Operating Manual

MELA*seal* Pro®

Rotary sealer

Software version 1.02.02

Dear doctor,

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 treatment 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 ISO 13485 and ISO 9001. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

CE

The MELAG management and team

General notes

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

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

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

About this manual

Symbols used

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

Formatting rules

Symbol	Explanation
Status: OK	Words or phrases appearing on the display of the device are marked as software citations.
see **Chapter 2**	Reference to another text section within this manual.
Fig. 1/(3)	Reference to a detail in a figure – in the example, to part no. 3 in figure 1.

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Safety Instructions

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

Power cable and mains socket

- Only the power cable included in the scope of delivery may be connected to the sealing device.
- Liquids may not be permitted to reach the interior of the sealing device. This could result in an electrical shock or short circuiting.

Repair

- Never open the housing of the sealing device. Incorrect opening and repair can compromise electrical safety and pose a danger to the user.
  The guarantee and warranty are forfeited as soon as the sealing device is opened by anyone other than a member of a MELAG-authorized technical customer service.

Fan

- The fan in the base of the sealing device must be free at all times and may not be allowed to become blocked or congested. Failure to observe this provision can result in the overheating of the electrical components in the interior of the sealing 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.

Automatic in-feed

- Ensure that small particles (e.g. tiny instrument parts) do not enter the in-feed with the sterilizing packaging to be sealed. The small particles could cause damage to the sealing device transport mechanism, the sterilization packaging and sterilization load.
- Never introduce any objects into the sealing device other than the packaging materials specified in the operating manual.

Chapter 1 – Performance Specifications

Intended Use

This sealing device is designed for application in a medical context, e.g. clinics and medical and dental practices. It was especially developed for the heat sealing of instruments in sterilization packaging and complies with the standards DIN EN ISO 11607-2 and the German DIN 58953 part 7. The MELAseal Pro rotary sealer is not a medical product as defined by the Medical Device Directive.

Suitable materials

It is suitable for the heat sealing of the following packaging materials:

- Heat-sealable transparent sterilization packaging, e.g. MELAfol

Should you wish to use packaging materials other than those specified above, please consult your stockist first or contact MELAG directly.

Unsuitable materials

- Polyethylene film
- Soft PVC film
- Hard PVC film
- Polyamide film
- Polypropylene film
- The use of other packaging materials carries the risk of damage to or malfunction of the device.

PLEASE NOTE

Please observe the manufacturer information regarding the respective packaging materials as well as the recommended sealing temperatures.

Chapter 2 – Device description

Scope of delivery

Please check scope of delivery before connecting the sealing device.

