

User 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 55 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 420,000 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 User 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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1 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. 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 (as defined by the Robert Koch Institute). It is only through sterilization that inactivation of particularly resistant bacterial spores (e.g., tetanus) is achieved.

2 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 dryheat sterilization. Powder should be packed such that it is in layers not more than 0.5 cm thick.

3 Technical data _____

Power ratings	230 V / 50 Hz
Power consumption	700 W
Protection category	1
Degree of protection	1
May acquetic power	IP 20
Max. acoustic power	56dB
Total mass (weight)	12 kg
External dimensions	31 cm wide \times 26 cm high \times 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)

The Sterilizer 75 is not designed for built-in installation. It is very important that all cooling and ventilation opening are kept open and not blocked. The minimum distance to walls and ceiling is 10 cm.

4 Device description

4.1 Illustration of the front of the device

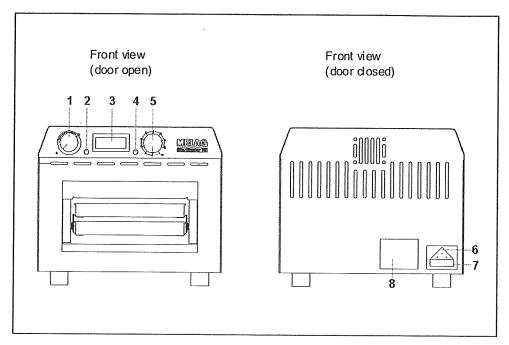


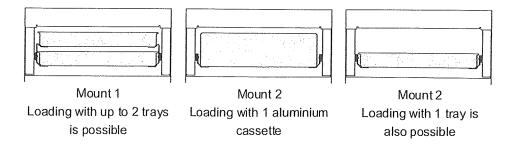
Fig. 1: Device views

- 1 Temperature controller
- 2 Signal lamp for heating system
- 3 Thermometer
- 4 Signal lamp for power ON
- 5 Timer switch / OFF-ON switch
- 6 Power supply socket
- 7 Mains fuse
- 8 Rating plate

4.2 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 $19 \times 4 \times 29 \text{ cm}$). It is simple to exchange these mounts in the sterilizer.





5 Pre-conditions and instructions for setting up and installing

5.1 Surrounding conditions

Room conditions:

Max. mains voltage supply variation:

Installation foundation:

Intervals:

Room temperatures between 5°C and 40°C relative humidity 31°C, max. 80%

40°C, max. 50%

+/- 10 % (207 V - 253 V)

Must be level and able to support the weight of the unit

Maintain at least 10 cm circumferential clearance to other devices and walls, especially flammable materials. Arrange so that warm air can be drawn off. Do not use as a fitted device.

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: "Troubleshooting – correcting malfunctions in section 12".

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).

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

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

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.

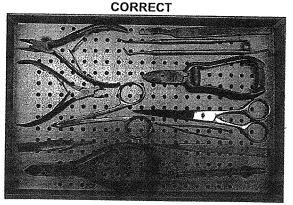
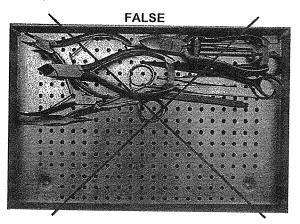


Fig. 1: Loading example on a tray



CORRECT

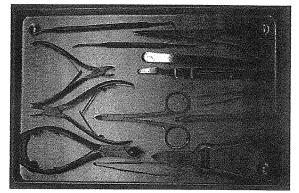
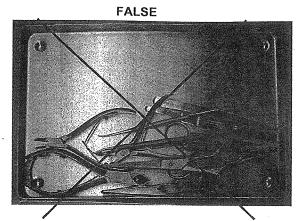


Fig. 2: Loading example in an aluminium cartridge



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	

Do not exceed the specified loading quantities.

Use only trays and cartridges made of metal. When needing to pack with foil, use aluminium cartridges.

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 (UVV/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. $\geq 30~\mu m$. 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 User Manual. This User 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 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 coolingdown, and the objects would not be sterilized for a sufficiently long period of time.

Check the following approx. 25 minutes before the end of sterilization:

- The device temperature display shows the preset temperature / at least 180°C.
- The two signal lamps (2 and 4, see Fig. 1 on page 3) illuminate.

