

User Manual

MELAseal[®] Pro

Sealing device

from software version 1.02.03



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.

Fan

- The fan in the device floor must be free at all times and may not be allowed to become blocked or congested. Failure to comply with this provision can result in the overheating of the electrical components in the interior of the device and malfunctions.
- Check the fan grating regularly for cleanliness in order to prevent it from becoming clogged with dust and thereby preventing insufficient cooling.

Light sensor for automatic in-feed

- Ensure that small components (e. g. from instrument) do not enter the in-feed with the sterilization packaging to be sealed. The small components could cause damage to the transport mechanism of the device, the sterilization material and the sterilization packaging.
- Never introduce any objects into the sealing device other than the packaging materials specified in the user manual.

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 rotary sealing device MELAseal Pro 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.

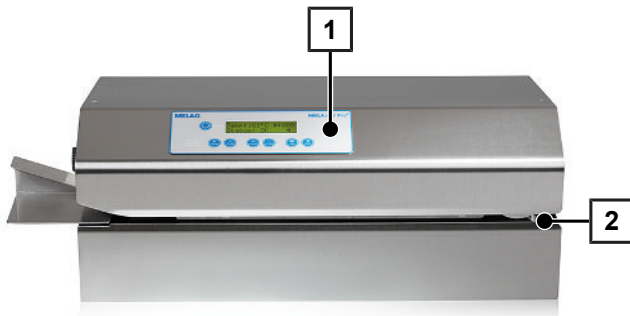
Standard scope of delivery

- Rotary sealing device MELAseal Pro
- User manual
- Checklist for installation and record of installation
- Declaration of conformity
- Warranty certificate
- Test and calibration protocol
- Power cable

¹⁾DIN = Deutsches Institut für Normung

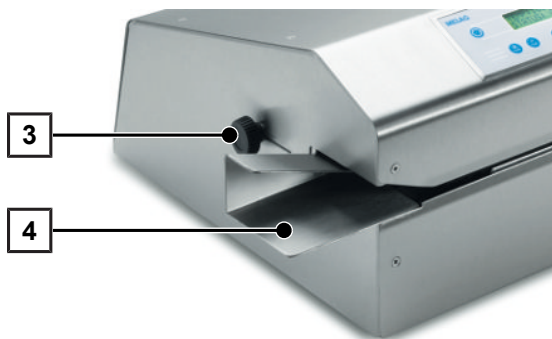
Views of the device

View from front



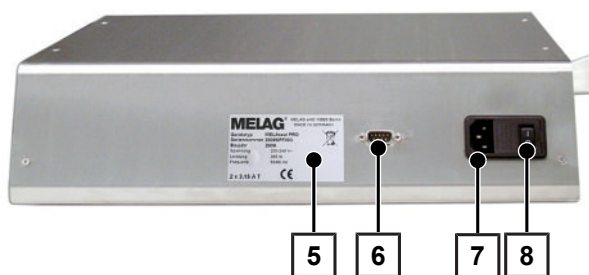
- 1 Operating and display panel
- 2 Conveyor belt

View from left



- 3 Adjustment wheel for adjusting the clearance between the seal seam to the packaging cutting edge
- 4 Guide rails

View from rear



- 5 Type plate
- 6 Serial interface (RS232)
- 7 Power cable connection
- 8 Power switch (On/Off)

