MELAG
competence in hygiene

User Manual

Sterilisator 205

Dry-heat sterilizer

EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument reprocessing and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE

Contents

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	Description
	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	Description
see **Chapter 2**	Reference to another text section within this document.
	Reference to the glossary or another text section.
	Information for safe handling.

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

- As with the preceding instrument reprocessing, only competent personnel should undertake the sterilization of instruments, using this device.

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.
- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- Never damage or alter the power plug or cable.
- Never bend or twist the power cable.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Ensure that the power cable does not become jammed in.
- Never lead the cable along a source of heat.
- Never fix the power cable with sharp objects.
- The mains socket must be freely accessible after installation so that the device can be disconnected from the electrical mains at any time if necessary by pulling the mains plug.

Preparation and sterilization

- In the case of obvious or suspected damage/defects, the device may not be operated further. In such cases, the device has to be repaired.

Storage and transport

- Store and transport the device frost-free.
- Avoid strong shocks/vibrations.

Opening the housing

- Never open the device housing. Incorrect opening and repair can compromise electrical safety and pose a danger to the user. The device may only be opened by an ▸authorised technician who must be a ▸qualified electrician.

3 Description of the device

Scope of delivery

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

- Sterilisator 205
- User manual
- Declaration of conformity
- Warranty certificate
- Power cable
- Mount 1 or mount 2 (depending on the order)

Intended use

This hot air sterilizer is intended for use in the cosmetics sector, the cosmetic chiropody and the veterinary sector. It was designed for the sterilization of objects made of non-flammable (inorganic) materials with a minimum temperature resistance of 220 °C (e.g. metal, glass, porcelain, stone or enamel). Comply with the restricting information from the instrument manufacturer. Porous sterilization material is unsuitable for hot air sterilization.

Views of the device

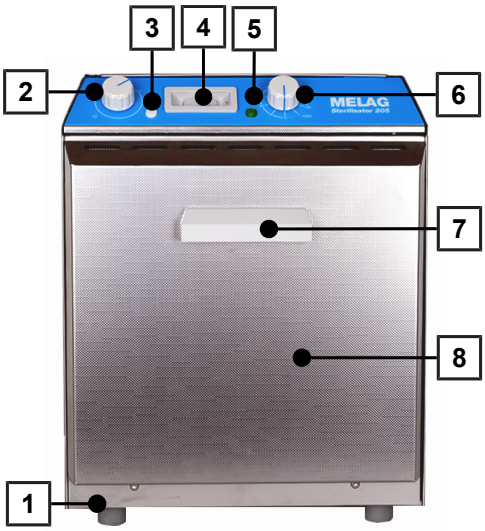


Fig. 1: Fore device view

1 Device foot
2 Temperature controller
3 Control lamp heater
4 Thermometer
5 Control lamp mains
6 On/Off switch and time setting
7 Door handle
8 Door (opens forwards)

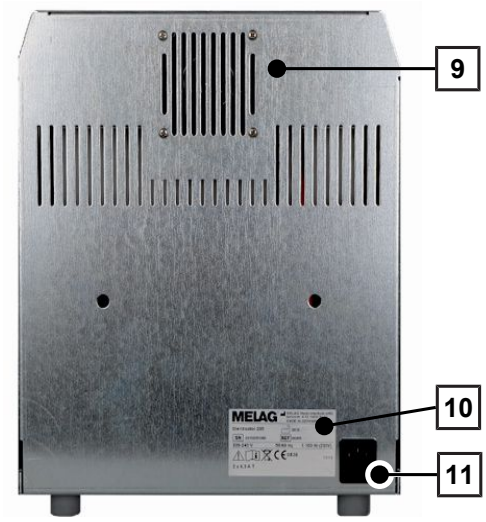


Fig. 2: Rear view of the device

9 Fans
10 Type plate
11 Connection for the power supply and the device fuse

Fig. 3: View of the interior

12 Mount
13 Sterilization chamber

Symbols on the device

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

Warning symbols

The marked area becomes hot during operation. Contact with it during or shortly after operation can pose the danger of burns.

