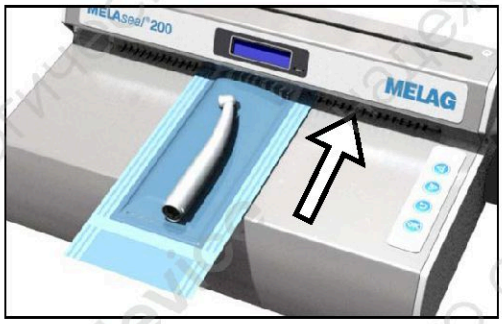
The sealing bar is heated continuously after the sealing device has been switched on. The surrounding metal components are hot!

Contact with the hot metal parts can result in burns.

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

In order to perform a simple sealing procedure, proceed as follows:

1. Introduce the packaging in the paper guide with the film side facing upwards and push the packaging through the pressure bar and sealing bar. Ensure maintenance of the correct clearance between the instrument and seal seam (consult the section **DIN Specifications**).



WARNING

The film side of the packaging must always face upwards. Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

2. Press the lever forwards to its fullest extent until it snaps.

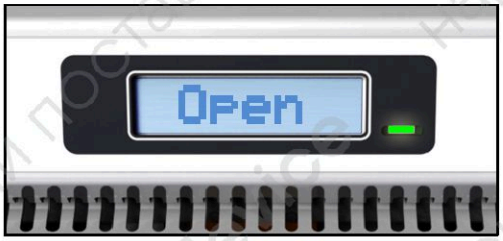


3. Leave the lever depressed as long as the progress bar in the display completes and the control lamp flashes green in short intervals (for 3 seconds).



4. When the display switches to **Open** and the control lamp is continually illuminated green again, return the lever (up) to its starting position.

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The sealing procedure has been completed successfully.

If the USB flash drive has been connected, a log will automatically be generated and saved on the USB flash drive.

If a USB flash drive has not been connected, the most important sealing parameters will be displayed alternately up to 4 times. Then the display returns to **Ready**.

Sealing procedure for roll stock

DANGER

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

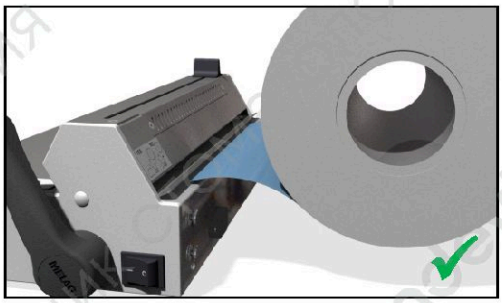
Contact with the hot metal parts can result in burns.

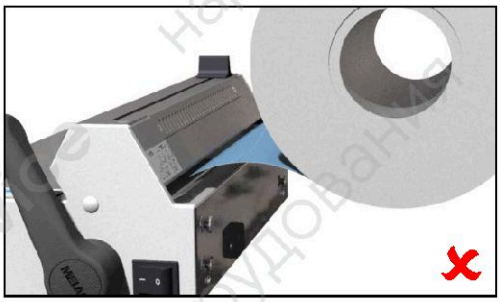
- Never touch the metal surface on the cutting bar and in the area of the rear and fore paper guide directly.

Cutting the film

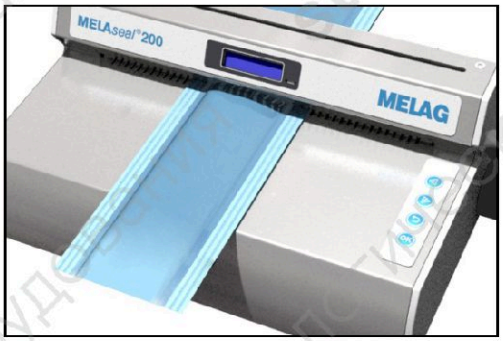
If the instruments are packaged from the roll in transparent sterilization packaging bags, proceed as follows:

1. Introduce the film in the paper guide **from the rear** with the paper-side pointing downwards (**lower slit**) and slide the film forward between the pressure and sealing bar up to the desired length.





