

User Manual

MELAseal® 200

Sealing device

from software version 2.28



EN

CE

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.

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

Example	Explanation
Universal-Program	Words or phrases appearing on the display of the device are marked as display text.
	Prerequisites for the following handling instruction.
	Refer to the glossary or another text section.
	Information for safe handling.

Disposal

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

Dispose of accessories and consumption media which you no longer require in the appropriate manner. Comply with all relevant disposal specification in terms of possibly contaminated waste.

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

2 Safety



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

Qualified personnel

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

Setup, installation and commissioning

- Check the device after unpacking for any damage suffered during transport.
- The device is not suitable for operation in explosive atmospheres.
- Install and operate the device in a frost-free environment.
- 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.

Power cable and power plug

- Only the power cable included in the scope of delivery may be connected to the device.
- The power cable may not be replaced by a cable determined to be insufficient.

Danger of short circuit

- Liquids may not be permitted to reach the interior of the device. This could result in an electrical shock or short circuiting.

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 sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was developed especially for the heat sealing of instruments in sterilization packages and complies with the standard EN ISO 11607-2 and the German standard DIN¹⁾ 58953-7.

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 package that is not compatible with the requirements of EN 868-5, is 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.
- Polyethylene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film



NOTICE

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

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

Scope of delivery

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

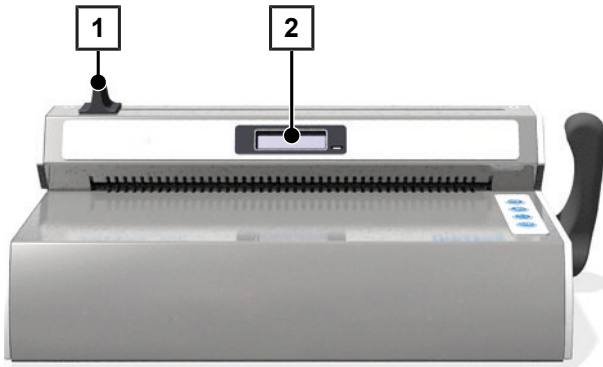
Standard scope of delivery

- Sealing device MELAseal 200
- User manual
- Checklist for installation and record of installation
- Declaration of conformity
- Warranty certificate
- Test and calibration protocol
- Power cable
- Sealing lever
- MELAG USB flash drive

¹⁾ DIN = Deutsches Institut für Normung

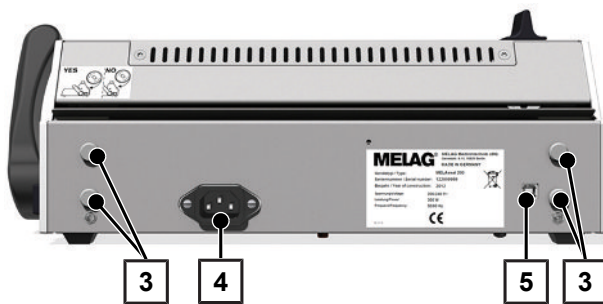
Views of the device

View from front



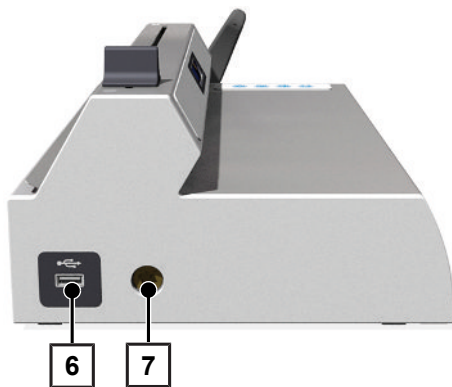
- 1 Knife handle
- 2 Display with control lamp

View from rear



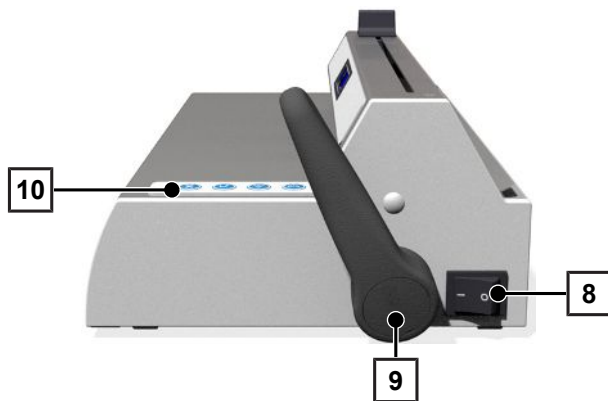
- 3 Bracket for reel dispenser
- 4 Power cable connection
- 5 USB interface (type B) for connection to the computer

