

Operating Manual

Sterilizer 75

The advanced dry-heat sterilizer with fan convection

Dear Doctor:

Thank you very much for the trust which you have shown by purchasing this dry-heat sterilizer.

For more than 50 years now, MELAG — a medium-sized family-owned and -operated business — has specialized in the production of sterilization equipment for medical practice. During this period, MELAG has succeeded in becoming a leading manufacturer of sterilization equipment. More than 345,000 MELAG units sold throughout the world testify to the exceptional quality of our sterilizers.

As all other MELAG products, this dry-heat sterilizer was manufactured and tested exclusively in Berlin, Germany, according to strict quality criteria. Before placing this unit into operation, please thoroughly read this Operating Manual. The long-term functional effectiveness and the preservation of the value of your dry-heat sterilizer will primarily depend on proper operation of the unit and on its proper care.

The staff and management of MELAG

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2 The difference between sterilization and disinfection

The term “sterilization” means the elimination of microbes from a liquid, or from a solid object, which are capable of reproduction. Sterilization further entails killing not only vegetative forms of such microorganisms, but also their permanent forms. Sterilization in dry heat requires a temperature of at least 180°C (DIN 58947). Effective sterilization means that spores in Effectiveness Ranges A, B, C, and D (as defined by the Robert Koch Institute), as

well as spores in Resistance Stage III (as defined by Professor Konrich), must be killed. Disinfection, on the other hand, means inactivation in Effectiveness Ranges A and B, but not in Effectiveness Ranges C and D (as defined by the Robert Koch Institute). It is only through sterilization that inactivation of particularly resistant bacterial spores (e.g., tetanus) is achieved.

3 What can be sterilized in dry heat?

Dry-heat sterilization is effective for objects made of incombustible (inorganic) materials such as metal, glass, porcelain, earthenware, and enamel: e.g., instruments, syringes, cannulae, etc. Only objects which can effectively withstand temperatures up to 220°C are suitable for dry-heat sterilization. Be sure to observe any restrictions which the manufacturers of such objects may stipulate. **Important:** Be sure to disinfect and then thoroughly clean all instruments, syringes, etc., immediately after they

are used. Place them into the sterilizer only after drying them. Do not place the objects to be sterilized on material produced from cellulose (e.g., paper, paper towels, staple fiber, bandage material, etc.); this material would produce excessive heat accumulation which would prevent the required heat equalization in the sterilizer.

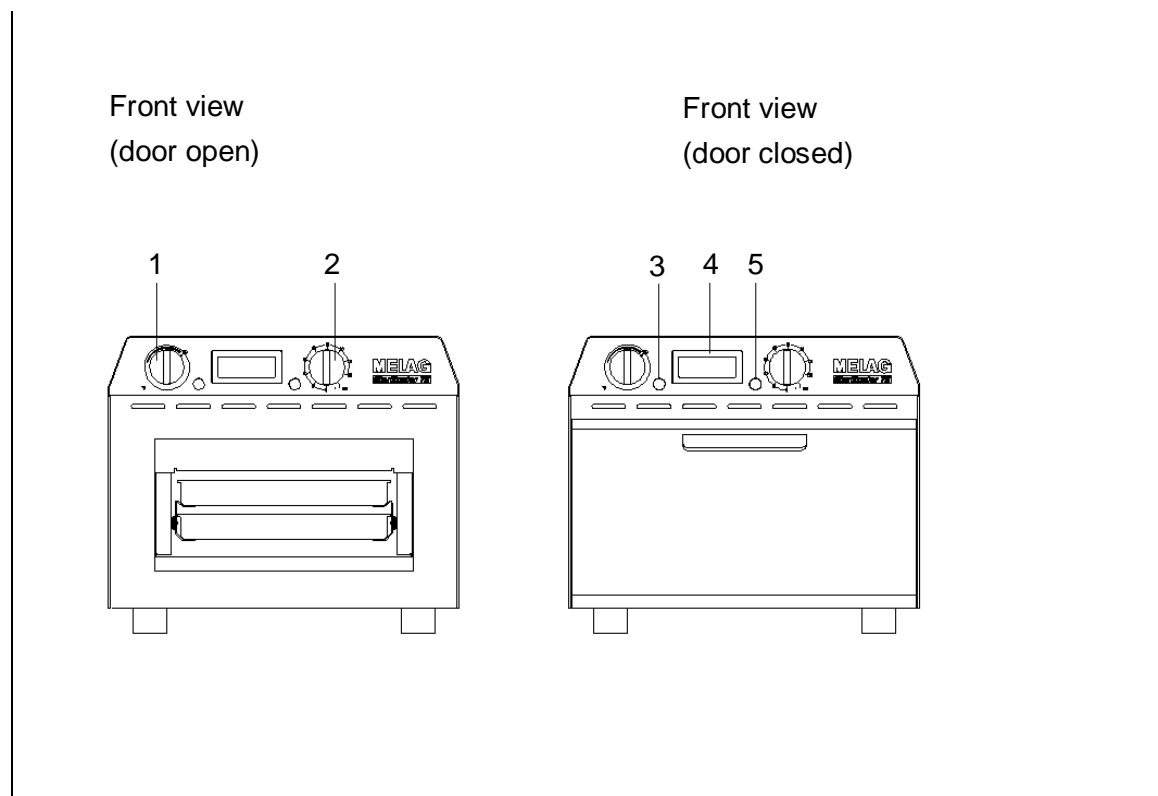
As a rule, porous objects are not suitable for dry-heat sterilization. Powder should be packed such that it is in layers not more than 0.5 cm thick.

