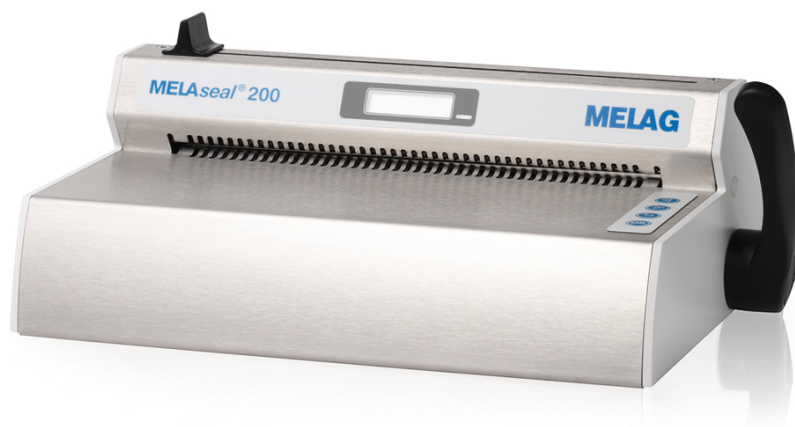


# User manual

## MELAseal® 200

### Sealing device

from software version 2.28



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.



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# 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](http://www.melag.com).

## Symbols used

Symbol	Description
 <b>WARNING</b>	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
 <b>CAUTION</b>	Indicates a dangerous situation, which if not avoided, could entail slight to moderate injuries.
<b>NOTICE</b>	Indicates a dangerous situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
 <b>PLEASE NOTE</b>	Draws your attention to important information.

## Formatting rules

Example	Description
see <b>Chapter 2</b>	Reference to another text section within this document.
<b>Log</b>	Words or phrases appearing on the display of the device are marked as display text.
	Prerequisites for the following handling instruction.
	Reference to the glossary or another text section.
	Information for safe handling.

## Disposal

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

Dispose of ▶[components](#), spare parts, ▶[accessories](#), ▶[equipment](#) and consumables that you no longer need properly. Comply with all relevant disposal regulations regarding potentially 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 cycle 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-authorized 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 200 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**

#### **Warning of material damage from incorrect use**

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.

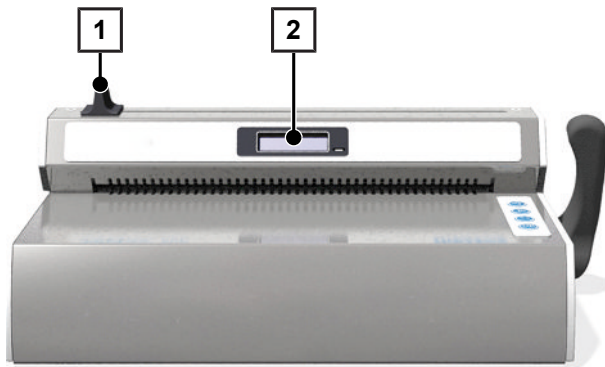
### Scope of delivery

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

- Sealing device MELAseal 200
- User manual
- Set-up checklist and training protocol
- Manufacturer's inspection report and declaration of conformity
- Warranty certificate
- Test and calibration protocol
- Power cable
- Sealing lever
- MELAG USB stick

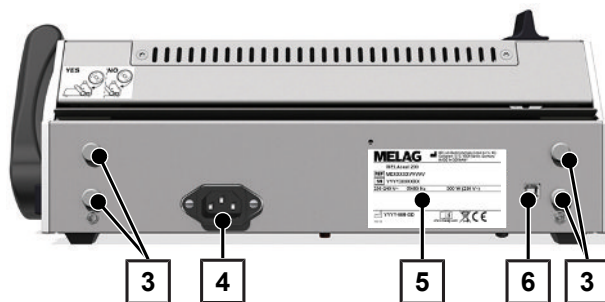
## Views of the device

### View from the front



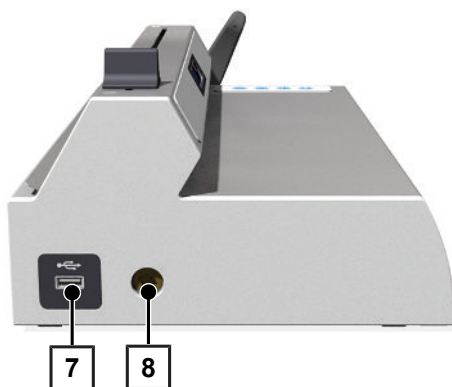
- 1 Knife handle
- 2 Display with control lamp

### View from the rear



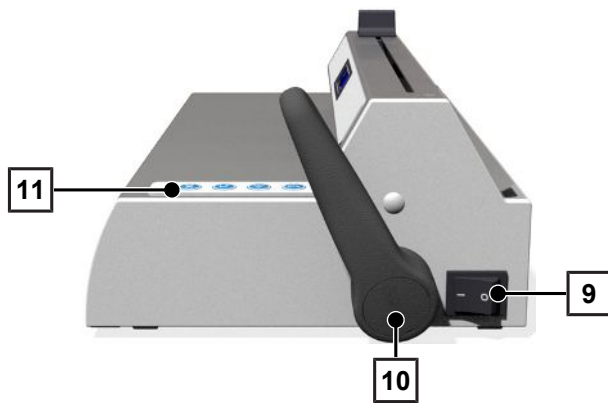
- 3 Bracket for reel dispenser
- 4 Power cable connection
- 5 Type plate
- 6 USB interface (type B) for connection to the computer
- 3