View from left



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

View from right



- 8 Power switch (On/Off)
- 9 Sealing lever
- 10 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

└ Standard display output	Key
└ 180°C/User 1/Ready	Temperature/User/Operational readiness
└ User	User
└ User 01	User 01
└ User 02	User 02
└ └ User...	User...
└ User 10	User 10
└ Seal chk	Function check with MELAcontrol Seal Check
└ approve?	Performing function check with seal check
└ reminder	Activate reminder for seal check
└ weekly	Weekly
└ Mon	on Mondays
└ Tue	on Tuesdays
└
└ Sun	on Sundays
└ daily	daily
└ Off	Deactivate reminder for seal check
└ Settings	Settings
└ Temp	Sealing temperature
└ Tone	Switch signal tones on/off
└ Time	Time
└ Adjust	Set current time
└ Auto_DST	Autom. change from summer/winter time (CET)
└ Date	Date (TT-MM-JJ)
└ Eco Mode	Eco Mode
└ On/Off	Switch Eco mode on/off
└ Wait Eco	1. Waiting time: Setting the Eco Mode
└ Wait Stby	2. Waiting time: Setting the standby
└ Adj Frc	Force calibration
└ 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 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 cause	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 achieved. 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 Open is issued. Raise the sealing lever as soon as the display notification Open is issued, otherwise the sealing procedure will not be completed successfully. NOTICE! Failure to observe these provisions can result in the melting of the transparent sterilization package 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 minimum sealing duration has been reached and the sealing procedure has been ended.	Raise the sealing lever and remove the transparent sterilization packages.
 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 Open .
 LED flashes 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.

4 Commissioning

Video tutorial

See also "Installation and Set-up".



Requirements of the installation location



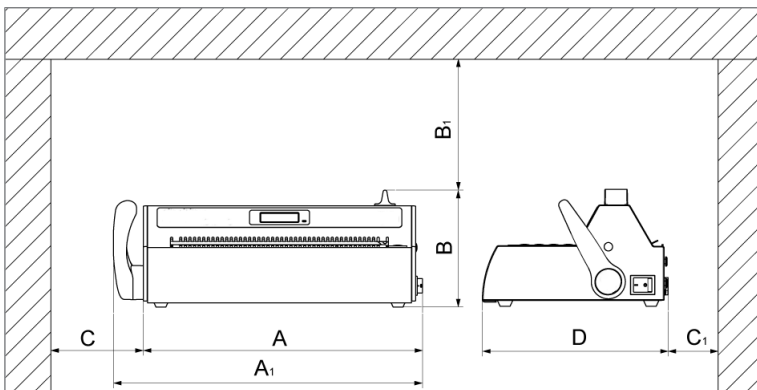
CAUTION

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

- Comply with all the specifications of this chapter for initial commissioning.
-
- The device is not suitable for operation in explosive atmospheres.
 - The device is only intended for use in interior spaces.
 - The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
 - Install the 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.
 - Set-up the device protected against blows or vibrations.

Space requirements

View from the front and right



Device dimensions		MELAseal 200
Width	A	36.5 cm
Width including sealing lever	A ₁	41.5 cm
Height	B	15 cm
Minimum clearance above	B ₁	25 cm
Minimum clearance to the side	C	10 cm
Minimum clearance to rear	C ₁	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

- ✓ The sealing device has been switched off.
- ✓ The power cable, delivered in the scope of delivery, is present.
- 1. Connect the IEC plug of the power cable to the rear side of the sealing device and connect the power plug in the power socket.
- 2. 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 sealing 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”.



Sealing procedure with pre-finished film pouches



CAUTION

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

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



NOTICE

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

The film side of the packaging must always face upwards.



PLEASE NOTE

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

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

1. Insert the packaging (film side facing upwards) from the front in the paper guide between the pressure rail and sealing rail. Ensure the correct clearance between instrument and seal seam (see [Standard specifications](#) [▶ page 37]).



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 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 four times. Then the display switches to **Ready**.

5. Perform a visual inspection of the seal seam after every successful sealing procedure.



PLEASE NOTE

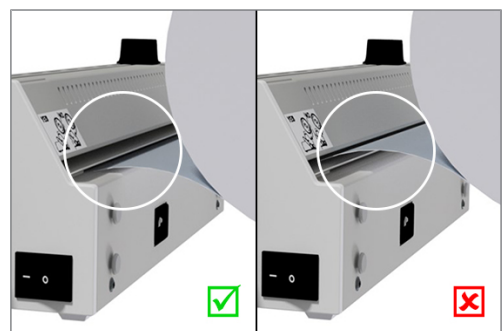
With pouches with side gussets, perform weekly checks of the seal seam using an ink test (e.g. MELAcontrol Ink Test).