2. Press the lever forwards to its fullest extent until it clicks.



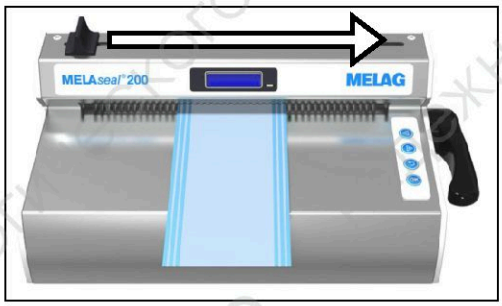
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3. Leave the lever depressed as long as the progress bar in the display completes (for 3 seconds).



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



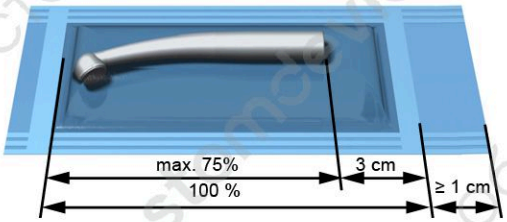
5. If the display switches to **Open** and the control lamp illuminates continuously green, raise the lever and remove the film bag thus produced.



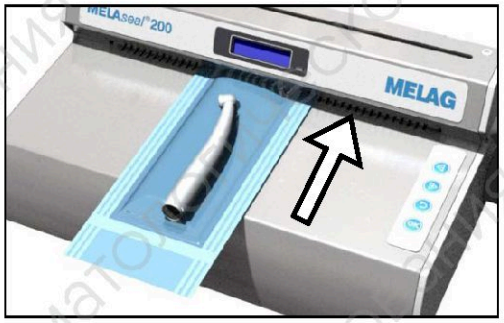
Sealing film bags

To seal on the corresponding length, proceed as follows:

1. Place the instrument in the film bag thus produced. Ensure maintenance of the correct clearance between instrument and seal seam (consult the section **DIN Specifications**).



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



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WARNING
The film side of the packaging must always face upwards. Should the packaging be inserted incorrectly, this could result in the deposit of film residue on the sealing rail.

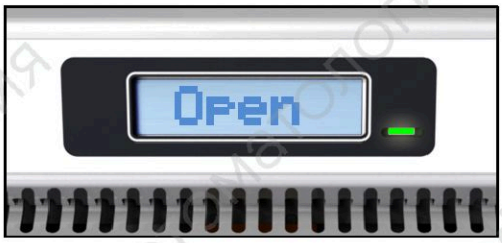
3. Press the lever forwards to its fullest extent until it clicks.



4. Leave the lever depressed as long as the progress bar in the display completes (for approx. 3 seconds).



5. When the display changes to **Open** and the control lamp is continually illuminated green again, return the lever (up) to its starting position.



6. The sealing procedure has been completed successfully.

PLEASE NOTE
When sealing MELAfol sealing bags with lateral creases, please observe and comply with the special information contained in the sealing bag operating manual regarding sealing cassettes.

Seal seam width

The sealing device produces homogeneous seal seams of 10 mm in width 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 6 mm.

> ***Section 4.3.2 of DIN EN 868-5 requires a min. total seal width of 6 mm. The sum of the individual seams should amount to min. 6 mm***

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Chapter 4 – Settings

Menu structure

	Key:
├ **Standard display output**	
│ └ Display of temperature/time/ready	
├ **User**	**User**
│ ├ User 01	User 01
│ ├ User 02	User 02
│ ├ …	…
│ └ User 10	User 10
├ **Settings**	**Settings**
│ ├ Temp	Sealing temperature
│ ├ Tone	Signal tones
│ ├ Time	Time
│ ├ Date	Date
│ └ Eco Mode	Eco Mode
└ **Info**	**Information**
├ Seal Cnt	Counter for the sealing procedures
├ Svc Date	Date of the next service
├ Svc Cnt	Counter until the next service
├ Version	Software version
└ S/N	Serial number

Pressing the keys  or.  repeatedly enables navigation to the ring menu.

Pressing  returns you to the next highest menu level.

Setting the date and time

NOTE
The date and time must be set correctly so that the time of the sealing procedure can be logged correctly and a clear allocation to the time of sealing can be generated.

Time

To set the current time, proceed as follows:

1. Switch on the sealing device at the power switch and wait until the temperature is issued on the display.
2. Press  twice in order to navigate to **`Settings`**.
3. Press  to navigate to the **`Settings`** menu. The display changes to **`Temp`**.
4. Press  twice to navigate to the **`Time`** option.
5. Press  to confirm. The hour display flashes.
6. Press  or  to change the hours forwards or backwards.