### View from left



- 7 USB interface for the USB flash drive
- 8 Square hole for sealing lever (on both sides)

*Fore right view*



- 9 Power switch (On/Off)
- 10 Sealing lever
- 11 Operating keys

**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

## Menu structure

<ul style="list-style-type: none"> <li>└ <b>Standard display output</b></li> <li>  └ 180°C/User 1/Ready</li> <li>└ <b>User</b></li> <li>  └ User 01</li> <li>  └ User 02</li> <li>  └ User...</li> <li>  └ User 10</li> <li>└ <b>Seal chk</b></li> <li>  └ approve?</li> <li>  └ reminder           <ul style="list-style-type: none"> <li>└ weekly               <ul style="list-style-type: none"> <li>└ Mon</li> <li>└ Tue</li> <li>└ ...</li> <li>└ Sun</li> </ul> </li> <li>└ daily</li> <li>└ Off</li> </ul> </li> <li>└ <b>Settings</b></li> <li>  └ Temp</li> <li>  └ Tone</li> <li>  └ Time           <ul style="list-style-type: none"> <li>└ Adjust</li> <li>└ Auto_DST</li> </ul> </li> <li>  └ Date</li> <li>  └ Eco Mode           <ul style="list-style-type: none"> <li>└ On/Off</li> <li>└ Wait Eco               <ul style="list-style-type: none"> <li>└ Wait Stby</li> </ul> </li> </ul> </li> <li>  └ Adj Frc</li> <li>└ <b>Info</b></li> <li>  └ Seal Cnt</li> <li>  └ Svc Date</li> <li>  └ Svc Cnt</li> <li>  └ Version</li> <li>  └ S/N</li> </ul>	<ul style="list-style-type: none"> <li><b>Key</b></li> <li>Temperature/User/Operational readiness</li> <li><b>User</b></li> <li>User 01</li> <li>User 02</li> <li>User...</li> <li>User 10</li> <li>Function check with MELAcontrol Seal Check</li> <li>Performing function check with seal check</li> <li>Activate reminder for seal check</li> <li>Weekly           <ul style="list-style-type: none"> <li>on Mondays</li> <li>on Tuesdays</li> <li>...</li> <li>on Sundays</li> </ul> </li> <li>daily</li> <li>Deactivate reminder for seal check</li> <li><b>Settings</b></li> <li>Sealing temperature</li> <li>Switch signal tones on/off</li> <li>Time           <ul style="list-style-type: none"> <li>Set current time</li> <li>Autom. change from summer/winter time (CET)</li> </ul> </li> <li>Date (TT-MM-JJ)</li> <li>Eco Mode           <ul style="list-style-type: none"> <li>Switch Eco mode on/off</li> <li>1. Waiting time: Setting the Eco Mode</li> <li>2. Waiting time: Setting the standby</li> </ul> </li> <li>Force calibration</li> <li><b>Information</b></li> <li>Counter for the sealing procedures</li> <li>Date of the next service</li> <li>Counter until the next service</li> <li>Software version</li> <li>Serial number</li> </ul>
---	--

Pressing the key  or  repeatedly enables navigation to the ring menu. Pressing  returns you to the next highest menu level.

## Status display and acoustic signals

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. The sealing lever has been raised early, despite the required sealing duration not having been reached. The sealing lever has not been raised, despite the required sealing duration having been completed.	Acknowledge the message with  and wait until the LED control lamp illuminates green continuously. Acknowledge the message with  and leave the sealing lever depressed during sealing until the message <b>Open</b> is issued. <b>NOTICE! Warning of material damage.</b> Sealing for too long can result in the melting of the transparent sterilization package and damage to the sealing device. Raise the sealing lever as soon as the display notification <b>Open</b> is issued, otherwise the sealing procedure will not be completed successfully.
 LED illuminates green	The sealing device has reached the pre-set sealing temperature and is ready for operation. The minimum sealing duration has been reached and the sealing procedure has been ended.	Raise the sealing lever and remove the transparent sterilization package.
 LED flashes green	The sealing lever is depressed and the sealing procedure runs. The progress bar is displayed.	Wait until the green LED control lamp is continuously illuminated or the display shows <b>Open</b> .
 LED illuminates red, warning signal sounds (malfunction)	Device malfunction: The heating phase takes too long (> 5 min). The sealing device does not reach the pre-set sealing temperature.	Switch off the sealing device and then on again. Upon repeated occurrence, inform an authorised technician.

 **PLEASE NOTE**

If further status displays or acoustic signals occur, please contact the technical service.