Sealing procedure for film reels

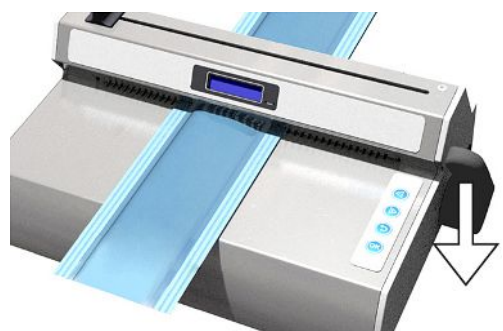
Producing a film pouch

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

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



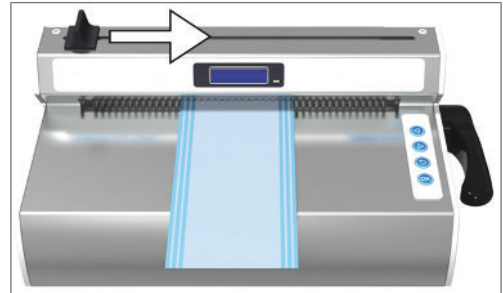
2. Press the sealing lever down until it latches.



3. Leave the sealing lever depressed 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



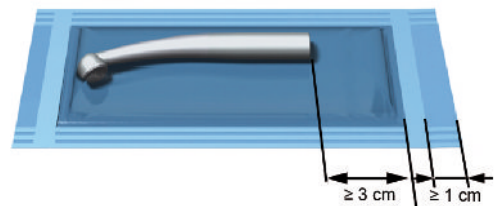
NOTICE

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

The film side of the packaging must always face upwards.

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

1. Place the instruments to be sterilized in the film pouch. Ensure the correct clearance between instrument and seal seam (see [Standard specifications](#) [▶ page 37]).



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 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 four times. Then the display switches to **Ready**.
6. Perform a visual inspection of the seal seam after every successful sealing procedure.

6 Logging

Documenting the sealing process

Video tutorial

See also “Documentation and User Administration”.



EN ISO 11607-2 requires that the sealing process is 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 sealing procedures, to output and archive them on the following output media:

- USB flash drive
- Computer with documentation software e.g. MELAview/MELAttrace 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

Danger of data loss through damage of the USB flash drive following improper use.

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

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 sealing device.

➔ As soon as the USB flash drive has been recognized and is ready for operation, the display shows **Mem_Conn** (= memory connected).

Comply with the following general information relating to logging with the USB flash drive:

- 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.
- Copy the log files from the USB flash drive to the computer at regular intervals.
- Select only a single logging type, either by USB flash drive **or** via the documentation software MELAttrace/MELAview. 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.

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 MELAview Docu/MELAtrace version 3.0.15.1.
- ✓ Firmware 2.10 and above requires MELAview Docu/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.

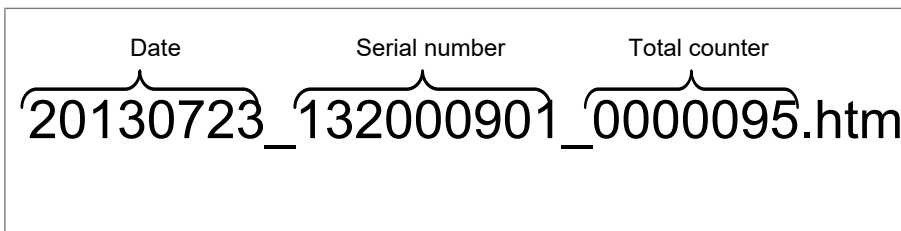


PLEASE NOTE

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. Alternatively the seal check can be performed manually.

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].

8 Settings

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”.









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".



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".



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.

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. To this end, the sealing force thresholds are automatically adapted to the changed sealing temperature.

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”.



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 QM 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”.










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 ± 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

Note the following:

- Switch off the sealing device at the power switch and remove the power plug 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.

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

MELAG recommends regular maintenance vital to ensure reliable operation and value retention of the device. Arrange for regular maintenance every 50,000 program cycles or at the latest after 4 years.



NOTICE

Continuing operation beyond the maintenance interval can result in malfunctions in the device!

- Maintenance should only be performed by trained and authorised technicians.
- Maintain the specified maintenance intervals.



Carry out maintenance with an original maintenance set prepared by MELAG. Only original MELAG spare parts may be used.