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7. Press OK to save the settings. The minute display will now flash.
8. Press ◁ or ▷ to change the minutes forwards or backwards.
9. Press OK to save the settings. The display no longer flashes.
10. Press ↩ repeatedly to leave the menu (press three times → start display).

Date

NOTE
The date will be displayed in the English date format (YY-MM-DD).

To set the current time, proceed as follows:

1. Switch on the sealing device at the power switch and wait until the temperature is issued on the display.
2. Press ▷ repeatedly in order to navigate to **`Settings`**.
3. Press OK to navigate to the **`Settings`** menu. The display changes to **`Temp`**.
4. Press ▷ to navigate to the **`Date`** option.
5. Press OK to confirm. The first value (year) flashes.
6. To alter the year, month and day, proceed in a way similar to setting the time.

Changing the sealing temperature

To alter the set sealing temperature proceed as follows:

1. Switch on the sealing device at the power switch and wait until the temperature is issued on the display.
2. Press ▷ repeatedly in order to navigate to **`Settings`**.
3. Press OK to navigate to the **`Settings`** menu. The display changes to **`Temp`**.
4. Press OK to confirm. The display flashes.
5. Press ◁ or ▷ to increase or decrease the sealing temperature.
6. Press OK to save the value.
7. Press ↩ repeatedly in order to leave the menu.

PLEASE NOTE
The extent to which individual components in the sealing device expand is altered upon temperature changes. This also influences the sealing force. To this end, the sealing force thresholds are automatically adapted to the changed sealing temperature.

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Switching the signal tones on and off

In order to switch off the signal tones where necessary, proceed as follows:

1. Switch on the sealing device at the power switch and wait until the temperature is displayed on the display.
2. Press  repeatedly in order to navigate to **`Settings`**.
3. Press  to navigate to the **`Settings`** menu. The display changes to **`Temp`**.
4. Press  to navigate to the **`Tone`** option.
5. Press  to confirm. The display flashes.
6. Press  or  to switch the signal tones on or off.
7. Press  to save the settings.
8. Press  repeatedly in order to leave the menu.

Selecting between up to 10 users

In order to guarantee exact traceability over every sealing procedure, you can select the respective user before sealing. Proceed as follows:

1. Switch on the sealing device at the power switch and wait until the temperature is displayed on the display.
2. Press  repeatedly in order to navigate to **`User`**.
3. Press  to confirm. The display flashes.
4. Press  or  to select from up to 10 users.
5. Press  to save the settings.

The display returns to the initial state.

We recommend that you draw up an overview in your QM documents from which you can find the allocation of each user in MELA*seal* 200.

Example:

The name of the trained member of staff	User name in MELA*seal*®200	Signature
Ms	User 01	
Ms	User 02	

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Eco Mode and Standby

The MELA*seal* 200 is equipped with a two-stage energy-saving function.

Eco mode: If the lever or keys are not activated within 15 minutes after the sealing device has been activated (Ready Mode), Eco Mode will be activated, i.e. the temperature will be reduced by 40°C. Activate one of the key in order to return to Ready Mode.
The sealing device is ready to operate after a short time.

Standby: If the lever or keys are not activated within 30 minutes after the sealing device has been activated (Ready Mode), the device switches to Standby, i.e. the heating and display are deactivated. The illuminated LED control lamp shows that the sealing device is still activated.

Activate one of the key in order to return to Ready Mode. The sealing device is ready to operate after c. 2 min.

In order to switch off this function, proceed as follows:

1. Press repeatedly in order to navigate to **`Settings`**.
2. Press OK to navigate to the **`Settings`** menu. The display changes to **`Temp`**.
3. Press to navigate to the **`Eco`** mode.
4. Press OK to confirm. The display flashes.
5. Press or to switch the Eco mode on or off.
6. Press OK to save the settings.
7. Press repeatedly in order to leave the menu.

The display returns to the initial state.

PLEASE NOTE
The Eco mode and standby are always switched off together. It is not possible to switch off the Eco mode or Standby separately.

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Chapter 5 – Logging

DIN EN ISO 11607-2 requires that the sealing process be monitored and documented in order to satisfy the requirement for compliance with the specifications contained in part 2 of the standard.
As a result, you are able to record the logs of the seal runs and output and archive them on the following output media:

- USB flash drive
- Computer with documentation software, e.g. MELA*trace*/MELA*view* from software version 3

If a computer or USB stick is not connected, the most important sealing parameters can also be documented by hand. The sealing parameters are displayed alternately up to 4 times.