Symbols on the device







Type plate





Manufacturer of the product



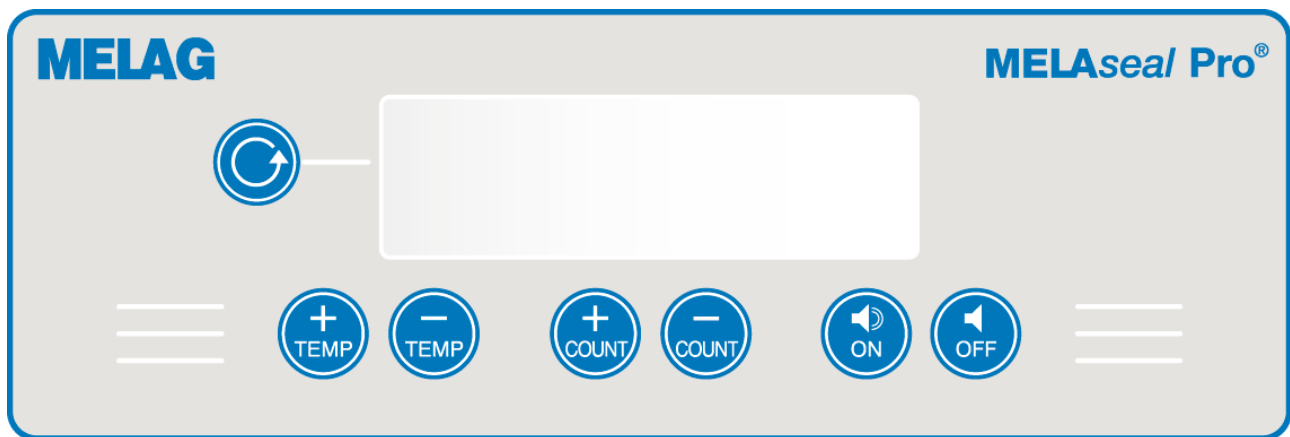
Date of manufacture of the product





-  Article number of the product
-  Serial number of the product
-  Observe user manual or electronic user manual
-  Do not dispose of product in household waste
-  CE marking
-  Electrical connection of the product: Alternating current (AC)

Symbols on the power switch

-  Switching on device
-  Switching off device

Operating and display field



Key	Description
	Setting the temperature
	Reverse key – removing the sterilization packaging upon a blockage of the conveyor belt
	Setting the total number of batches of a day
	Switch signal tone on and off upon the pre-set total number of batches having been reached

4 Commissioning

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.



PLEASE NOTE

In rare cases, direct light can result in the activation of the sealing device conveyor belt which is controlled by a light-sensitive sensor.

Connecting the sealing device

- ✓ The sealing device has been switched off.
- ✓ The power cable, delivered in the scope of delivery, is present.
- ▶ 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.

Setting the clearance between the cutting edge and the packaging

The sealing device permits individual setting of the clearance of the seal seam to the cutting edge of the packaging. An adjusting screw in a slot is located on the left-hand side of the sealing device.

- ▶ Loosen the screw a little in order to slide the guide rail forwards or backwards.



The scale next to the adjusting screw on the right displays the overhang in millimeters (measured from the outer edge of the sealed seam).

Switching on the sealing device

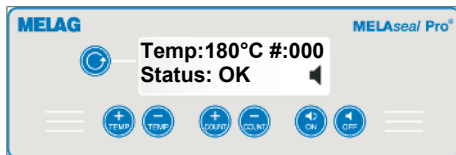
- ✓ The sealing device is connected to the power supply.
- ▶ Switch on the sealing device at the power switch.



- ➔ After switching on the sealing device, the display shows the message **Heating up**. It takes approx. 3-5 min before the pre-set sealing temperature of 180 °C is reached.

Operational readiness

As soon as the set sealing temperature has been reached, two tones will be issued and the display will change to **Status: OK**. The sealing device is ready for operation.



5 Sealing

Sealing procedure



NOTICE

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

- Always guide the packaging 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. Instructions for handling MELAfol pouches with side gusset) especially when wishing to seal cassettes.

The following must be fulfilled or present:

- ✓ The sealing temperature has been reached.
- ▶ Insert the transparent sterilization package in the guide rail on the left-hand side of the device.
- ↪ The transport belt begins to turn as soon as the internal optical sensor recognises the packaging. The packaging is then guided through the sealing device automatically.

Should you wish to perform a specific number of sealing procedures one after each other, you can set an automatic counter which issues a signal tone once a set number of sealing procedures have been reached (see [Automatic sealing counter](#) ▶ page 12]).