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. Please contact an authorised technician to obtain the latest software version.
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 .

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

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

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

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

Note the following:

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

11 Optional accessories

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

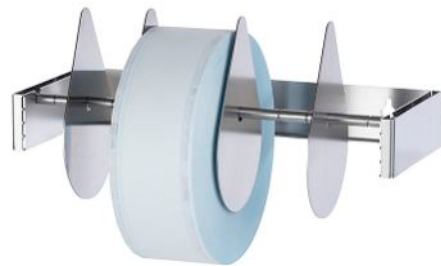
When using the reel dispenser Deluxe, the film reels are stored above the sealing device, thus saving space. The integrated feeding device enables easy feeding of the film via a hand wheel.

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>).



WARNING

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

- Never open the sealing device housing cover without authorisation.
- The sealing 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 achieved.	Check whether the sealing device display shows Ready . 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 bar 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 Settings/Temp menu.	Working in the Settings/Temp menu, check the sealing temperature setting and adapt it; see Sealing temperature [▶ 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 Open 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 Open 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).

Event	Possible causes	What you can do
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.
F12	No logs can be saved on the USB flash drive.	<ol style="list-style-type: none"> 1. Check whether the USB flash drive is write protected. 2. Connect the USB flash drive with a computer and check its function. 3. If necessary, format the USB flash drive (FAT 32, no quick formatting). 4. Rename the USB flash drive on the computer. 5. If necessary, replace the USB flash drive. MELAG recommends the use of a MELAG USB flash drive.
	There is no connection between the sealing device and the computer.	<ol style="list-style-type: none"> 1. Working in the device manager of your computer, check whether the sealing device is connected with the computer. 2. Check the cable for damage and replace it if necessary. 3. Check whether the sealing device is incorporated in the documentation software. If necessary, restart the documentation program.
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"> 1. Check whether the USB flash drive has been connected correctly to the USB port of the sealing device. 2. Connect the USB flash drive with a computer and check its function. 3. If necessary, format the USB flash drive (FAT 32, no quick formatting). 4. Rename the USB flash drive on the computer. 5. If necessary, replace the USB flash drive. MELAG recommends the use of a MELAG USB flash drive.
	The USB cable is not recognised or was not connected correctly. The log cannot be recorded.	<ol style="list-style-type: none"> 1. Check whether the USB cable drive has been connected to the USB port of the sealing device correctly. 2. Check the device manager of your computer so that the sealing device is connected with the computer. 3. Check whether the sealing device is incorporated in the documentation software. If necessary, restart the documentation program.

Event	Possible causes	What you can do
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

Video tutorial

See also “Manufacturer’s Recommendation for Routine Operation”.



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

Performing the peel test

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

MELAG seal seam stability test

Video tutorial

See also “Test for seal seam stability”.



To ensure that the sealing process complies with all normative specifications, MELAG recommends carrying out an annual seal seam stability test.

MELAG offers a seal seam stability test for the validation of your sealing processes. 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

Term	Explanation
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 pouch, 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 packaging 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).
- In packaging made of porous materials and plastic composite film, a minimum of 30 mm must remain free between the sterilization material and the seam to be sealed (DIN 58953-7).
- When using transparent sterilization package 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 a min. 6 mm. Thus for grooved seal seams, the sum of the individual grooved seams should amount to 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 package, 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:

- Comply with the maximum storage duration in accordance with the packaging type. Comply with the manufacturer's information on the packaging.
- Do not store the sterile material in the reprocessing room.
- 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

Device type	MELAseal 200
Device dimensions (W x D x H)	41.5 x 24 x 15 cm
Weight	5.4 kg
Electrical connection	
Power supply	200-240 V, 50/60 Hz
Electrical power	max. 300 W, average 100 W
Device fuse	1x 2 A
Overheat protection	> 240 °C
Length of the power cable	2 m
Ambient conditions	
Installation location	interior of a building
Max. altitude	2000 m
Ambient temperature	5-40 °C (ideal range 16-26 °C)
Relative humidity	max. 80 % at 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)
Sealing characteristics	
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

16 Accessories and spare parts

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

	Article	Art. no.
Accessories	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
	MELAcontrol Seal Check	ME01079
	MELAcontrol Ink Test	ME01089
	USB flash drive	ME19901
	USB cable, 1.8 m	ME19902
	MELAtrace documentation software	ME21138
Spare parts	Sealing lever (black) for MELAseal 100+/200	ME77000



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Original instructions

Responsible for content: MELAG Medizintechnik GmbH & Co. KG
We reserve the right to technical alterations

Your stockist