Using the USB flash drive as an output medium

WARNING

Inappropriate handling can result in damage to the USB flash drive, the USB interface and data loss.

- Do not exert any force on the USB flash drive whilst inserting it.
- Do not place any objects on the inserted USB flash drive.

A USB flash drive will be delivered with every sealing device as standard.
Should you wish to save the log of a sealing procedure on the USB flash drive automatically, connect it as follows:

1. Switch off the sealing device.
2. Insert the USB flash drive in the USB interface on the left-hand side of the sealing device.



3. Switch on the USB flash drive. As soon as the USB flash drive has been recognized and is ready for operation, the display will show **`Mem_Conn`** (=memory connected).

PLEASE NOTE

- Always switch off the sealing device before connecting or removing the USB flash drive.
- If the USB flash drive has been reformatted, it must be issued with a name.
- Save the log files on the computer at regular intervals.
- Select only a single logging type, either by USB flash drive or via MELA*trace*/MELA*view*. Otherwise, this can result in a failure to recognize that the output media has been disconnected, which can result in data loss.
- Do not save any further non device-relevant files on the USB flash drive.

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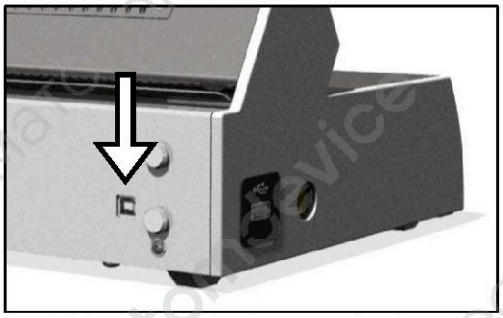
Using the computer as an output medium

The following conditions must be fulfilled in order to use the computer as an output device:

- ✓ *The computer is equipped with an USB interface.*
- ✓ *A MELAG USB driver is installed on the computer.*
- ✓ *The documentation software MELAtrace/MELAview (from software version 3) is installed on the computer.*
- ✓ *The sealing device is connected to the computer via a USB cable (art.-no. 19902, optionally available).*

Proceed as follows to connect the sealing device to a computer:

1. Install the MELAseal 200 PC driver on your computer. The driver can be downloaded from the download centre on the MELAG Website (www.melag.de/service/download-center/pc-anwendungen/MELAview).
2. Connect the type B USB connector of the USB cable to the rear of the sealing device and connect the other end to the computer. Please use MELA*trace*/MELA*view* (from software version 3) to record the logs.

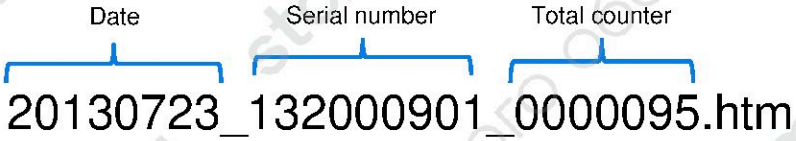


3. Establish a connection between the documentation software and the sealing device and determine the folder in which the sealing logs are to be archived. Further information relating to the operation of the sealing device with the documentation software can be found in the corresponding operating manual.

PLEASE NOTE
The daily log is continued even if the sealing device is switched on and off; i.e. a new log will not be started.

File names and ending

The log is stored in HTML format (in English).
The file name consists of the actual date, the serial number of the sealing device and the total counter.



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Reading logs correctly

A log includes all printing procedures of one day. A row in the log is written for every sealing procedure. If a malfunction occurs during a sealing procedure, this is recorded in the log by a fault number, e.g. F4.

The corresponding fault value (e.g. sealing temperature, or force) will, depending on the nature of the fault, be displayed in square brackets or no value will be displayed.