Standard scope of delivery

- MELAseal Pro rotary sealer
- Power cable
- Operating Manual

Views of the device

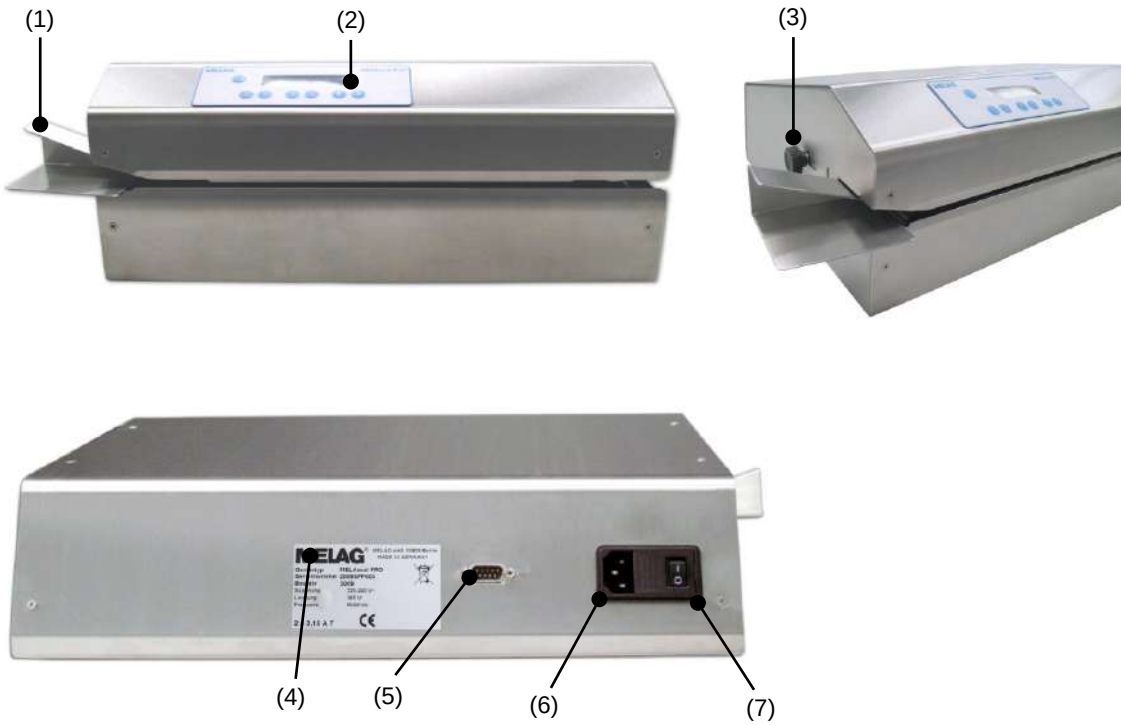
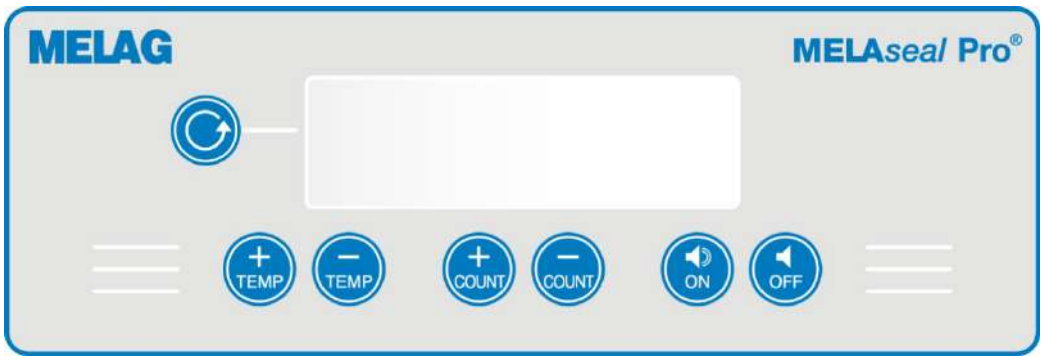


Fig. 1: Views of the device

(1) Guide rail for straight introduction of the sterilization packaging
(2) Operating and display field
(3) Adjustment screw for adjusting the clearance between the seal seam to the packaging cutting edge
(4) Type plate
(5) RS232 Interface
(6) Power cable socket
(7) Power switch

The control panel

Table 1: Meaning of the keys



Keys	Explanation
TEMP TEMP	Temperature setting – to increase or reduce the sealing temperature
	Reverse key – for removing the sterilization packaging upon a blockage of the conveyor belts.
COUNT COUNT	Daily batch counter – for increasing or reducing the total number of batches of a day.
ON OFF	Key to switch signal tone on and off upon the pre-set total number of batches having been reached.

Chapter 3 – Commissioning

Transport and storage

WARNING

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

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

Storage

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

Conditions of storage and installation

- In accordance with current VDE specifications, the sealing device is unsuitable for operation in areas exposed to the danger of explosion.
- The sealing device is conceived for use outside patient surroundings. The device should be located at least 1.5 m away (radius) from the treatment area.
- Observe all the information contained in this chapter during commissioning.

DANGER!

Failure to comply with the set-up conditions can result in malfunctions or damage to the sealing device and/or human injury.

Requirements of the installation location

- Install the sealing device in a dry and dust-protected location.
- Maintain sufficient clearance to the surrounding surfaces in order to ensure sufficient ventilation.
- Ensure that the sealing device is located away from direct sunshine and outside the range of other sources of heat.
- The sealing device must be protected against blows or vibration.

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.

Commissioning

Connecting the sealing device

Check the following points before connecting:

- ✓ *The device power switch is off.*
- ✓ *The power cable included in the scope of delivery is used for connecting.*

1. Connect the one end of the power cable with the port on the rear of the sealing device and the other end with a mains socket with an approved voltage supply.

Setting the clearance between the cutting edge and the packaging

The German standard DIN 58953, part 7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with transparent bags on the removal edge. This ensures aseptic removal. We recommend a minimum overhang of 10 mm.

The rotary sealer enables you to set the clearance individually.
An adjusting screw in a long hole is located on the left-hand side of the sealing device.