# 4 Commissioning

## Video tutorial

See also “Installation and Set-up” (<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



## Requirements of the installation location

Comply with the following for safe handling:

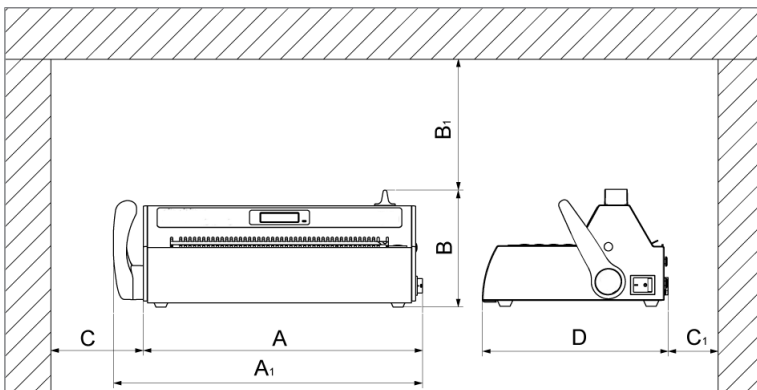
- Check the device after unpacking for any damage suffered during transport.
- Do not install or operate the device in potentially explosive areas.
- The device is only intended for use in interior spaces.
- The device is conceived for use outside the patient area. The device should be located a minimum 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.

## Space requirements

View from the front and right



Device dimensions		MELaseal 200
Width	A	36.5 cm
Width including sealing lever	A <sub>1</sub>	41.5 cm
Height	B	15 cm
Minimum clearance above	B <sub>1</sub>	25 cm
Minimum clearance to the side	C	10 cm
Minimum clearance to rear	C <sub>1</sub>	8 cm
Depth	D	24 cm

When using film reels, additional space is required for a reel dispenser e.g. the Reel dispenser Standard or Reel dispenser Deluxe.

## 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

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 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.
- ✓ The USB flash drive is connected for documentation purposes.
- ▶ Switch on the sealing device at the power switch.



- ↳ After activation, the display issues system information. These are 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 fore side of the sealing device will illuminate orange. The sealing device is heated to the pre-set temperature.

### **Operational readiness**

The sealing device is ready for operation as soon as the pre-set sealing temperature has been reached, the display shows **Ready** and the control lamp illuminates continuously green.



## 5 Sealing

### Video tutorial

See also "Wrapping Instruments"  
(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



### Sealing procedure with pre-finished film pouches

#### ⚠ CAUTION

#### Warning of burns

The sealing rail is heated continuously when the sealing device is switched on. Touching hot metal surfaces can cause burns.

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

#### NOTICE

#### Warning of material damage from incorrect use

If the transparent sterilisation packaging is inserted incorrectly, film residues may adhere to the sealing bar. Sticking of the sealing bar may result.

- Always guide the transparent sterilization package into the device with the film side pointing upwards.

#### 📌 PLEASE NOTE

When sealing MELAfol pouches with a side gusset, ensure compliance with the manufacturer's specifications (e.g. 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 36].



2. Press the sealing lever down until it latches.



3. Leave the sealing lever depressed as long as the progress bar in the display completes and the control lamp flashes green at short intervals (approx. 3 s).



4. When the display switches to **Open** and the control lamp is continuously illuminated green, raise the sealing lever to its starting position. Remove the film pouch from the sealing device.



- If the USB stick has been connected, a log will automatically be generated and saved on the USB stick.
- If a USB stick has not been connected, the most important sealing parameters will be displayed alternately up to four times. Then the display switches to **Ready**.

5. Perform a visual inspection of the seal seam after every successful sealing procedure. There must be no channels, bubbles, creases or open areas present.



*Example view of a defect-free seal seam*

**PLEASE NOTE**

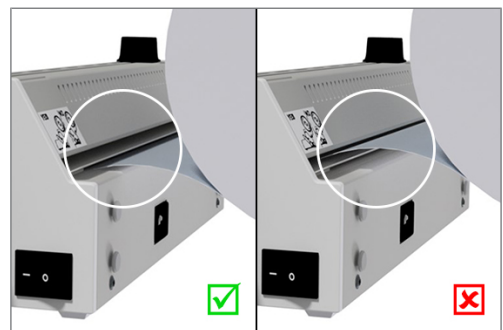
Carry out weekly checks of the sealing seam on gusseted pouches using an ink test (e.g. MELAcontrol Ink Test).

## Sealing procedure for film reels

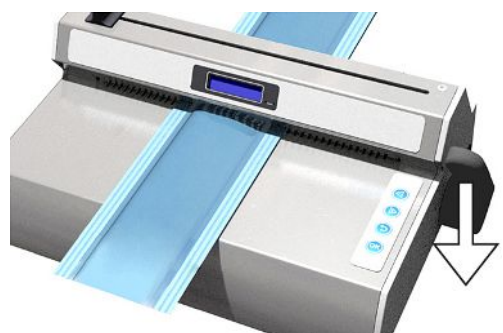
### Producing a film pouch

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.



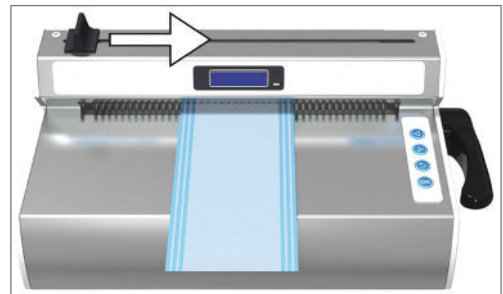
2. Press the sealing lever down until it latches.



3. Leave the sealing lever depressed as long as the progress bar in the display completes and the control lamp flashes green at short intervals (approx. 3 s).



4. Cut off the film roll during the sealing procedure. Leave the sealing lever depressed and move the handle of the knife to the other end of the sealing device quickly. Do not return the knife handle.