Example of a log of multiple sealing procedures

```
--------------------
MELAG MEDIZINTECHNIK
--------------------
10 MELAG MELAseal 200
15 Date:      2014-08-14
20 S/N:       132000901
25 Ver:       V1.12
30 Op.Hrs:    0000102
35 Svc.Date: 2015-02-19

|Stat |Time    |Dur    |Temp |Force|Limits - Dur, Temp, Force|Usr|SCnt|SvcCnt|TtlCnt |CS
|-----|--------|-------|-----|-----|-------------------------|---|----|------|-------|---
|OK   |15:23:19| 03.3  | 180 | 211 |03.0-08.0 175-185 170-230|U02|0001|049820|0000180|031
|OK   |15:23:30| 03.3  | 177 | 211 |03.0-08.0 175-185 170-230|U02|0002|049819|0000181|020
|OK   |15:23:38| 03.5  | 177 | 209 |03.0-08.0 175-185 170-230|U02|0003|049818|0000182|043
|F3   |15:23:42|[01.6] | 177 | 209 |03.0-08.0 175-185 170-230|U02|0004|049817|0000183|098
|OK   |15:23:50| 03.4  | 179 | 209 |03.0-08.0 175-185 170-230|U02|0005|049816|0000184|054
```

Key

Row 10 – Designation of the sealing device

Row 15 – Date of the sealing procedure

Row 20 – Serial number of the sealing device

Row 25 – Software version installed

Row 30 – Total operating hours

Row 35 – Date of the next servicing

Start – OK: Sealing procedure successful
– Warn_01: Warning
– Err_01: Fault number/sealing procedure unsuccessful

Time – Time of the sealing procedure

Dur – Duration of the sealing procedure

Temp – Sealing temperature (in °C)

Force – The force (in N), with which the packaging was sealed

Limits – The threshold range of sealing duration (Dur), sealing temperature (Temp) and force (Force)

Usr – User

SCnt – Daily batch counter for sealing procedures

SvcCnt – No. sealing procedures until the next service

TtlCnt – Total number of the sealing procedures

CS – Coded proof of log authenticity

S/N - Serial number of the sealing device

Op. Hrs. - Total of previous operating hours

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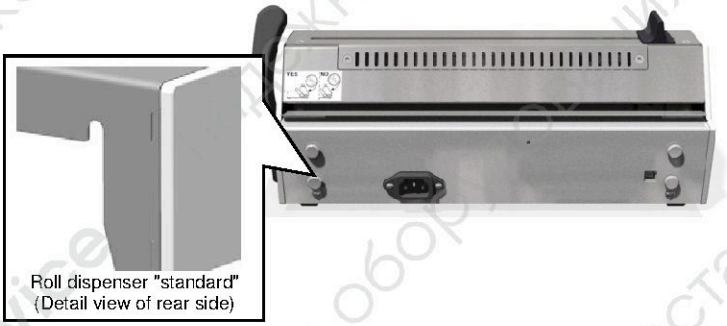
Chapter 6 – Optional Accessories



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 mounts on the rear of the sealing device.



Roll dispenser "standard"
(Detail view of rear side)

Roll dispenser "comfort" and "deluxe"



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.



In the roll dispenser "deluxe", the film rolls are stored above the sealing device, thus saving space.

The integrated feeding device enables easy feeding of the film via a hand wheel.

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The roll dispensers “komfort“ and "deluxe" are hooked onto the mounts on the rear of the sealing device.



Roll dispenser "comfort"
(Detail view of rear side)

Wall-mounted roll dispenser



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

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Chapter 7 – Maintenance

Pause times

The sealing device can remained switched on over longer operating pauses of many hours.

The sealing device automatically switches into Eco Mode (= energy-saving mode) after only 15 minutes and then into standby after a further 15 minutes. See **Chapter 4 – Settings, Eco Mode and Standby**.

Replacing the blade

DANGER

A short circuit brings the danger of an electric shock.

- Switch off the sealing device at the mains and remove the cable.

DANGER

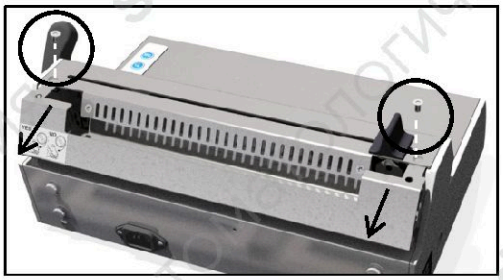
Metal surfaces on the sealing device become hot during operation.

Contact with hot metal parts can result in burns.

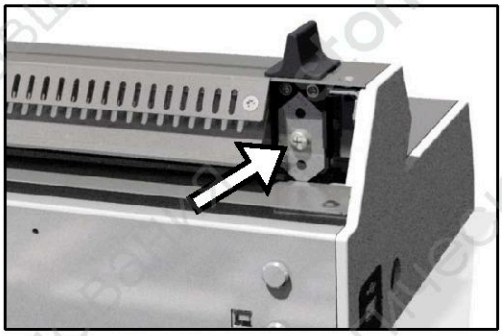
- Allow the sealing device to cool sufficiently before opening.