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

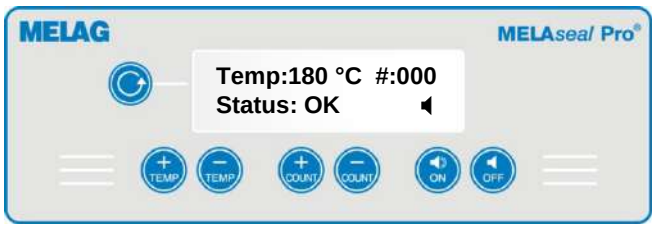
The scale, to the right of the adjusting screw displays the overhang in mm (measured from the outer edge of the sealed seam).

Switching on the sealing device

1. Switch on the sealing device at the mains switch (position: I).

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

As soon as the set temperature has been reached, two tones sound. The display jumps to **`Status: OK`** and the sealing device is ready for operation.

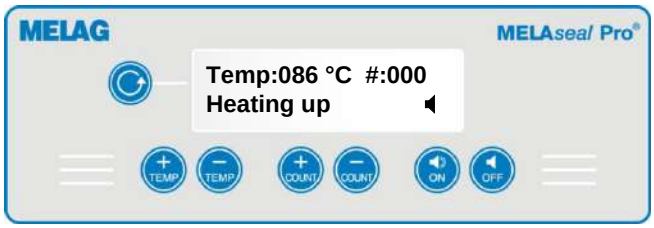


PLEASE NOTE
Please observe all manufacturer information for the sterilization packaging regarding recommended temperatures. The recommended sealing temperature for the transparent sterilization packaging MELAfol is 180 °C. If the recommended sealing temperature of the materials used is not 180 °C, the sealing temperature must be adapted (see page **Chapter 4 – Settings**, **Changing the sealing temperature**).

As long as the sealing temperature has not been reached, the display shows the message **`Heating up`**.

Minimal temperature differences of ± 5 °C are possible during the sealing procedure.

In the case of deviations over 5 °C, wait until the sealing device display shows Status: **`OK`**.



Sealing procedure

As soon as the sealing temperature has been reached, you can insert the sterilization packaging as follows:

1. Insert the sterilization packaging in the guide on the left-hand side of the device.

The conveyor belt begins to turn as soon as the inbuilt optical sensor recognizes the packaging. The packaging is then guided through the sealing device automatically.

WARNING

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

Using the reverse key

Should either the sterilization packaging become jammed in the device or the conveyor belt come to a halt, you can reverse the conveyor belt by pressing the reverse key . This enables the operator to remove the packaging on the left-hand side of the device.

- If it is not possible to remove the packaging by pressing the reverse key, please consult your stockist or the MELAG customer service department.

WARNING!
Failure to observe this provision could result in damage to or malfunction of the sealing device.

- Do not attempt to remove the packaging from the device with violence.

Display of the daily batches

The daily batch counter is displayed in the upper corner of the display (#: 000). It counts the number of seals carried out 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.

Chapter 4 – Settings

Changing the language

To change the currently set language proceed as follows:

1. Activate 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.

Setting date and time

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

Date

To set the current date, proceed as follows:

1. Activate 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 “Date” menu.
4. Press  to change 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 re-adjust the selected parameters. The value will be saved as soon as it has been adjusted.
7. Press  to navigate out of the menu item Date.
8. Press  to leave the SETUP menu entirely.

Time

To set the current time, proceed as follows:

1. Select the SETUP menu.
2. Press the key  repeatedly to access the “Time” menu. The selection and value reset of the parameters Hour, Minutes and Seconds is conducted in a manner similar to the setting of the date.

Changing the sealing temperature

To alter the set sealing temperature proceed as follows:

1. Hold the two keys  and  depressed for approx. 2 seconds until two arrows ⬍ appear on the right edge of the display.
2. Holding one of the arrows depressed initiates the temperature display. The temperature ranges from 100 °C until 199 °C.
3. Release the key when the desired sealing temperature has been reached.

Temperature too high

If the device has been switched on for a while and had already reached the previously set temperature, the display will switch to **`Cooling`** if the newly-set sealing temperature is lower than that already set.

Temperature too low

If the device has been switched on for a while and had already reached the previously set temperature, the display will switch to **`Heating up`** if the newly-set sealing temperature is higher than that already set.

The sealing temperature set is saved, even after the sealing device has been switched off.