5. When the display switches to **Open** and the control lamp is continuously illuminated green, raise the sealing lever to its starting position. Remove the film pouch from the sealing device.



## Sealing film pouches

**NOTICE**

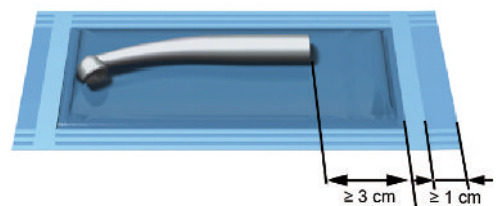
**Warning of material damage from incorrect use**

If the transparent sterilisation packaging is inserted incorrectly, film residues may adhere to the sealing bar. Sticking of the sealing bar may result.

- Always guide the transparent sterilization package into the device with the film side pointing 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 36].



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 as long as the progress bar in the display completes and the control lamp flashes green at short intervals (approx. 3 s).



5. When the display switches to **Open** and the control lamp is continuously illuminated green, raise the sealing lever to its starting position. Remove the film pouch from the sealing device.



- If the USB stick has been connected, a log will automatically be generated and saved on the USB stick.
- If a USB stick has not been connected, the most important sealing parameters will be displayed alternately up to four times. Then the display switches to **Ready**.

6. Perform a visual inspection of the seal seam after every successful sealing procedure. There must be no channels, bubbles, creases or open areas present.

*Example view of a defect-free seal seam*



## 6 Logging

### Documenting the sealing procedure

#### Video tutorial

See also “Documentation and User Administration”  
(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



▶ **EN ISO 11607-2** requires that the sealing process must be monitored and documented. As a result, you are able to record the logs of the sealing procedures, to output and archive them on the following output media:

- USB stick
- Computer with documentation software, e.g. MELAtrace (from software version 3.6)

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 four times.

### Using the USB flash drive as an output medium

#### NOTICE

#### Warning of data loss

Improper handling may result in damage to the USB stick.

- Do not exert any force on the USB stick whilst inserting it.

Comply with the following for safe handling:

- Switch off the sealing device before connecting or removing the USB stick.
- Assign a name to the USB stick when reformatting it.
- Copy the log files from the USB stick to the computer at regular intervals.
- Select only a single logging type, either by USB stick or via the documentation software MELAtrace. 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 stick.

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 device.



3. Switch on the sealing device.
  - ▶ As soon as the USB flash drive has been recognized and is ready for operation, the display shows **Mem\_Conn** (= memory connected).

## Computer as output medium

- ✓ The computer is equipped with an USB port.
- ✓ The MELAG USB driver is installed on the computer.
- ✓ The sealing device is connected to the computer via a USB cable (optionally available).
- ✓ Firmware 1.12 requires MELAtrace version 3.0.15.1.
- ✓ Firmware 2.10 and above requires MELAtrace from version 3.6.2.1.

1. Install the MELAseal 200 PC driver on your computer. Download the driver from the MELAG website (Service/Download Center).



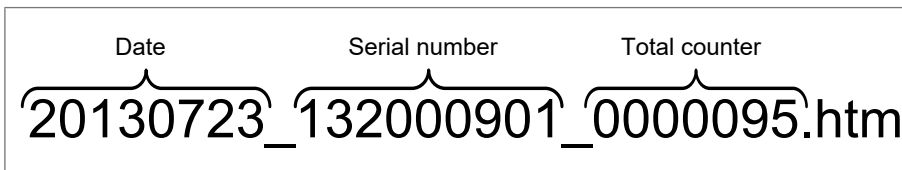
2. Connect the type B USB cable to the rear panel of the sealing device and connect the other end to the computer.
3. Establish a connection between the documentation software and the sealing device and determine the folder in which the logs are to be archived. Further information relating to the operation of the sealing device with the documentation software can be found in the corresponding user manual.

**PLEASE NOTE**

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

## Structure of the log files

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. A log includes all printing procedures of one day. A row in the log is written for every sealing procedure.



A successful sealing procedure is marked with "OK" in the respective log row. If a malfunction occurs during a sealing procedure, this is recorded in the log by an event number, e.g. F4. The corresponding fault value (e.g. sealing temperature, sealing force) will, depending on the nature of the malfunction, be displayed in square brackets or no value will be displayed.

**Example of a log with several sealing procedures:**

```

-----
MELAG MEDIZINTECHNIK
-----
10 MELAG MELAseal 200
15 Date:      15-09-2015
20 S/N:      152001111
25 Ver:      V02.10
30 Op.Hrs:   0000108
35 Svc.Date: 14-08-2017

|Stat|Time   |Dur  |Temp|Force|Limits - Dur, Temp, Force|Usr|SCnt|SvcCnt|TtlCnt|CS
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|OK  |11:59:08|03.5|179|200|03.0-08.0 175-185 170-230|U06|0008|049985|0000016|016
|OK  |11:59:13|03.9|179|201|03.0-08.0 175-185 170-230|U06|0009|049984|0000017|025
|OK  |11:59:19|03.5|179|201|03.0-08.0 175-185 170-230|U06|0010|049983|0000018|116
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|OK  |11:59:29|03.9|179|201|03.0-08.0 175-185 170-230|U06|0011|049982|0000019|119
|OK  |11:59:37|03.5|179|202|03.0-08.0 175-185 170-230|U06|0012|049981|0000020|067
|F3  |11:59:40|[01.2]|179|203|03.0-08.0 175-185 170-230|U06|0013|049980|0000021|010
-----