4 Setup and installation

WARNING

Warning of short circuit, fire, water damage and electrical shock.

An incorrectly performed installation may result in a short-circuit, fire, water damage or an electric shock. This could result in serious injury.

- The device should only be setup, installed and commissioned by MELAG authorised persons.

Comply with the following for safe handling:

- After unpacking the product, check it for transport damage.
- The device is not suitable for operation in explosive atmospheres.

Requirements of the installation location

- Install the device with a minimum clearance of 10 cm to other devices and walls, especially flammable objects.
- Ensure sufficient ventilation. Ensure sufficient clearance to the top for free removal of the warm air. The device may not be used as an installation device and not be used in the immediate treatment area.
- The installation surface must be level and have a load-carrying capacity of at least the weight of the device.

Make sure that the ambient conditions meet the requirements, see Technical Data [▸ Page 19].

Tests after setup

Perform a temperature check after setting-up the device using thermo sensors or bio indicators. Place the test equipment in the area of the sterilization chamber in which the sterilization temperature is reached the most slowly. This also depends on the arrangement and nature of the sterilization material.

5 First steps

Switching the hot air sterilizer on and off again

The hot air sterilizer is activated via the time setting (On/Off switch) and switches itself off automatically after a pre-set time. The fan comes to a standstill after approx. 45 s.

PLEASE NOTE

Disconnect the power plug if the device is not to be operated for a long period of time.

Setting the operating time

- ▶ Set the On/Off switch to the required operating time (turn clockwise).
- ↪ The mains control lamp will remain illuminated; the control lamp for the heater will switch on and off until the time has elapsed.
- ↪ The hot air sterilizer can be set to continuous operation. In this case, the hot air sterilizer must be switched off manually.

Activating and deactivating continuous operation

- ▶ Switch the On/Off switch to the “I” position (turn anti-clockwise).
- ↪ The mains control lamp will remain illuminated; the control lamp for the heater will switch on and off. The set temperature will be kept constant by the heater switching on and off.
- ▶ Switch the On/Off switch to the “0” position to switch off continuous operation.
- ↪ The mains and heater control lamps will extinguish.

Opening and closing the door

CAUTION

Danger of burns from hot metal surfaces

- Allow the device to cool sufficiently before opening.
- Do not touch any hot metal parts.

PLEASE NOTE

The device must always be deactivated before it is opened.

Do not add any objects or open the door after the sterilization procedure has started; this could result in cooling and the objects not being sterilized for a sufficient time.

1. Move the On/Off switch to the “0” position to switch off.
2. Move the door forwards to open.
3. Move the door backwards to close.

Replacing the mount

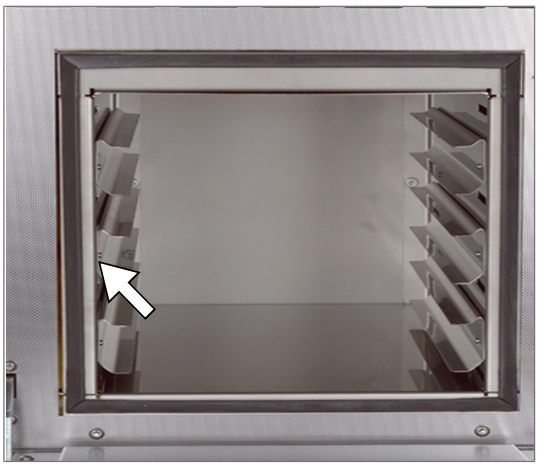
CAUTION

The mounts can have sharp edges.

- Wear suitable protective gloves.

The mounts are installed to the left and the right in the sterilization chamber and can be replaced as follows:

1. Slide the mount upwards from below and pull off to the side.
2. Set the mount with the screws into the larger aperture and press the mount downwards.