4 Technical data

Power ratings	230 V / 50 Hz
Power consumption	650 W
Total mass (weight)	12 kg
External dimensions	31 cm wide × 26 cm high × 37.5 cm deep
Dimensions of the interior compartment.....	18 cm wide × 7.4 cm high × 29.5 cm deep
Maximum load	2 kg
Operating time (for unpacked objects)	60 min (up to a maximum of 500 g loading, including trays)
Operating time (for unpacked objects)	75 min (up to a maximum of 2 kg loading, including trays)
Operating time (packed in an aluminum cassette)	75 min (up to a maximum of 500 g loading, including aluminum cassette)
Operating time (packed in an aluminum cassette)	120 min (up to a maximum of 500 g loading, including aluminum cassette)

5 Device description

5.1 Illustration of the front of the device

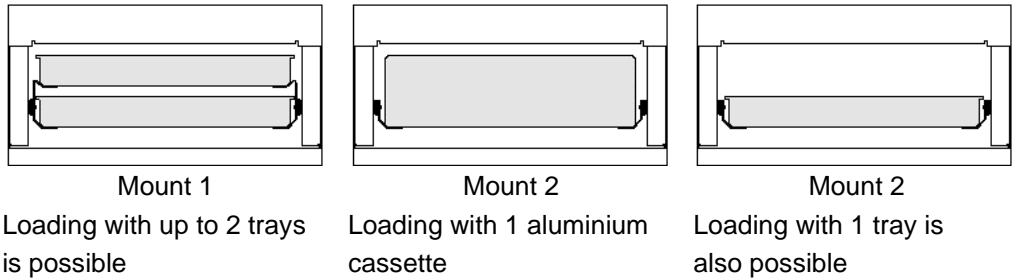


- | | |
|----------------------------------|----------------------------|
| 1 Temperature controller | 4 Thermometer |
| 2 Timer switch / OFF-ON switch | 5 Signal lamp for power ON |
| 3 Signal lamp for heating system | |

5.2 Different ways of loading the sterilizer

The standard, series-production version of *Sterilizer 75* includes “Mount 1” (article no. 59030) to hold 2 trays (article no. 02075 with dimensions 19 x 2 x 29 cm). The tray lifter is included with the sterilizer if 1 or 2 trays are also ordered with the *Sterilizer 75*. “Mount 2” (article no. 59040) is necessary to load

Sterilizer 75 with a closed aluminum cassette (article no. 00287 with dimensions 19 x 4 x 29 cm). It is simple to exchange these mounts in the sterilizer.



6 Operation of the sterilizer

6.1 Setting the temperature

Set the temperature controller (1) to the sterilization temperature of 180°C. If the value set on this controller differs from the value shown on the thermometer (4) by more than 8°C, then check to

see whether the controller knob has slipped: see the troubleshooting section below: “Instructions for correction of malfunctions”.