```

**Key:**

- Row 10 Designation of the sealing device
- Row 15 Date of 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 maintenance

- Stat OK: Sealing procedure successful  
F03: Event number/sealing duration too short
- Time Time of the sealing procedure
- Dur Sealing duration
- Temp Sealing temperature (in °C)
- Force Sealing force (in N), with which the packaging was sealed
- Limits The threshold ranges of the sealing duration (Dur), sealing temperature (Temp) and sealing force (Force)
- Usr User
- SCnt Daily batch counter for sealing procedures
- SvcCnt Number of sealing procedures until next maintenance
- TtlCnt Total number of sealing procedures
- CS Coded proof of authenticity
- S/N Serial number of the sealing device
- Op. Hrs. Total of previous operating hours

## 7 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.

The device is fitted with a reminder function which reminds e.g. at the daily seal check.

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

### Setting the reminder function

Should you wish to perform a regular functional check of the seal seam e.g. on a daily or weekly basis on a recurring day, you can set up an automatic reminder function.


1. Press  to navigate to the **Seal chk** menu.
2. Press  to navigate to the **Seal chk** menu.  
↳ The display changes to **approve?**
3. Press  to navigate to the **reminder** option.
4. Press  to confirm.  
↳ **off** flashes i.e. the reminder function is inactive.
5. Press  to navigate to **daily** or **weekly**.
6. Press  to confirm.  
↳ If you have set the reminder function to daily, the setting has been completed and you can leave the menu by pressing the key .  
↳ If you have set the reminder function to weekly, the display changes to the week days. The display flashes.
7. Press  to navigate to the desired day of the week.
8. Press  to confirm.
9. Press  repeatedly in order to leave the menu.

### MELAcontrol Seal Check with reminder function


If you have set a reminder function for a regular seal check, the following displays will appear in alternation at the given time:



**If you wish to perform a seal check, proceed as follows:**




- ✓ MELAcontrol Seal Check (available separately)
  - ✓ Transparent sterilization package (width min. 10 cm and length min. 18 cm)
1. Confirm the display with the key .
    - ↳ The display changes to **Sea1 chk** and flashes.
  2. Prepare the MELAcontrol Seal Check test strip with the transparent sterilization package in accordance with the applicable instructions for use and perform a test seal.
    - ↳ The log will display the corresponding information “seal chk” in the row above the test seal.

**If you wish to perform no seal check, proceed as follows:**

- ▶ Press the key .
- ↳ The reminder will be displayed every time that the sealing device is switched on until a seal check has been performed.

## MELAcontrol Seal Check without reminder function

**If you have not set a reminder function, proceed as follows to perform a seal check:**

- ✓ MELAcontrol Seal Check (available separately)
  - ✓ Transparent sterilization package (width min. 10 cm and length min. 18 cm)
1. Switch on the sealing device and wait until the temperature is displayed.
  2. Press  repeatedly to navigate to **Sea1 chk**.
  3. Press  to get into the **Sea1 chk** menu.
    - ↳ The display changes to **approve?**
  4. Press  to confirm. The display flashes.
  5. Prepare the MELAcontrol Seal Check test strip with the transparent sterilization package in accordance with the applicable instructions for use and perform a test seal.
    - ↳ The log will display the corresponding information “seal chk” in the row above the test seal.

To set the reminder function if necessary, see [Setting the reminder function](#) [▶ page 21].

## 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.

## 8 Settings

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### Access settings menu

Proceed as follows to reach the settings menu and the desired submenu:

1. Switch on the sealing device and wait until the temperature is displayed.
2. Press  repeatedly in order to navigate to **Settings**.
3. Press  to navigate to the **Settings** menu.  
↳ The display changes to **Temp**.
4. Press  or  to navigate to the desired submenu.
5. Press  to confirm.

### Time

#### Video tutorial










See also "Date and Time"

(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).









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 established.

To set the current time, proceed as follows:

- ✓ You are in the menu **Settings > Time**.
1. Press  to confirm.  
↳ The display changes to **Adjust**.
  2. Press  to confirm.  
↳ The hour display flashes.
  3. Press  or  to change the hours forwards or backwards.
  4. Press  to save the settings.  
↳ The minute display flashes.
  5. Press  or  to change the minutes forwards or backwards.
  6. Press  to save the settings.  
↳ The display no longer flashes.
  7. Press  repeatedly to leave the menu (press three times > start display).

## Automatic change from summer/winter time (CET)

To set the automatic change from summer/winter time, proceed as follows:

- ✓ You are in the menu **Settings > Time > adjust**.
- 1. Press  to navigate to the **Auto DST** option.
- 2. Press  to confirm.
  - ↳ The display changes to **On** and flashes.
- 3. Press  or , to change between **On** and **Off**.
  - ↳ **On** = The time is automatically changed to summer or winter time (CET).
  - ↳ **Off** = The time must be changed manually from summer to winter time (CET).
- 4. Press  to save the settings.
- 5. Press  repeatedly in order to leave the menu.

## Date

### Video tutorial


See also “Date and Time”  
(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



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 established.

The date is displayed in the DD/MM/YY format.

To set the current date, proceed as follows:

- ✓ You are in the menu **Settings > Date**.
- 1. Press  to confirm.
  - ↳ The first value (year) flashes.
- 2. To alter the year, month and day, proceed in a way similar to setting the time.