6 Sterilization

Preparing the load

Always clean and disinfect properly before sterilization. Only in this way is it possible to guarantee the subsequent sterilization of the ▸load. The materials used, cleaning agents and reprocessing procedure are of decisive significance.

Comply with the following for safe handling:

- Use only original MELAG accessories or those from other suppliers authorised for use by MELAG.

Reprocessing instruments

Unwrapped sterile material loses its sterility on contact with ambient air. If you intend to store your instruments sterilely, wrap them in suitable packaging before sterilization.

When ▸reprocessing used and brand-new instruments, comply with the following:

- Always observe both the instrument manufacturer's reprocessing instructions and the relevant standards, guidelines and directives (in Germany, for example, from ▸RKI, ▸DGSV and ▸DGUV Regulation 1).
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with demineralised or distilled water, and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- When using ultrasound devices and washer-disinfectors, comply with the manufacturer's reprocessing instructions.
- Remove any residual disinfection and cleaning fluids to avoid corrosion. Otherwise, this could result in increased maintenance requirements and a restriction of the device function.

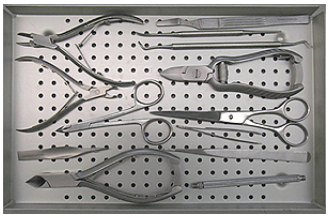
Loading the dry-heat sterilizer

Effective sterilization and successful drying is only possible if the hot air sterilizer is loaded correctly. Ensure the following during loading:

- Always pack the sterilization material in aluminium containers. Stainless steel is unsuitable due to its reduced heat conductivity. Do not use any textiles, paper or polyamide film as packaging. This packaging is unsuitable for high sterilization temperatures.
- Do not place the sterile material on material produced from cellulose; this material would produce excessive heat accumulation which would prevent the required heat equalisation in the sterilizer.
- Insert trays or standard tray cassettes in the sterilization chamber only with their appropriate mount.
- When loading, ensure that air can circulate around the instruments unhindered. Do not load the trays or standard tray cassettes one-sided and do not stack the sterilization material.

Example of a correct load

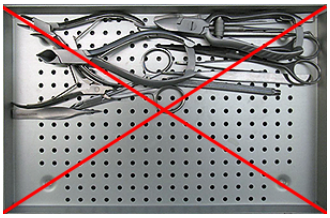
Tray



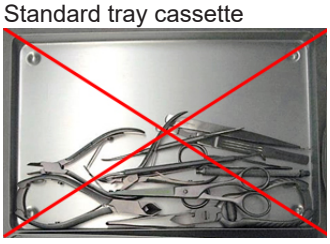
Standard tray cassette

Example of an incorrect load

Tray



Standard tray cassette



Loading variations

The hot air sterilizer is delivered with a mount for the acceptance of trays or standard tray cassettes. If one or two trays are ordered with the device, the scope of delivery will include a tray lifter.

The following loading versions are possible in devices with trays and standard tray cassettes of the following sizes:

- Tray (W x H x D): 19 x 2 x 36 cm
- Standard tray cassette (W x H x D): 19 x 4 x 29 cm

Mount 1

Mount 1 can hold up to six trays.

Mount 2

Mount 2 can hold three standard tray cassettes or three trays.

Both mounts are easy to replace. Comply with the instructions under Replacing the mount [▸ Page 11].

Information regarding routine operation

The sterilization temperature must amount to 180 °C before the start of every sterilization procedure. The ▸equilibration time must be taken into account when setting the sterilization time. The pure elimination time amounts to 30 min at 180 °C.

1. Wait 15 min after the thermometer has reached 180 °C.
2. Set the required sterilization time. Comply with the information in the sterilization times table.
3. Check whether the mechanical air movement is functioning correctly via the ventilator noise.