PLEASE NOTE

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

Automatic sealing counter

It is possible to set a signal tone to control the number of packages to be sealed. It will sound after the pre-set number of seals has been completed. This function is useful when needing to seal a larger quantity of packages.

To set the counter to a particular number, proceed as follows:

1. Press the key  for approx. 2 s until the display switches to **Counter: xxx**.
2. Press and hold  or  for starting the counter running to a maximum of 999.
3. Release the key when the required number of packages to be sealed has been reached.

The number set will be saved automatically. Set the number to 000 to reset the sealing counter.

Display of the daily batches

The daily batch counter #: 000 is displayed in the upper right-hand corner of the display: It counts the number of seals performed in the course of one day. If the sealing device is switched off, the counter is reset to 000.



PLEASE NOTE

This does not reset the total batch counter.

Resetting the daily batch counter

The following must be fulfilled or present:

✓ The sealing device remains activated in between the sealing runs.

1. Switch on the sealing device.

2. Press the key  for some seconds.

→ The daily batch counter is reset to #: 000.



PLEASE NOTE

Switching the sealing device off and then on, also resets the daily batch counter to 000. This does not reset the total batch counter.

6 Logging

Documenting the sealing process

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:

- MELAprint 42/44 log printer
- MELAflash CF card printer (from software version 1.9)
- Computer with documentation software e.g. MELAview/MELAttrace (from software version 2.2)

Using the log printer as an output medium

Should you wish to use the MELAprint 42/44 log printer as an output medium, connect it as follows:

1. Connect the serial connection cable of the MELAprint 42/44 log printer to the RS232 interface on the rear of the sealing device.
2. Connect the power cable included in the scope of delivery of the log printer in accordance with the appropriate user manual.
 - ↳ The sealing device recognizes the MELAprint 42/44 log printer automatically.
 - ↳ The log printer outputs a log row consecutively for every sealing procedure performed.

Using the MELAflash CF-Card-Printer as an output medium

The MELAflash CF-Card-Printer saves the logs on a CF card. The logs can be outputted from the CF card on the practice computer using a card reader. A CF card and the card reader are included in the scope of delivery of the MELAflash CF-Card-Printer. MELAflash CF-Card-Printers from software version 1.9 and above support the recording of logs from the MELAseal Pro sealing device.

Connect the MELAflash CF-Card-Printer as follows:

1. Connect the serial connection cable of the MELAflash CF-Card-Printer to the RS232 interface on the rear of the sealing device.
2. Connect the power cable included in the scope of delivery of the CF card printer in accordance with the appropriate user manual.
 - ↳ The MELAflash CF-Card-Printer is automatically recognised by the sealing device.
 - ↳ A daily log is saved on the CF card in the MELAflash CF-Card-Printer after the first sealing procedure of the day. Here a log row is written for every further sealing procedure of the same day.



PLEASE NOTE

Complete documentation

Ensure that the CF card is inserted in the MELAflash CF-Card-Printer during every sealing procedure.

Using the computer as an output medium

The following must be fulfilled or present:

- ✓ The computer is connected to the rear of the sealing device via the serial interface.
- ✓ The documentation software MELAview/MELAttrace is used to output the log.
- ▶ Take from the documentation software the information as to how you operate the MELAview/MELAttrace program and output this via the program logs.
 - ↳ A daily log is saved on the CF card in the MELAflash CF card printer after the first sealing procedure of the day. Here a log row is written for every further sealing procedure of the same day.



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.

Storage structure of the log files

A directory with the encrypted sealing device serial number will be created on the CF card and the computer. The folder name consists of five characters identical with the first five characters of every log, e.g. 9K0EQ. This directory contains a sub-directory with the month of log generation e.g. 10_2009. This contains all logs generated by the sealing device in this month.



PLEASE NOTE

Never store logs from different months in a common folder as the daily logs for the various months have the same file name.