## Sealing temperature

### Video tutorial


See also “Sealing Temperature and Eco Mode”  
(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).







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. When using MELAfol transparent sterilization package retain the works setting sealing temperature of 180 °C. When using sterilization packages from other manufacturers, comply with their specifications. Set the sealing temperature at the sealing device if the material has a recommended sealing temperature other than 180 °C.

**PLEASE NOTE:** To ensure that the sealing process complies with all normative specifications, MELAG recommends carrying out a seal seam stability test when the transparent sterilization package is changed, see [MELAG seal seam stability test](#) [▶ page 35].

To alter the pre-set sealing temperature proceed as follows:

- ✓ You are in the menu **Settings > Temp**.
- 1. Press  to confirm.
  - ↳ The display flashes.






2. Press  or  to increase or decrease the sealing temperature.
3. Press  to save the value.
4. 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. Therefore, the tolerance limits of the sealing force are automatically adjusted in the log when the sealing temperature is changed.

### Signal tones

In order to switch on or off the signal tones, proceed as follows:

- ✓ You are in the menu **Settings > Tone**.
1. Press  to confirm.  
 ↳ The display flashes.
  2. Press  or  to switch the signal tones on or off.
  3. Press  to save the settings.
  4. Press  repeatedly in order to leave the menu.






### User administration

#### Video tutorial

See also “Documentation and User Administration” (<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



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 on and wait until the temperature is issued on the display.
2. Press  repeatedly in order to navigate to **User**.
3. Press  to confirm.  
 ↳ The display flashes.
4. Press  or  to select between up to ten users.
5. Press  to save the settings.  
 ↳ The display returns to the initial state.

**PLEASE NOTE**

MELAG recommends drawing up an overview in your quality management documents from which you can find the allocation of each user for the sealing device.

**Example of a user overview**

Name of the instructed employee	User name in the sealing device	Signature
Mrs/Mr _____	User 01	...
Mrs/Mr _____	User 02	...

## Eco Mode and Standby

### Video tutorial

See also "Sealing Temperature and Eco Mode"  
(<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).










The sealing device is equipped with a two-stage energy-saving function.

### 1. Waiting time: Eco Mode

If with a sealing device ready for operation (Ready mode) the sealing lever or keys are not activated within a certain time, the Eco Mode will be activated. The temperature is reduced by 40 °C. Activate one of the keys in order to return to Ready mode. The sealing device is ready to operate after a short time.


Proceed as follows to set the waiting time until the activation of Eco mode:

- ✓ You are in the menu **Settings** > **Eco mode**.
- 1. Press  to confirm.
  - ↳ The display changes to **On/Off**.
- 2. Press  to navigate to the **Wait Eco** option.
- 3. Press  to confirm.
  - ↳ The display changes to **05 min**. The minute value flashes.
- 4. Press  or  to set the waiting time (in min) until the activation of the Eco mode.
- 5. Press  to confirm.
  - ↳ The setting is completed.
- 6. Exit the menu by repeatedly pressing the key .

### 2. Waiting time: Standby

If with a sealing device is in Eco mode and the sealing lever or keys are not activated within a certain time, the Standby will be activated. The heater and display are switched off. The sealing device remains activated and the LED control lamp illuminates. Activate one of the keys in order to return to Ready mode. The sealing device is ready to operate after approx. 2 min.

Proceed as follows to set the waiting time until the activation of standby:

- ✓ You are in the menu **Settings** > **Eco mode**.
- 1. Press  to navigate to the **WaitStby** option.
- 2. Proceed in a fashion similar to the setting if the first waiting time for Eco mode.






## Switching off Eco mode and Standby

**PLEASE NOTE**

Eco mode and Standby are always switched off together. It is not possible to switch off Eco mode or Standby separately.

Proceed as follows to switch off Eco mode and Standby:

✓ You are in the menu **Settings > Eco mode**.




1. Press  to confirm.  
↳ The display flashes.
2. Press  or  to switch the Eco mode on or off.
3. Press  to save the settings.
4. Press  repeatedly in order to leave the menu.  
↳ The display returns to the initial state.

## Force calibration

When the malfunction messages **Err\_05/Force\_Lo** or **Err\_06/Force\_Hi** are displayed, before contacting the authorised technician you may be able to solve the problem by performing a force calibration. This recalibrates the device by setting to a pre-set tolerance range. It is only necessary to summon the authorised technician if this tolerance range is exceeded.

Proceed as follows to perform a force calibration:

✓ You are in the menu **Settings > Adj Frc**.

1. Press  to confirm.  
↳ The display shows **Lever down then OK**.
2. Press the sealing lever down until it latches.
3. Press  to start the calibration. The display shows the deviation from the nominal value (in N), e.g. + 10 N.
4. Raise the sealing lever upwards to its starting position.
5. Press  to confirm.  
↳ If the value lies in the pre-set tolerance range of  $\pm 40$  N, the display shows **Force OK**. In this case, you can continue operation.  
↳ If the tolerance range is exceeded, the display shows the message **Err\_15**. Please consult your authorised technician.