Setting the temperature

Set the temperature for the hot air sterilization as follows:

1. Turn the temperature controller to 180 °C.
2. Wait until the thermometer displays 180 °C and allow the device to heat up for 15 min.
   ➥ During this time, the hot air sterilizer heats up the complete sterilization chamber.
3. Set the sterilization time via the On/Off switch. Comply with the information in the sterilization times table.

Selecting the sterilization times

Do not exceed the specified loading quantities. Use only trays and cartridges made of aluminium. When needing to pack with foil, use aluminium foil.

Load quantity	Packaging	Pre-heating time	Operating time
max. 1 kg inc. 2 trays	unwrapped	15 min	60 min
max. 4 kg inc. 6 trays	unwrapped	15 min	75 min
max. 1 kg inc. 1 standard tray cassette	wrapped	15 min	75 min
max. 4 kg inc. 3 standard tray cassettes	wrapped	15 min	120 min

Removing the sterile material

CAUTION

Danger of burns from hot metal surfaces

- Allow the device to cool sufficiently before opening.
- Do not touch any hot metal parts.

WARNING

Warning of non-sterile instruments resulting from damaged or burst packaging.

Damaged or burst packaging endangers the health of your patients and practice team.

- Should the packaging be damaged or have burst after sterilization, wrap the load again and re-sterilize it.

Comply with the following when removing the sterile material:

- Use a tray lifter to remove the tray.
- Never touch the ▸sterile material, the device interior or the inside of the door with unprotected hands. The components are hot.

Storing sterile material

The maximum storage time is dependent on the packaging and the storage conditions. Please observe the regulatory requirements for the storage period of ▸sterile materials (in Germany e.g. ▸DIN 58953, Part 8 or the ▸DGSV guidelines) as well as the following listed criteria:

- Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterile material in an environment protected against moisture.
- Store the sterile material in an environment protected against excess temperature variations.

7 Function checks

Periodical checks

MELAG recommends an annual inspection using bio-indicators, thermocouples or maximum thermometers.

- Comply with the valid regional legal specifications.
- When performing the spore test using biological indicators, the spore packets are to be clamped under an instrument in order to prevent the package from being sucked into the fan motor.

8 Maintenance

Checks and cleaning

CAUTION

The mounts can have sharp edges.

- Wear suitable protective gloves.

NOTICE

Inappropriately performed cleaning can lead to the scratching of and damage to surfaces and the development of leaks in sealing faces. This also favours the development of soiling deposits and corrosion in the sterilization chamber.

Comply with all information regarding cleaning of the parts affected.

Check the sterilization chamber, including the door seal and the mounts for the load once a week for impurities, deposits or damage. If you find any impurities, remove the trays or standard tray cassettes and the mount from the sterilization chamber. Clean the soiled components. When cleaning the sterilization chamber, the mount for the load and the door seal, comply with the following:

- Switch off the device before cleaning and disconnect the power plug from the socket.
- Ensure that the sterilization chamber is not hot.
- Use a soft, non-fuzzing cloth.
- Use a chlorine and vinegar-free cleaning agent.
- Soak the cloth in cleaning alcohol or spirit and attempt to wipe away impurities.
- Only if the sterilization chamber or mount has persistent soiling, use a mild stainless steel cleaning agent with a pH value between 5 and 8.
- Use a neutral liquid cleaning agent to clean the door seal.
- Do not use any hard objects such as a metal saucepan cleaner or a steel brush.
- Check the door seal for damage on a daily basis. Replace the door seal if necessary.
- Check the contact pressure of the door. The entire surface of the door must be in contact with the frame.