Proceed as follows to replace the blade:

1. Slide the knife handle to the outside edge.
2. 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.



3. Remove the upper rear housing cover rearwards.
4. Loosen the fastening screws on the blade.



5. Turn the blade by 180° in order to use its other side or replace with another blade. Check whether the knife point is behind the cover and is not on the cover.
6. Return the screws.
7. 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.

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Cleaning and regular controls

The outside of the sealing device should be cleaned at least twice a year. Only use a non-fuzzing cloth (either dry or damp) and a stainless steel-cleaning agent suitable for use with medical products. It should not deposit any oily residue.

Follow the following information when cleaning:

- 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.

Maintenance

WARNING

Continuing operation despite maintenance messages can result in malfunctions in the device.

- Maintenance should only be performed by trained customer services technicians, or stockist technicians. Consult your stockist or the nearest MELAG customer services point.
- Maintain the specified servicing intervals.

Regular maintenance is vital to ensure reliable operation and value retention of the device.

Arrange for servicing in two year intervals or after every 50,000 sealing procedures.

Validation

Your MELA*seal* 200 sealing device complies with all standard requirements for the validation of the sealing process in accordance with DIN EN ISO 11607-2. Conformity is confirmed with the declaration of conformity included in the scope of delivery.

We recommend performing the initial validation before commissioning and then conducting a renewed performance test within the scope of the maintenance. Only then is it possible to confirm the full-functioning of the sealing device and check all sensors.

The practice team can use the MELAG validation instructions to perform the initial validation quickly and easily. The validation instructions were drawn up based on the DGSV guidelines for validating sealing processes. These instructions are available for download from our MELAG website: http://www.melag.de/en/products/packaging/melaseal-200. The most important working steps lead the reader step by step through the validation process.

Validation using measuring technology may only be performed by trained personnel using the intended test equipment.

Software update

A software update is performed by service technicians during maintenance. If necessary, you can perform an update yourself:

1. Contact your stockist/MELAG customer services to obtain the current software version.
2. Copy the update files into the main directory of the USB flash drive. The USB flash drive is included in the scope of delivery.. Any log folders and log files can remain on the USB flash drive.
3. Connect the USB flash drive to the sealing device.
4. Switch on the sealing device. The following display will appear after only a few seconds: `Update?`
5. If you wish to perform an update, confirm with OK. The update will then be started, the display will extinguish and the LED control lamp flashes yellow.
6. Should you not wish to perform an update, interrupt the procedure by pressing the ↩ button.
7. Once the update has been competed, the display will issue `Update OK` and the LED will illuminate green.

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8. Press OK to complete the procedure. The display changes to **MELASEAL**.
9. Switch off the sealing device and remove the USB flash-drive.
10. Delete the update file from the USB flash drive. Otherwise, an update will be requested after every activation.

The device settings e.g. date/time etc. are retained during a software update.

A renewed performance qualification (revalidation) is not necessary after the software update.

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Chapter 8 – Malfunctions

WARNING

Improper opening of the housing brings the danger of an electric shock.

- To avoid the risk of electrical shocks, never open the housing of the sealing device.
- The device may only be serviced by a technician authorized by the MELAG customer services.

PLEASE NOTICE

The warning and fault messages are generally confirmed with OK

Problem	Possible cause	What you can do
Warn_01/No_Prot	USB flash drive / USB cable not recognized or connected incorrectly. No USB flash drive or USB cable connected.	Check whether the USB flash drive has been inserted correctly and that the USB cable has been connected correctly. Check the USB flash drive/the USB cable on the computer for function. If logging is not required, the warning must be confirmed with OK
Warn_02/Mem_Lo	Memory on the USB flash drive almost full. Less than 10 further logs can be saved.	Transfer the logs from the USB flash drive to the computer and then delete the files on the USB flash drive.
Warn_04/Service	Maintenance necessary.	Notify MELAG customer services/your stockist.
Err_F01/Temp_Lo	Sealing temperature too low. Sealing temperature decreases as a result of too short an interval between the sealing procedures.	The required sealing temperature has not yet been reached. Wait until the display shows ready and the LED control lamp is illuminated continuously green.
Err_F02/Temp_Hi	Sealing temperature too high.	Wait until the display shows ready and the LED control lamp is illuminated continuously green.
Err_F03/Time_Lo	Sealing duration too short.	Leave the lever depressed until the progress bar in the display has completed and the display shows **Open**.
Err_F04/Time_Hi	Sealing duration too long.	Move the lever immediately upwards until the progress bar in the display has completed and the display shows **Open**.
Err_F05/Force_Lo	Sealing force too low.	Switch off the sealing device and then back on again. Upon repeated occurrence, inform your stockist/MELAG customer services.
Err_F6/Force_Hi	Sealing force too high: Instruments are stuck in the sealing bar. The film has been folded multiple times or the film material is too thick.	 Check the sealing area for stuck instruments or foreign bodies. Use only suitable film material for this sealing device.