## 9 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.

### Maintenance

Comply with the following for safe handling:

- Maintain the specified maintenance intervals. Continuing operation beyond the maintenance interval can result in malfunctions in the device.
- Have maintenance performed only by trained and authorised technicians using the original MELAG maintenance set.
- If components that are not included in the maintenance set have to be replaced during maintenance, only original spare parts from MELAG may be used for the replacement.

Regular maintenance is vital to ensure reliable operation and value retention of the device. All function and safety-relevant components and electrical units are checked during maintenance and replaced where necessary.



Maintenance is to be performed after every 50,000 sealing procedures (cycles), but after 4 years at the latest. At the appropriate time, a warning message is shown on the display.


### Validation

Your sealing device complies with all standard requirements for the validation of the sealing procedure in accordance with [EN ISO 11607-2](#). Conformity is confirmed with the declaration of conformity included in the scope of delivery.

### Software update

A software update is performed by an authorised technician during maintenance. If necessary, you can perform an update yourself as follows:

1. Download the current software version. You can find the file in the download centre on our website at [www.melag.com/en/service/downloadcenter](http://www.melag.com/en/service/downloadcenter).
2. Copy the update files into the main directory of the USB flash drive (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 switched-off 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 .
  - ➔ The update starts, the display extinguishes and the LED control lamp flashes yellow.
  - ➔ Once the update has been completed, the display issues **Update OK** and the control lamp illuminates green.
6. Should you not wish to perform an update, interrupt the procedure by pressing the  button.

7. Press  to complete the procedure.
  - ↳ The display changes to **MELASEAL**.
8. Switch off the sealing device and remove the USB flash drive.
9. 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 performance requalification (validation) is not necessary after the software update.

# 10 Pause times

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## Pause times

The sealing device can remain switched on over longer operating pauses of many hours. The sealing device switches into Eco mode (= energy-saving mode) after a user-defined time and then into standby following a further waiting time, see [Eco Mode and Standby](#) [▶ page 26].

## Transport and storage

**NOTICE****Warning of material damage**

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.

Comply with the following for safe handling:

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

## 11 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

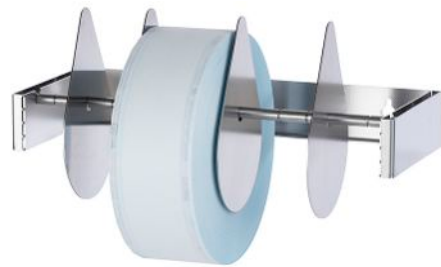
When using the reel dispenser Deluxe, the film reels are stored above the sealing device, thus saving space. The integrated feeding device enables easy feeding of the film via a hand wheel.

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.



# 12 Malfunctions

## Troubleshooting online



All messages with current descriptions can be found in the Troubleshooting portal on the MELAG website (<https://www.melag.com/en/service/troubleshooting>).

Comply with the following for safe handling:

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.
- The device may only be serviced by ► **authorised technicians**.

Confirm warning and malfunction messages with .

### Malfunction messages

Event	Possible causes	What you can do
F01	The sealing temperature has not yet been reached.	Check whether the sealing device display shows <b>Ready</b> . If it does, instruct the personnel in the operation of the device.
	The sealing device is located in a draught or too cold environment.	Check whether one or more windows are open and/or the sealing device is located in the air path of an activated air conditioning device. Place the sealing device in an equally acclimatized location.
	After starting the sealing procedure, the pressure rail is still too cold and draws heat from the sealing rail during the sealing procedure.	Leave more time between the sealing procedures (approx. 20 s) after the start of the sealing device.
F02	The sealing temperature was set incorrectly in the <b>Settings/Temp</b> menu.	Working in the <b>Settings/Temp</b> menu, check the sealing temperature setting and adapt it; see <a href="#">Sealing temperature</a> [► page 24].
F03	The sealing lever was raised too early during the sealing procedure. The required sealing duration was not achieved (less than 3 s).	Leave the sealing lever depressed as long as the progress bar in the display completes and the control lamp flashes green in short intervals. When the display switches to <b>Open</b> and the control lamp is illuminated green continuously, return the sealing lever upwards to its starting position.
F04	The sealing lever was held depressed for too long during the sealing procedure. The sealing duration was exceeded (over 8 s).	Move the sealing lever upwards immediately as soon as the display moves to <b>Open</b> and the control lamp illuminates green continuously.
F05	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F06	One or more instruments are stuck in the sealing area or block the sealing procedure.	Check the sealing area and if necessary, work carefully to remove any blocking instruments.
	The packaging material is too thick, has been folded or is kinked.	Make sure that you use only suitable film. The film may not be creased, folded, or sealed under multiple layers.
F07	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F08	The ambient temperature is too hot for operation of the sealing device.	The ambient temperature should not exceed 40 °C. Place the sealing device on a suitable location (< 40 °C).
F09	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F10	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F11	This malfunction can only be remedied by a technician.	Please consult your authorised technician.

Event	Possible causes	What you can do
F12	No logs can be saved on the USB flash drive.	<ol style="list-style-type: none"> <li>1. Check whether the USB flash drive is write protected.</li> <li>2. Connect the USB flash drive with a computer and check its function.</li> <li>3. If necessary, format the USB flash drive (FAT32, no quick formatting).</li> <li>4. Rename the USB flash drive on the computer.</li> <li>5. If necessary, replace the USB flash drive. MELAG recommends the use of a MELAG USB flash drive.</li> </ol>
	There is no connection between the sealing device and the computer.	<ol style="list-style-type: none"> <li>1. Check the device manager of your computer so that the sealing device is connected with the computer.</li> <li>2. Check the cable for damage if replace it if necessary.</li> <li>3. Check whether the sealing device is incorporated in the documentation software. If necessary, restart the documentation program.</li> </ol>
F13	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F14	This malfunction can only be remedied by a technician.	Please consult your authorised technician.
F15	This malfunction can only be remedied by a technician.	Please consult your authorised technician.