6.2 Setting the time

Set the time for *Sterilizer 75* by turning the timer switch (2) to the required operating time (see **Section 6.3** here).

continuous operation (until it is switched back off again).

For longer sterilization processes (or if the timer switch is defective), it is possible to use the OFF/ON switch to continuously operate the sterilizer for as long as required. In *Sterilizer 75*, this manual, continuous-operation switch is integrated into the timer switch. If you turn the timer knob counterclockwise (left) to “I”, the device is set for

The signal lamp (5) lights up when the power is on.

The signal lamp (3) lights up to show the automatic mode of the temperature controller. This controller maintains constant the set temperature by switching the heating system off and on. The signal lamp (3) goes off and on to show whether the heating is off or on.

6.3 Loading the sterilizer

Load the sterilizer in such a way that the hot air can circulate freely around all objects to be sterilized.

Do not place the objects close to each other in groups, since this will prevent the free compensation of heat.

Operating time	Type of loading	Loading
60 min	Unpacked	max. of 500 g, including trays
75 min	Unpacked	max. of 2 kg, including trays
75 min	Packed	max. of 500 g, including aluminum cassette
120 min	Packed	max. of 2 kg, including aluminum cassette

6.4 Switching off the power

The power is automatically switched off when the timer switch (2) runs out.

Continuous operation (with timer set to “I”) is interrupted by setting the timer knob back to “0”.

The two signal lamps (3 and 5) go out when the power is switched off.

6.5 VDE regulations

According to the currently valid VDE regulations, this sterilizer is not suited for operations in potentially explosive environments.

This sterilizer may be repaired only by its manufacturer or by a company expressly authorized by the manufacturer (by specialist dealers or customer service).

7 Preparation of instruments

Instruments must be especially prepared before they are sterilized. As set forth in the German Regulation for Prevention of Accidents (VBG 103), this preparation consists of the following steps:

- 1) Soaking the instruments in a disinfection solution;
- 2) Thorough cleaning of the instruments in distilled or demineralized water;
- 3) Drying the instruments.

8 Packing the objects to be sterilized

Sterilization containers made of aluminum must be used. Containers made of stainless steel are not so effective, owing to their poor heat conduction. Wrapping in disposable aluminum foil or packages is also possible: the instruments must be packed in

three layers of aluminum foil, each layer with a thickness of approx. $\geq 30 \mu\text{m}$. Textiles, paper, or polyamide sheeting are not suitable owing to the high temperature of sterilization.

9 Instructions for operation and maintenance

To ensure proper functioning, dry-heat sterilizers must be operated according to certain instructions. The instructions which must be followed here are contained in this Operating Manual. This Operating Manual must be considered as part of the sterilizer unit itself, and must be kept in a place such that it is easy to find and to read at all times by any person who may operate the unit.

Periodic testing in accordance with DIN 58 947, Part 6 (German standard for the operation for dry-heat

sterilizers) must be conducted every six (6) months with the aid of bio-indicators or thermoelements. Test reports must be filed and kept available for reference for at least one (1) year.

If the sterilizer is loaded, and if the sterilization cycle has begun, do not open the sterilizer and place additional objects inside. This would cause cooling-down, and the objects would not be sterilized for a sufficiently long period of time.

10 Those persons operating this sterilizer

Before any person is allowed to operate this sterilizer, he or she must be sufficiently familiar with this operating manual.

The owner and operator of this sterilizer is responsible to ensure that the operating staff is sufficiently well instructed in the operation of this unit.

11 Warning: danger of injuries!

- The power to this device must be switched off before opening the door. To turn off the power, turn the timer switch (5) back to the position "0". The power signal lamp (4) will then go off.
- **IMPORTANT:** Be sure that the personnel take the necessary care to avoid burning themselves when loading and unloading the *Sterilizer 205* when it is still hot (for example, the use of gloves and the like). The trays and the sterilized objects are very hot.
- The blower fanblades come to a stop approx. 45 seconds after the sterilizer has switched off. **Warning:** Some parts of the enclosure of the sterilizer are hot to the touch during and after the sterilization process.
- This appliance is not suitable for the sterilization of liquids and for the warming up of rinse solvents !

12 Cause of unsatisfactory results: operating mistakes

Dry-heat sterilization is a fully recognized sterilization process in accordance with (DIN 58947). This technique is, however, often the subject of criticism because bacteriological tests of

dry-heat sterilizers quite frequently reveal that test spores are growing.