Setting the Signal tone

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. Hold the  key depressed for approx. 2 seconds until the display changes to Counter: xxx.
2. Depressing and holding one of the  and  keys starts the counter running. It runs to a maximum of 999.
3. Release the key when the desired number of packages to be sealed has been reached.

Signal tone power down

1. Press  to switch off the signal tone for counting the seals.
2. Press  to switch on the signal tone.

Resetting the daily batch counter

The daily batch counter counts the number of sealing procedures performed during a day. The daily batch counter is displayed in the upper corner of the display: # 000.

In order to perform an update, proceed as follows:

- Hold the  key depressed for a few seconds. The daily batch counter is then reset to #:000.

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

Chapter 5 – Logging

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

- Log printer MELAprint 42/44
- MELAflash CF-Card printer (from version 1.9)
- Documentation software MELAview (from version 2.2)/MELAtrace

Log printer as output medium

If you want to employ the log printer MELAprint 42/44 as the output medium, connect it to the sealing device as follows:

1. Connect the cables of the log printer to the printer connection (RS232 interface) on the back side of the sealing device.
2. Connect the power supply cable included in the scope of delivery of the log printer in accordance with the appropriate operating instructions.

The sealing device recognizes the log printer automatically.
The log printer issues a log row for every sealing procedure performed.

MELAflash CF-Card Printer as output medium

The MELAflash CF-Card printer serves for storage of logs on the MELAflash CF card. The readout of the logs from the CF card to the practice computer is carried out with the MELAflash 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-Printer (from software version 1.9) supports the recording of logs for the MELAseal Pro rotary sealer.

If you want to employ the MELAflash CF-Card printer as the output medium, connect it to the autoclave as follows:

1. Connect the cables of the log printer to the printer connection (RS232 interface) on the back side of the sealing device.
2. Connect the power supply cable included in the scope of delivery of the log printer in accordance with the appropriate operating instructions.

The sealing device recognizes the MELAflash CF-Card printer automatically. 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

To ensure 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

In order to be able to use a computer as an output medium, the computer must be connected via the series interface on the rear of the sealing device.
Please use the documentation software MELAview (from version 2.2)/MELAtrace to read out the logs. How to run and read out logs via the program MELAview/MELAtrace is outlined in the internal help function in the program.

The computer generates daily logs in the same manner as the MELAflash CF-Card printer; i.e. a daily log is entered in the computer following the first sealing procedure of the day. Here a log row is written for every further sealing procedure of the same day.

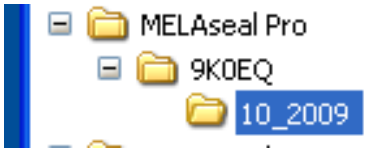
PLEASE NOTE
The daily log is continued even if the sealing device is switched on and off once; i.e. a new daily log is not started.

Opening and printing log files on the computer

The log files are simple text files and can be opened with the text editor of the computer.
A computer is initially not aware of the extensions of the log files. After assigning the file ending to the program you can open this file type with a double click.
Alternatively, you can open the log files with the program MELAview/MELAtrace.

Log folder structure

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



File name and ending

Position	1	2	3	4	5	6	7	8		X	X	X
Example	**9**	**K**	**0**	**E**	**Q**	**-**	**1**	**2**	**.**	**M**	**S**	**E**
Meaning	5-digit code					Day				Log file ending		
Explanation	Five-digit number including 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 Log file ending		

Reading logs correctly

The daily logs are saved in English.

The structure of the log for the MELAflash-CF-Card printer and the output on the computer via MELAview/MELAtrace have the following appearance:

Example of a log of multiple sealing procedures:

```
--------------------
MELAG MEDIZINTECHNIK
--------------------
10 MELAG MELAseal Pro
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 - Description of the sealing device

Row 25 - Date of sealing procedure (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 - Number of the total sealing procedures

Tmp - Sealing temperature (in °C)

Prs - Pressure with which the packaging was sealed

Vel - Speed of the conveyor belt in [dm/min.]

Limits - Parameter limits: Sealing temperature (185 °C until 175 °C), Sealing pressure (120 N until 90 N), Speed (120 dm/min. until 78 dm/min.)

CRC - Coded proof of authenticity

(PC) - Indication that the log was produced on the computer via MELAview/MELAtrace

Example of a log row for a successfully concluded sealing procedure

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

***Key** (The following parameters are displayed successively):*

Total number of batches; Serial number; Date (YY-MM-DD); Time; Seal temperature; Pressure; Speed; Limits | CRC-Code

Sealing procedure successful

A log includes all sealing 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 output via the MELAflash CF-Card printer or MELAview/MELAtrace through two exclamation marks “!!“ instead of the “OK“.
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 a “+“ if the respective value has been exceeded. If the value falls short of the settings, the space will be marked with a “–“.

WARNING

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

Chapter 6 – Optional Accessories

Work table “comfort“

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

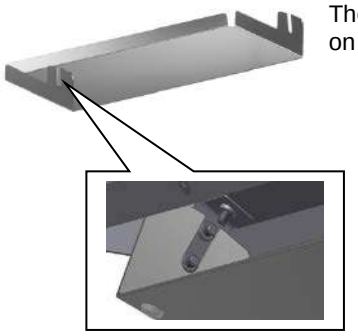
Work table “standard“

Work table “standard” is placed directly in front of the sealing device. The work table is a practical and inexpensive solution suitable for sealing light packaging.

Roll dispenser

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

Foot for roll dispenser



The foot for the roll dispenser MELAseal enables use of the roll dispenser on the work top. Setup is easy and quick.

Chapter 7 – Maintenance

Cleaning and regular controls

Period	Cleaning and control
after 6 months	The outside of the sealing device should be cleaned at least twice a year. Only use a lint-free damp cloth stainless steel-cleaning agent suitable for use with medical products. It should not deposit any oily residue.
After 1 year	Clean the fan on the base of the sealing device once a year in order to prevent it from becoming clogged with dust, in order to prevent insufficient cooling.

Maintenance

Regular maintenance is recommended to preserve its value and ensure reliable operation of the sealing device.

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

Chapter 8 – Malfunctions

WARNING

Incorrect opening can compromise electrical safety and pose a danger to the user.

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

PLEASE NOTE

If an error message is displayed during a sealing procedure, this must be cleared by pressing the  key. Normal operation can then be continued.

Incident	Possible cause	Remedy
No display on the screen fan is not functioning.	The sealing device is not switched on at the power switch. The power cable is not connected or is not connected with the mains socket.	Switch on the sealing device at the mains switch (see p.6 Fig. 1/(7)), check the connection of the power cable from the sealing device to the mains socket. On repeated occurrence, inform your MELAG customer services.
The required sealing temperature is not reached. The seal seam is burned.	The sealing temperature has not been set correctly.	Check the sealing temperatures set on the sealing device and if necessary, change the setting (see page 12). On repeated occurrence, inform your MELAG customer services.
The seal seam is not correct.	The sealing device is not capable of generating the sealing temperature recommended for the packaging.	Check the sealing temperatures set on the sealing device and if necessary, change the setting (see page 12). On repeated occurrence, inform your MELAG customer services.
Seal seam is irregular and contains defects.	The packaging material is not suitable for use with this sealing device. The pressure roll is soiled. The pressure roller is soiled.	Use packaging material suitable for this sealing device (see seal seam strength test). The pressure roller requires cleaning by the MELAG customer services.
The conveyor belt does not start.	The sealing device has not yet reached operating temperature.	Wait until the sealing device has reached operating temperature. On repeated occurrence, inform your MELAG customer services.
The display flashes.	The energy supply has been interrupted.	Please consult your MELAG customer services.

Incident	Possible cause	Remedy
Force high	The packaging material is too thick, has been folded or kinked.	Make sure that you use only suitable film. The film may not be creased, folded, or sealed under multiple layers.
	An instrument has blocked the sealing procedure.	Use sufficient film so that no instruments are able to enter the sealing device and block the sealing procedure.
	The pre-set maximum sealing force has been mal-adjusted.	On repeated occurrence, inform your MELAG customer services.
TEMP 1	The temperature does not increase fast enough after switching on the sealing device.	Switch off the sealing device and then on again. On repeated occurrence, inform your MELAG customer services.
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. If necessary, place the sealing device in an equally acclimatized, draught-free location.
Temp too low		If the malfunction message disappears after a few minutes, you can continue operation as usual. On repeated occurrence, inform your MELAG customer services.
Temp too high	The sealing temperature is too high for a short period.	If the malfunction message disappears after a few minutes, you can continue operation as usual. On repeated occurrence, inform your MELAG customer services.