**Warnings**

Event	Possible causes	What you can do
W01	The USB flash drive was not recognised or was not connected correctly. The log cannot be recorded.	<ol style="list-style-type: none"> <li>1. Check whether the USB flash drive has been connected correctly to the USB port of the sealing device.</li> <li>2. Connect the USB flash drive with a computer and check its function.</li> <li>3. If necessary, format the USB flash drive (FAT32, no quick formatting).</li> <li>4. Rename the USB flash drive on the computer.</li> <li>5. If necessary, replace the USB flash drive. MELAG recommends the use of a MELAG USB flash drive.</li> </ol>
	The USB cable is not recognised or was not connected correctly. The log cannot be recorded.	<ol style="list-style-type: none"> <li>1. Check whether the USB cable drive has been connected to the USB port of the sealing device correctly.</li> <li>2. Check the device manager of your computer so that the sealing device is connected with the computer.</li> <li>3. Check whether the sealing device is incorporated in the documentation software. If necessary, restart the documentation program.</li> </ol>
W02	The memory on the USB flash drive almost full. Fewer than ten logs can be saved.	Copy the log files from the USB flash drive to the computer. Then delete the data from the USB flash drive.
W04	The maximum time or number of sealing procedures has been reached. Perform maintenance of the sealing device	Check the date in the log header. If the date is correct, then arrange for a MELAG authorised technician to perform maintenance.

# 13 Manufacturer's recommendation for routine operation

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## Video tutorial

See also "Manufacturer's Recommendation for Routine Operation" (<https://www.melag.com/en/service/tutorial/sealing-unit/melaseal200>).



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

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### 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 procedure. 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).

# 14 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.

# 15 Technical Data

<b>Device type</b>	<b>MELAseal 200</b>
Device dimensions (W x D x H)	41.5 x 24 x 15 cm
Weight	5.4 kg
<b>Electrical connection</b>	
Power supply	220-240 V, 50/60 Hz
Max. voltage range	198-264 V
Electrical power	max. 300 W, average 100 W
Building fuse	10 A, RCD 30 mA (1.3 A operation)
Overvoltage category	transient overvoltages up to the values of overvoltage category II
Pollution degree (in accordance with EN 61010-1)	Category 2
Device fuse	1x 2 A FF
Overheat protection	> 240 °C
Length of the power cable	1.5 m
<b>Ambient conditions</b>	
Installation location	interior of a building (dry and protected from dust)
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
<b>Sealing characteristics</b>	
Sealing temperature range	100-210 °C
Sealing force	200 N ± 15 % (factory settings, fix)
Heating duration (from 25 °C to 180 °C)	approx. 90 s
Sealing duration	min. 3 s (factory settings, fix)
Seal seam width	10 mm
Seal seam length	max. 27.5 cm
Maximum load quantity - transparent sterilization package	3 kg

# 16 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+ (roll, 5 cm x 200 m)	ME00530
	MELAfol+ (roll, 7.5 cm x 200 m)	ME00531
	MELAfol+ (roll, 10 cm x 200 m)	ME00532
	MELAfol+ (roll, 15 cm x 200 m)	ME00533
	MELAfol+ (roll, 20 cm x 200 m)	ME00534
	MELAfol+ (roll, 25 cm x 200 m)	ME00535
	MELAfol+ (pouch, 5 cm x 25 cm, 1000 pcs.)	ME00536
	MELAfol+ (pouch, 7.5 cm x 25 cm, 1000 pcs.)	ME00537
	MELAfol+ (pouch, 10 cm x 25 cm, 1000 pcs.)	ME00538
	MELAfol+ (pouches with side gusset, 20 cm x 50 cm, 100 pcs.)	ME00539

## 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
	Calibration box for MELAseal 200 (without thermometer and scale)	ME10121
	Suspension scale with calibration certificate	ME87500
	Thermometer with sensor and calibration certificate	ME87580
Testing equipment	MELAcontrol Seal Check	ME01079
	MELAcontrol Ink Test	ME01089
Documentation	USB stick	ME19901
	USB cable, 1.8 m	ME19902
	MELAtrace documentation software	ME21138

## Spare parts

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

## Glossary

### **Accessory**

Accessories are independent articles that are used with one or several medical devices. Accessories specifically and directly assist the intended purpose of the medical device.

### **Authorised technician**

An authorised technician is a person intensively trained and authorised by MELAG who has sufficient specific device and technical knowledge. to perform maintenance and installation work on MELAG devices. Only they may carry out this work.

### **Component**

A component is a part of a medical device, which is delivered with it but is not permanently connected to it. A component supports or achieves the intended purpose of the medical device for at least one use case. It is not an independent accessory or medical device.

### **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"

### **Equipment**

Equipment is an article that can be used with the medical device, however, it is not necessary for assisting and/or achieving the intended purpose of the medical device. It is not an independent accessory or medical device.

### **Sterile material**

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



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