Closer investigation reveals almost always, however, that staff operating mistakes are primarily the cause.

12.1 The most common operating mistake is too short operating time

Often, the operating staff will correctly assume that a temperature of 180°C must act on the instruments for a period of 30 min. A common mistake, however, is that the staff will observe only the thermometer display of the device. As soon as the thermometer shows 180°C, the mistake is made of calculating 30 min from this time onward, and of then switching the sterilizer off when the 30 min has run out. This procedure only takes the warm-up time into account, and not the equilibration time. This procedure is false, because the microbe killing time does not begin directly after the end of the warm-up time. The total time must take not only the warm-up time, but

also the following equilibration time into account. The equilibration time is the time which is necessary for all points inside the sterilizer, and all the objects to be sterilized, to reach the required temperature. The kill time begins only after the end of the equilibration time. The kill time is 30 min at 180°C. This time period contains a safety factor as set forth in DIN 58947, Part 5.

All these time sequences are included in the operating times given in this Operating Manual. It is necessary to operate this unit in accordance with the exact operating times given in Table 1 under Section 6.2 of this Manual.

13 Troubleshooting – correcting malfunctions

13.1 Repairs

Order spare parts only from an authorized specialist dealer. For quick and simple service, the dealer will need information on the sterilizer type and the plant

number. Repairs to this unit may be conducted only by specialist dealers or customer service authorized by MELAG.

13.2 Problem: the timer switch does not automatically switch off the power

If the timer switch is defective, it is possible to continue to operate the unit on a semi-automatic basis with the continuous-operation switch (2).

Warning: Before replacing the timer switch, do not fail to first unplug the power plug from the wall socket. First unscrew the screws of the housing and remove the housing. Remove the thermometer from the scale and take off the temperature controller knob and the timer knob. Pull off the adhesive printed scale (always order this adhesive scale, order no. 58980, when ordering a new timer). Pull

out the push-on sleeves of the cable ends from the flat-pin plugs located on the timer. Then unscrew the timer from the front of the scale. Connect the new timer and install it in the same manner, in reverse order.

A replacement timer can be ordered only from a specialist dealer. For quick and simple service, the dealer will need information on the sterilizer type and the plant number.

13.3 Problem: the temperature controller does not react

If you determine that the temperature controller (1) is defective (see a description of defects in Sections 13.4 and 13.5 below), then proceed as follows:

Important: It is very important to pull out the power plug before exchanging the temperature controller. Unscrew the screws of the device enclosure, and take off the enclosure. Pull off the cap of the temperature-controller knob. Loosen the nuts, then remove the knob from the axle of the temperature controller. Pull off the recessed punch holes in the scale film (to the right and left of the temperature-controller axis). The front of the scale is attached to

the front metal of the enclosure by spacer bolts (M3, with inside thread). If it is necessary to exchange the temperature controller, first remove the front of the scale. Then remove the push-on sleeve of the cable ends from the flat-pin connectors on the temperature controller, and remove the timer from the scale faceplate. Connect and attach the new temperature controller in the reverse order. Bond the recessed punch holes in the scale film back in their proper place, and attach the temperature-controller knob again.

13.4 Instructions on readjustments

After the temperature controller or the thermometer has been exchanged, the sterilizer must be readjusted. To do this, first place a comparison thermometer (for example, a calibrated thermometer to read seconds) into the sterilization compartment to check for the required 180°C. In case of exchanging the temperature controller, perform the further adjustment as described below in Section 13.5. If you exchange the thermometer, it will be

necessary to perform calibration as follows: There is a setting screw on the top side of the thermometer; around it is a ring. If the comparison thermometer in the sterilization chamber shows you the required 180°C (after approx. 30 min with a 1-kg load), and if the new, exchange thermometer shows 160°C (for example), then hold the ring tight with pointed pliers. Then turn the setting screw with a screwdriver until the reading shows 180 °C.