Structure of the log files

The log files are simple text files and can be opened with the text editor of the computer. The ending of the log file is initially unknown to the computer. After assigning a file ending to a text program you can open this file type with a double-click. Alternatively, you can open the log files with the documentation software MELAviiew/MELAttrace.

Position	1	2	3	4	5	6	7	8		X	X	X
Example	9	K	0	E	Q	-	1	2	.	M	S	E
Meaning	Five-digit code					Day			Log file ending			
Explanation	Five-digit number which includes the device type, serial number and year of construction in encrypted form					The day on which the log was generated (the date set on the sealing device is counted)			MSE = file ending			

The daily logs are saved in English.

Example of a log with several sealing procedures:

```

-----
MELAG MEDIZINTECHNIK
-----
10 MELAG MELAseal Pro
25 Date: 06.01.2010
80 SerNr: 2009SPF0001
| |Time |Charge|Tmp|Prs|Vel|Limits |CRC
|---|-----|-----|---|---|---|-----|-----|-----|
|OK|09:19| 00012|180|098|087|185-175 120-090 120-078|F228 (PC)
|!!|09:19| 00013|180| + |086|185-175 120-090 120-078|F25D (PC)
|OK|09:20| 00014|179|098|086|185-175 120-090 120-078|F25C (PC)
  
```

Key:

Row 10	- Designation of the sealing device
Row 25	- Date of sealing procedures (dd.mm.yyyy)
Row 80	- Serial number of the sealing device
OK / !!	- Sealing procedure successful / sealing procedure unsuccessful
Time	- Time of the sealing procedure
Batch	- Total number of charges
Tmp	- Sealing temperature (in °C)
Prs	- Pressure with which the packaging was sealed (sealing force, in N)
Vel	- Speed of the conveyor belt in (dm/min.)
Limits	- Parameter thresholds: Sealing temperature (175-185 °C), sealing force (120-120 N), speed (120-120 dm/min)
CRC	- Coded proof of log authenticity
(PC)	- Indication that the log was produced on the computer via MELAview/MELAtrace

Example of a log row from a log printer:

01161; 2009SPF1000; 09-12-15;14:28;180;099;88;185-175 120-090 120-078|F300

Key: The example above shows the following parameters in this order:

Total number of batches; serial number; date (yy-mm-dd); time; sealing temperature; sealing force; speed; thresholds | CRC-Code

Sealing procedure successful

A log includes all printing procedures of one day. A row in the log is written for every sealing procedure. If an output is made via the MELAflash CF card printer or MELAview/MELAtrace, a successful sealing procedure is marked in the log row with an "OK".

Unsuccessful sealing procedure

If a malfunction occurs during a sealing procedure, this is recorded in the log with two exclamation marks !!. A value will not be recorded in the log row for the parameter for which the malfunction occurred. Instead, this space will be marked with "+" if the respective value has been exceeded. If the value has fallen below the relevant value, the space will be marked with "-".











7 Settings

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.



Date

To set the current date, proceed as follows:

1. Switch on the sealing device at the power switch.
2. Press  as soon as the display shows the current software version.
3. Press  repeatedly to access the menu item **Date**.
4. Press  to set the value.
↳ Two arrows  will appear behind the currently selected parameters.
5. Press  or  to navigate between the parameters Day, Month and Year.
6. Press  or  to set the selected parameter.
↳ The value will be saved after setting.
7. Press  to leave the menu item **Date**.
8. Press  to leave the setup menu entirely.







Time

To set the current time, proceed as follows:

1. Press  as soon as the display shows the current software version.
2. Press  repeatedly to access the menu item **Time**.
3. Proceed in a fashion similar to the setting the date.

Language




To change the currently set language proceed as follows:

1. Switch on the sealing device at the power switch.
2. Press  as soon as the display shows the current software version.
3. Press . Two arrows  will appear behind the language.
4. Press  or  to select the preferred language.
5. Press  to save the setting and leave the menu entirely.