Speed low	The device is blocked by packaging material or a badly positioned instrument	Check the sealing area for packaging or instruments. Working carefully, remove the blockage by hand or by pressing the reverse key.
	The drive was braked during the sealing procedure by e.g. over-heavy sealing objects (one or more instruments).	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.
Housing temperature too high	The housing fan is soiled.	Switch off the sealing device and clean the fan suction opening in the base plate. This should be cleaned on a monthly basis.
Display becomes dark	The housing fan is soiled.	Switch off the sealing device and clean the fan suction opening in the base plate. This should be cleaned on a monthly basis.
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.
Execute service		Please consult your MELAG customer services/stockist (routine maintenance of the sealing device).

Manufacturer's Recommendation for Routine Operation

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

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

MELAG seal seam strength test

For validating your sealing processes MELAG provides a seal seam stability test for a cost price of 125.00 € plus VAT (state 01/2017).

After the film test strips have been tested, MELAG will issue verification of testing and if successful, a certificate. This certificate confirms conformity of the seal seam with the standard DIN EN 868-5, Appendix D. Use the MELAG seal seam strength test application form from the MELAG homepage (Service/Downloadcenter/Recommendations).

DIN Specifications

Concepts

Sterile barrier system

DIN EN ISO 11607-2:2006 replaces the terms "packaging" "end packaging" and “primary packaging" with the single term "sterile barrier system".
A sterile barrier system is the minimum level of packaging facilitating successful sterilization, serving as a micro-biological barrier and permitting aseptic provision.

Protective packaging

The protective packaging is designed to provide the sterile barrier system with protection up until its final application.

Packaging system

The sterile barrier system and protective packaging combine to form the packaging system.

Peel test

A procedure to determine the peeling characteristics of paper/plastic composite material in accordance with DIN EN 868-5, Appendix E.

General information regarding the packaging and sealing procedure

Please observe the following during packaging and sealing:

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

Seal seam width

Maintain the seal seam width stipulated in the standard:

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

Clearance of the seal seam to the cutting edge

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

- The German standard DIN 58953, part 7 requires the maintenance of a sufficient overhang between the seal seam and the cutting edge when working with transparent bags on the removal edge. This ensures aseptic removal. We recommend a minimum overhang of 10 mm.

Strength of seal seam

When using MELAfol transparent sterilization packaging, the sealing device guarantees seal strength in accordance with EN 868-5.

Storage length for sterile medical products

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

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

This standard applies to all medical products delivered in a sterile state and which are to be handled in such a manner so as that their quality is maintained until coming to aseptic application.

According to DIN 58953-8 section 7.1.1, responsibility for compliance with the specified storage requirements and period is lies with the operator of the institution.

According to section 7.2, loss of sterility is dependent less on the length of the storage time as from external influences during storage, as well as transport and handling. An ideal storage time can thus not be generally specified. Table 2 only makes recommendations regarding the storage length of sterile medical products.

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

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

Table 2: Storage length for sterile medical products

Packaging type	**Storage period**	
Sterile barrier system	***Unprotected storage[1)]***	***Protected storage***
Paper bag in accordance with DIN EN 868-4 and heatable, self-sealing transparent bag and tubing of paper and plastic composite film in accordance with DIN EN 868-5, or other equivalent packaging.	Serves provision for immediate use[2)] Should be avoided as a method of storage.	6 months, not longer than the expiry date
Packaging system (a combination of a sterile barrier system and sterile packaging)	5 years, as far as the manufacturer has not determined an alternative expiry date.	

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

Accessories and Replacement Parts

	Article	Art. no.
Accessories	Work table “standard“	00119
	Work table “comfort“	00118
	Roll dispenser	00116
	Foot for the roll dispenser	71490
	MELAflash CF-Card printer	01039
	MELAflash CF card	01043
	MELAflash card reader	01048
	USB serial adapter	80270
Replacement parts	Separating plate with roll dispenser	71200
	Angle adapter for RS232 socket	80210
	Device fuses; 3,15 A T 5x20	74320

Technical Data

Model name	**MELAseal Pro**
Device dimensions (WxDxH)	46 x 29.5 x 15.5 cm
Weight	11.4 kg
Electrical connection	220 = 9 kW, 50 = 60 Hz
Power input	max. 365 W, average 180 W
Fuses	2 x 3.15 AT, 1 x 1.6 AT, 1 x 250 MAT (220 VAC/240 VAC)
Sealing temperature range	100 °C until 199 °C
Speed of sweep	± 8 m/min
Seal seam width	14 mm (grooved)
Sealing force	100 ± 10 % Newton

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We reserve the right to technical alterations

Your stockist:

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