9 Malfunctions

General events

Event	Possible cause	What you can do
The temperature display of the thermometer deviates from the set temperature by more than 8 °C.	The temperature controller has been set incorrectly.	Increase or reduce the temperature by turning the temperature controller: **Higher temperature:** turn anti-clockwise **Lower temperature:** turn clockwise
The device does not switch off. The “mains” and “heater” indicator lamp illuminate.	The timer is defective or is set to continuous operation.	Check whether the On/Off switch is set to “I” or “0”. If the timer is defective, inform an authorized customer services. The device can be operated provisionally on a semi-automatic basis by actuating the On/Off switch manually.
The temperature displayed deviates from the set temperature. The thermometer displays less than 180 °C or falls from 180 °C to approx. 150 °C within approx. 5 min and continues to fall. Under certain circumstances, there is no audible ventilator noise.	The temperature has been set too low. The temperature controller rotary knob was turned or set incorrectly when unpacking the device or because of incorrect handling e.g. during cleaning.	Set a higher temperature. The temperature controller must be readjusted by a service technician. Contact the authorized customer services / stockist technician. Provisionally, turn the temperature controller until the desired temperature is displayed on the device thermometer.
The device is too hot (more than 180 °C). The temperature fluctuates between 210 and 240 °C. The mains control lamp is illuminated. The heater control lamp is continuously off or on and off every 20 s.	The temperature controller has been set incorrectly or is defective.	Set the temperature controller to e.g. 180 °C and check whether this temperature has been reached / is displayed on the thermometer (note the heating and equilibration time). Should the values deviate, the temperature controller must be readjusted. Contact the authorized customer services / stockist technician. If the thermostat is defective, contact the authorized customer services / stockist technician. Provisionally, turn the temperature controller until the desired temperature is displayed on the device thermometer.

10 Technical Data

Device type	**Sterilisator 75**
Device dimensions (W x H x D)	31 x 38.5 x 47 cm
Weight	17 kg
Maximum load	5.5 kg including 6 trays
Sterilization chamber	
Dimensions (W x H x D)[1)]	19 x 20 x 36 cm
Volume	14 l
Electrical connection	
Power supply	220-240 V 50/60 Hz | 110 V 50/60 Hz
Maximum voltage range	207-253 V
Maximum mains voltage supply variations	± 10 %
Electrical power	1100 W
Device fuse	2 x 6.3 A T | 12.5 A T (110 V)
Ambient conditions	
Installation location	Interior of a building (dry and protected from dust)
Noise emission	49 dB(A)
Waste heat	1.3 MJ | 1.3 MJ (110 V)
Ambient temperature	5-40 °C
Degree of protection (in accordance with IEC 60529)	IP 20
Relative humidity	up to 31 °C max. 80 % | up to 40 °C max. 50 %
Protection category	I

[1)] with installed mounts

11 Accessories

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

Article	Art. no.
Mount 1	60030
Mount 2	60040
Tray	02000
Standard tray cassette	00287
Tray lifter	28890
Lifter for standard tray cassette	28895

Glossary

Ausgleichszeit
The equilibration time comprises the time required to to heat all the locations of the device and the load to the required temperature of 180 °C.

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

DGSV
DGSV is the abbreviation for “Deutsche Gesellschaft für Sterilgutversorgung” [German Society for Sterile Supply]. The training guidelines of the DGSV are listed in DIN 58946, Part 6 as requirements for personnel.

DGUV Regulation 1
DGUV is the abbreviation for “Deutsche Gesetzliche Unfallversicherung” [German Statutory Accident Insurance]. The regulation 1 governs the principles of prevention.

DIN 58953
Standard for “Sterilization – Sterile supply”

Load
The load includes products, equipment, or materials that are reprocessed together in one operating cycle.

Qualified electrician
The qualified electrician has the suitable technical training, knowledge, and experience to recognise and avoid hazards that can be caused by electricity, see IEC 60050 or for Germany VDE 0105-100.

Reprocessing
Reprocessing is a measure to prepare a new or used healthcare device for its intended purpose. Reprocessing includes cleaning, disinfection, sterilization and similar procedures.

RKI
RKI is the abbreviation for “Robert Koch-Institut” [Robert Koch Institute]. The Robert Koch Institute is the central institution for the detection, prevention, and control of diseases, especially infectious diseases.

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

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Original instructions

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

Your stockist

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