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Problem	Possible cause	What you can do
		Perform the sealing procedure without film Upon repeated occurrence, inform your stockist/MELAG customer services.
Err_07/Tmp_Sens	Temperature sensor defective.	Switch the sealing device off and then on again. If this is unsuccessful, inform MELAG customer services/your stockist
Err_08/Temp_PCB	Sealing device overheated, ambient temperature too high.	Operate the sealing device only within the prescribed ambient temperature If the ambient temperature is not the cause, inform MELAG customer services/your stockist.
Err_09/Frc_Sens	Force sensor defective.	Switch the sealing device off and then on again. If this is unsuccessful, inform MELAG customer services/your stockist.
Err_F10/Heating	The sealing device has overheated, the overheating control has tripped.	Confirm the message with OK Switch off the sealing device and allow to cool. Switch on only after 5-10 minutes (the overheating protection requires this time to reset itself automatically).
	Heating not possible	Switch the sealing device off and then on again. If this is unsuccessful, inform MELAG customer services/your stockist.
Err_F11/RTC	Deviation in the time measurement.	Switch the sealing device off and then on again. If this is unsuccessful, inform MELAG customer services/your stockist.
Err_F12/USB	The log could not be saved on the USB flash drive. It could be write-protected or the USB flash drive/interface could be damaged.	Check the USB flash drive for any write-protection. Delete any of the data on the USB flash drive or use another USB flash drive If the USB flash drive has to be reformatted, a device name must be issued for faultless function. Upon repeated occurrence, inform your stockist/MELAG customer services.
Err_F13/Update	Update file damaged.	Use only MELAG-authorized update file.
Display freezes	USB flash drive defective.	Remove the USB flash drive and switch the sealing device off and on again.
Seal check unsuccessful	Temperature too low.	Check whether the necessary sealing temperature has been reached and the display outputs **Ready**. Wait c. 30 seconds after operational readiness before performing a MELAG seal check. Please observe and comply with the information provided in the MELAG seal check operating manual.

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Manufacturer's Recommendation for Routine Operation

Frequency	Check/action	Criteria
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 sealing seam should be almost identical with the works sealing seam, i.e. an industrial seal with an identical edge in terms of colour. If the sealing seam is too light, → the sealing temperature and/or the contact pressure (sealing force) is too low; If the sealing seam is brown, → the sealing temperature is too high or the sealing duration too long **Mechanical check** ▪ Tear-resistance check: the strength required to open the seam must be exactly equal to that required to open the factory-produced seam → Peel test[1)] ▪ When peeled off, the paper should free itself from the film, leaving almost no residue
Following every sterilization	Batch-related check of the seam	▪ Control the entire packaging for dryness and integrity. ▪ Clearance after sterilization, documentation within the scope of process clearance ▪ Check for dryness and integrity once again, before using the instruments.
Weekly	Checking the seal seam with aids	Perform a visual control using MELAG seal check and document the results - for criteria and further information, see the MELAG seal check operation manual
Annually	Check the seal seam for tear-resistance in accordance with DIN EN 868-5, Appendix D.	See the supplementary instructions of the MELAG seal seam strength test
After 50,000 cycles or 2 years (MELA*seal* 200, MELAseal Pro)	Maintenance	Perform the maintenance in accordance with the MEALG maintenance instructions, including the replacement of wear parts
Upon malfunction messages or obviously faulty seals	Remedying the fault	Do not operate a defective sealing device. Notify the authorized customer services

[1)] Performing the peel test:
1. Seal the sterilization packaging in the sealing device.
2. Place a sealed sterilization packaging in a sterilization cycle.
3. Slowly pull apart (by hand) the sealing seam in the direction of peeling. The visual check is to verify whether the sealing seam extends along the whole width and length. No paper residue greater than 10 mm is permitted on the seal seam. Document the results.