13.5 The temperature value set on the controller scale is not the same as the temperature shown by the thermometer in the sterilizer

MELAG dry-heat sterilizers are calibrated at the factory for 180°C by setting the controller axle such that the sterilizer thermometer will read 180°C when this temperature is set on the controller, and if the sterilizer heats up properly. Then the controller knob is inserted at the factory onto the controller axle so that the marking of the knob points to the 180°C marking on the controller scale. If strong pressure is unintentionally applied to the controller knob to turn it beyond its stop limit, then the knob on the controller axle can slip out of place. This can happen when the sterilizer is unpacked from its packing, or during cleaning. Or, the screw in the tapered fitting can become loose. If this happens, the temperature in the sterilization chamber (as read off on the thermometer) will not be the same as the temperature as set on the controller scale. It is easy and fast to correct this by turning the controller knob slightly in a clockwise direction, in order to point to a higher temperature – or in the anti-clockwise direction, to show a lower temperature. Then you

can make a mark on the scale on the necessary point. It is also possible in the same manner to determine a lower temperature and to mark it on the scale (for example, for drying processes). To make a full, correct new setting, proceed as follows: First pull the cap of the controller knob off, and unscrew the visible nut. Then pull the temperature-controller knob off the controller axle. Close the door of the sterilizer and switch on the sterilizer. Then set the temperature controller by using small pliers to turn the axle, and allow the a certain temperature to be reached on the device thermometer after the heating-up and equilibration time has run out: for example, 180°C. Now set the controller knob back on the axle so that the marking points to the value on the controller which the temperature has actually reached as shown by the thermometer (in this example, 180°C). Finally, place the knob on the controller axle and tighten the nut again (but do not change the position of the controller axle). Then press the cap of the controller knob back onto place.

13.6 Problem: the sterilizer does not heat up

If the *Sterilizer 75* does not function, first check the fuses in the unit. To replace the fuses, pull the power plug out of the wall socket and pull the other cable end out of the sterilizer socket. Press down the tab located on the fuse mount on the rear wall of

the sterilizer and pull the fuse mount out of the power socket on the sterilizer. Visually check the fuses to see if a fuse wire is broken. If so, replace the blown fuse.

Possible causes if the sterilizer does not heat up:	Signal lamp for power	Signal lamp for the heater
• Power cable, wall socket, or fuses are defective	OFF	OFF
• The temperature controller setting is too low • The temperature controller knob has slipped on the controller axis • The temperature controller is defective (does not close)	ON	OFF
• The overheating-protection system is defective; the sterilizer remains cold • The heating system is defective; the sterilizer remains cold	ON	ON

13.7 The sterilizer becomes too hot

Possible causes:	Signal lamp for power	Signal lamp for the heater
<ul style="list-style-type: none"> The temperature controller is defective; the display fluctuates between 210...240°C 	ON	Always ON
<ul style="list-style-type: none"> The temperature controller knob has slipped on the controller axis; the display is >180°C 	ON	ON/OFF (at intervals of 20 sec.)

13.8 The sterilizer does not reach the required temperature

Possible causes:	Signal lamp for power	Signal lamp for the heater
<ul style="list-style-type: none"> Temperature controller knob is out of adjustment; the display is < 180°C 	ON	ON/OFF (at intervals of 20 sec.)
<ul style="list-style-type: none"> The overheating protection system triggers too soon; the display is < 180°C with large fluctuations 	ON	ON/OFF (with long phase intervals)
<ul style="list-style-type: none"> The fan does not function; no fan noise from the start; the display goes up only to approx. 100°C 	ON	ON (1 min) OFF (2.30 min)
<ul style="list-style-type: none"> The fan stops during operation; there is no fan noise; the display falls from 180°C to approx. 150°C within approx. 5 min and continues to fall 	ON	ON (1 min) OFF (2.30 min)

13.9 The sterilizer does not switch off

Possible causes:	Signal lamp for power	Signal lamp for the heater
<ul style="list-style-type: none"> The timer is defective 	ON	ON
<ul style="list-style-type: none"> The sterilizer is on continuous operation 	ON	ON

14 Spare parts

Article no.	Designation of article	Article no.	Designation of article
59044	Door seal	59120	Heating system
43520	Temperature controller	59030	Mount 1
43635	Knob for temperature controller	59040	Mount 2
43660	Timer switch	02075	Tray
43655	Knob for timer switch	00287	Aluminum cassette
33470	Thermometer	58980	Adhesive printed scale
59140	Green signal lamp	59190	Sterilizer fuse
59150	White signal lamp	59110	Motor