Sealing temperature

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:

1. Depress one of the two keys  or  for approx. 2 s until two arrows  are displayed on the right-hand border of the display.
2. Holding one of the keys depressed initiates the temperature display. The temperature range ranges from 100-199 °C.
3. Release the key when the required sealing temperature has been reached.

8 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.
Annually	Clean the fan on the base of the sealing device with a dry or damp, non-fuzzing cloth in order to prevent it from becoming clogged with dust and insufficient cooling.

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 2 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.

9 Pause times

Pause times

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

Transport and storage



NOTICE

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

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

Note the following:

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

10 Optional accessories

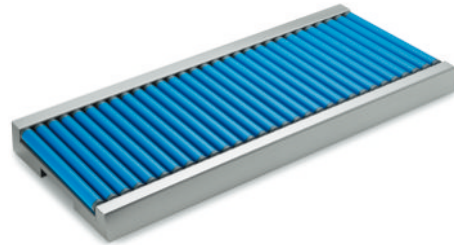
Work table Standard

The work table Standard is placed directly in front of the sealing device. The work table makes it easier to seal light packaging.



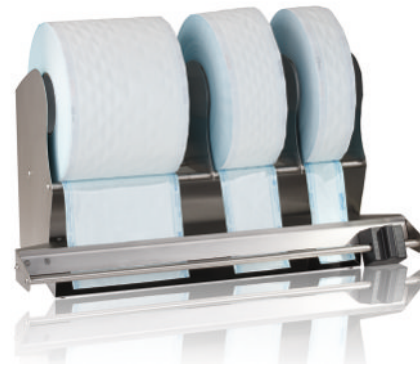
Work table Comfort

The work table Comfort is placed directly in front of the sealing device. The work table is fitted with smooth running rollers on which heavy / length-ways wrapped instruments or cartridges can glide easily. This represents the ideal precondition to safe and comfortable sealing.



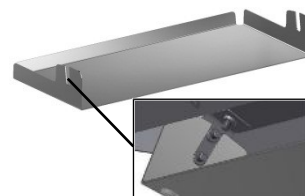
Reel dispenser

The reel dispenser represents the ideal assistant when you need to process MELAfol transparent sterilization package from the reel. It can be mounted on the wall above a work station or placed on the work surface with accessories. With an effective width of 42 cm, the reel dispenser provides considerable space for multiple rolls of varying widths. The integrated cutting knife cuts the film to the desired length cleanly and quickly.



Foot for the wall mounted reel dispenser

The foot for the wall mounted reel dispenser enables use of the reel dispenser on the work surface. Setup is quick and easy.



11 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.

The following tables indicate possible causes for certain events and the corresponding operating information for their remedy. Should you be unable to find the relevant event in the tables below, or your efforts do not redress the problem, you can contact your nearest authorised technician.

Event	Possible causes	What you can do
Empty display Fan does not work	The sealing device is not switched on; the power cable is not connected or is not connected with the power socket.	Switch on the sealing device at the power switch and check the connection of the power cable from the sealing device to the power socket.
Seal seam is not correct	The sealing temperature is too low; the sealing temperature decreases as a result of too short an interval between the sealing procedures.	Check the set sealing temperature (see Sealing [▶ page 12]). Wait until the required sealing temperature has been reached.
Seal seam dark/ burned	The sealing temperature is too high.	Check the set sealing temperature and correct it if necessary (see Sealing [▶ page 12]). Upon repeated occurrence, inform an authorised technician.
Seal seam is not correct	The sealing temperature recommended for the packaging has not been reached.	Check the set sealing temperature and correct it if necessary (see Sealing [▶ page 12]). Upon repeated occurrence, inform an authorised technician.
Seal seam is irregular or contains defects.	a) The packaging material is not suitable for use with this sealing device. b) The pressure roller is soiled.	a) Use only suitable packaging material for this sealing device. b) If necessary, arrange for the pressure roller to be replaced by an authorised technician.
The transport belt does not start.	The operating temperature has not yet been achieved.	Wait until the sealing device has reached operating temperature.
The display flashes	The energy supply has been interrupted.	Contact an authorised technician.
Housing temperature is too high	The housing fan is soiled.	Switch off the sealing device and allow it to cool. Clean the fan suction ports in the base plate.
Display goes dark	The housing fan is soiled.	Switch off the sealing device and allow it to cool. Clean the fan suction ports in the base plate.
Drive does not stop	The sealing device is located in too bright an area. If direct light (room illumination or sun) shines on the infeed side of the sealing device, the start sensor will be activated automatically.	Setup the sealing device at a location with less or no direct light.