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MELAG seal seam strength test

For validating your sealing processes MELAG provides a seal seam stability test for a cost price of 125.00 € plus V.A.T. (state 01/2015)

After the film test strips have been tested, MELAG will issue verification of testing and if successful, a certificate. This certificate confirms conformity of the seal seam with the standard DIN EN 868-5, Appendix D. Use the MELAG seal seam strength test application form (http://www.melag.de/en/service/download-center/recommendations).

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DIN Specifications

Terms

Sterile barrier system

DIN EN ISO 11607-2:2006 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 facilitating successful sterilization, serving as a micro-biological barrier and permitting aseptic provision. This includes transparent sterilization packaging, 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 DIN EN 868-5, Appendix E.

General information regarding the packaging and sealing procedure

Please observe the following during packaging and sealing:

- Do not select undersized packaging.
- Packaging made of porous materials and plastic composite film should be filled with a max. of up to 3/4 of its volume (DIN 58953-7:2010).
- When using transparent sterilization packaging from a roll, the removal side must have an overlap of min. 1 cm between the cutting edge and the seal seam, enabling an aseptic removal (DIN 58953-7:2010).
- Pressing together should remove all air before sealing.

Seal seam width

Maintain the seal seam width stipulated in the standard:

- The width of the seal seam for sterilization packaging e.g. transparent sterilization packaging should amount to a min. 6 mm. With grooved seal seams, the sum of the individual seams should amount to min. 6 mm (DIN EN 868-5:2009).

Clearance of the seal seam to the cutting edge

Maintain the clearance between seal seam and cutting edge as prescribed in the standard:

- 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 side. This ensures aseptic removal. We recommend a minimum overhang of 10 mm.

Strength of seal seam

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

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Storage length for sterile medical products

Guidelines for the storage period of sterile medical products according to DIN 58953-8:2010:

This standard applies to the delivery, storage, commissioning, transport and provision (including the packaging and marking necessary for these ends) of all sterile medical products to be used in healthcare institutions such as hospitals, dental and medical practices.

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.

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 7.2, 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. **Table 2** only makes recommendations regarding the storage length of sterile medical products.

The following requirements apply to the storage of sterile medical products:

- The rooms must be dry, cool and easy to clean.
- The rooms must not be accessible to everyday activity.
- We recommend protected storage in cupboards or drawers.

Table 2: Storage length for sterile medical products

Packaging type	**Storage period**	
Sterile barrier system	***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.	Serves provision for immediate use.[2] Should be avoided as a method of storage.	6 months Not longer than the expiry date.
Packaging system (a combination of a sterile barrier system and sterile packaging)	5 years, as far as the manufacturer has not determined an alternative expiry date.	

1) On shelves in rooms which do not correspond with room class II as defined by DIN 1946-4:2008-12
2) Immediate use means application / use of the product within a maximum of 2 days / 48 hours.

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Accessories and Spare Parts

	Article	Art. no.:
Accessories	Roll dispenser “standard”	00117
	Roll dispenser “comfort”	00111
	Roll dispenser "deluxe“	00108
	Wall-mounted roll dispenser	00106
	Spacer washers (1x) for roll dispenser "comfort“ or wall-mounted roll dispenser	13330
	Spacer washers (1x) for roll dispenser "deluxe"	88110
	Distance plate (2x) for roll dispenser „standard“	72335
	MELAG seal check	01079
	MELAG USB flash drive (8 GB) for documentation	19901
	USB cable, 1.8 m	19902
	MELA*trace*/MELA*view* documentation software	21127
Spare Parts	Knife blade	17781
	Blade mount black (without blade)	45610
	Knife handle black	45600
	Handle black	77000

Technical Data

Model name	MELA*seal*® 200
Device dimensions (WxDxH)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	220 - 240 V 50/60 Hz
Power input	300 W
Fusing	1x 2 A
Seal temperature range	100 - 210°C
Seal seam width	10 mm
Seal length	max. 27.5 cm
Sealing time	min. 3.0 sec. (factory settings, fix)
Overheat control	> 240°C
Sealing force	200 N ± 10% (factory settings, fix)

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