Malfunction messages

The warning and malfunction messages are confirmed with .

Event	Possible causes	What you can do
TEMP 1	The temperature does not increase fast enough after switching on the sealing device.	Switch off the sealing device and then on again.
TEMP 2	The max. permissible temperature has been exceeded.	Switch off the sealing device and allow it to cool sufficiently. Switch the sealing device back on.
TEMP 3	The temperature falls too strongly during the sealing procedure.	Check whether the sealing device is standing in a draught or if the ambient temperature is too low.
Force high	The max. permissible sealing force been exceeded. a) The packaging material is too thick, has been folded or is kinked. b) An instrument has blocked the sealing procedure. c) The pre-set maximum sealing force has been maladjusted.	<p>a) Make sure that you use only suitable film. The film may not be creased, folded, or sealed under multiple layers.</p> <p>b) Use sufficient film so that no instruments are able to enter the sealing device and block the sealing procedure.</p> <p>c) Working in the setup menu, check the set maximum sealing force and correct the value if necessary as follows:</p> <ol style="list-style-type: none"> Switch on the sealing device and press  as the display shows the current software version. Press  three times. The display shows the sealing force currently set. The value must be 120-125 N. If a different value is displayed, correct this to 125 N. To do so, press  and adapt the value by pressing  or . Save the setting with . Press  to leave the setup menu. Perform a test seal to check the correct function of the sealing device.
Speed too low	The minimum sealing speed has been undercut (< 78 dm/min). a) The device is blocked by packaging material or an instrument. b) The drive was braked during the sealing procedure by e.g. over-heavy sealing objects (one or more instruments).	<p>a) Check the sealing area for packaging or instruments. Working carefully, remove the blockage by hand or by pressing the reverse key.</p> <p>b) Always guide the sealing material to prevent braking of the drive. If possible, always use less sealing material per film or the optional work table Comfort with rollers.</p>

12 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).

13 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.

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 MELAG 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.

14 Technical Data

Device type	MELAseal Pro
Device dimensions (W x D x H)	46 x 29.5 x 15.5 cm
Weight	11.4 kg
Electrical connection	
Power supply	220-240 V, 50/60 Hz
Electrical power	max. 365 W, average 180 W
Device fuse	2x 3.15 A T, 1x 1.6 A T, 1x 250 mA T
Overheat protection	> 220 °C
Length of the power cable	2.5 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 speed	8.5 m/min
Sealing temperature range	100-199 °C
Heating duration (from 25 °C to 180 °C)	approx. 240 s
Sealing force	100 N ± 10 %
Seal seam width	14 mm (7 grooves)
Seal seam length	unlimited

15 Accessories and spare parts

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

	Article	Art. no.
Accessories	Work table Standard	ME00119
	Work table Comfort	ME00118
	Wall mounted reel dispenser with cutting device	ME00116
	Foot for wall mounted reel dispenser / cutting device	ME71490
	MELAflash CF-Card-Printer incl. CF card and card reader	ME01039
	CF card	ME01043
	Card reader for CF card	ME01048
	USB serial adapter	ME80270
	MELAcontrol Seal Check	ME01079
	MELAcontrol Ink Test	ME01089
Spare parts	Separating plate for reel dispenser MELAseal Pro	ME71200
	Angled adapter, interface (RS232) for MELAseal Pro	ME80210
	Mains fuse for MELAseal Pro (3.15 A)	ME74320



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Original instructions

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

Your stockist