Warning! During sterilization, it is necessary to ensure that the pre-set temperature is maintained (and a minimum of 180°C).

9.1 Testing the sterilizer after setting up

The operator has to do the testing with bioindicators after the setting up of the sterilizer. These are to be laid in the sterilization chamber so that they occupy the location sterilization chamber where the pre-set sterilization temperature is reached as slowly as possible. This also depends on the arrangement and nature of the equipment to be sterilized.

The biological indicators are obtainable from the responsible health authorities and / or hygiene laboratories.

9.2 Periodic testing of the sterilizer

Periodic testing in accordance must be conducted every six months with the aid of bio-indicators or thermoelements by the operator. est reports must be filed and kept available for reference for at least one year.

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.

9.3 Routine checks

During the sterilization process, check whether the sterilization temperature as displayed by the thermometer has reached a minimum of 180°C, and that the subsequent sterilization time has reached a minimum of 45 minutes. The sterilization temperature including the adjustment time amounts

to the remaining operating time / time remaining until the clock switches off.

Also check the ventilator noise: ensure that the mechanical air movement is functioning correctly.

9.4 Servicing

The door seal must be subject to constant control for leakage / should be changed where necessary. It is also necessary to check whether the door has sufficient contact pressure via the hinge, so that the entire surface is in contact with the frame. No further servicing measures are necessary.

Upon soiling, the hot air sterilizer should be wiped out with a soft, non-fuzzing cloth with a little alcohol. Remove all trays and the tray brackets from the chamber in order to do so.

With stubborn soiling, we recommend using a small amount of mild stainless-steel cleaning solution such as Sidol (pH 5-8). The cleaning materials should not include chlorine and may not be alkali. Do not use a metal saucepan cleaner or steel brushes.

The housing of the hot air sterilizer can be cleaned with a standard, mild fluid cleaner or spirit.

9.5 Those persons operating this sterilizer

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

10 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!
- The device should be unplugged when left idle for long periods.
- Disconnect the device from the mains before opening the housing.
- Set up the device so that the socket can be removed quickly from the mains in case of danger.
- In the case of obvious or suspected damage / defects, the device may not be operated further. In such a case, arrange for servicing by a service company.

11 Cause of unsatisfactory results: operating mistakes_

Dry-heat sterilization is a fully recognized sterilization process. 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.

11.1 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.

All these time sequences are included in the operating times given in this User 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.

12 Troubleshooting – correcting malfunctions _____

12.1 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.



12.2 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 ON/OFF switch (5). 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 timer knob. Remove the scale film perforations (right and left next to the clock 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 timer, first remove the front of the scale.

Pull out the push-on sleeves of the cable ends from the flat-pin plugs located on the timer, and remove the timer from the scale face plate. Connect and mount the replacement clock in the corresponding fashion. Now return the film and remount the clock button. Return the scale film back in their proper place. Attach the timer knob again.

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.

12.3 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.

12.4 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.

12.5 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.

12.6 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.

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

12.7 The sterilizer becomes too hot

Possible causes:		Signal lamp for power	Signal lamp for the heater
6	The temperature controller is defective; the display fluctuates between 210240°C	ON	Always ON
9	The temperature controller knob has slipped on the controller axis; the display is >180°C	ON	ON/OFF (at intervals of 20 sec.)

12.8 The sterilizer does not reach the required temperature

Possible causes:		Signal lamp for power	Signal lamp for the heater	
6	Temperature controller knob is out of adjustment; the display is < 180°C	ON	ON/OFF (at intervals of 20 sec.)	
•	The overheating protection system triggers too soon; the display is < 180°C with large fluctuations	ON	ON/OFF (with long phase intervals)	
9	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)	
6	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)	

12.9 The sterilizer does not switch off

Possible causes:		Signal lamp for power	Signal lamp for the heater	
•	The timer is defective	ON	ON	
0	The sterilizer is on continuous operation	ON	ON	



13 Electromagnetic compatibility _____

13.1 Electromagnetic environment

The sterilizer is designed for operation in an environment as described below. The customer or user must ensure that the sterilizer is operated in such an environment as here described.

The abbreviation HF is used for high frequency in the following tables.

Emitted interference measurements	Compliance	Electromagnetic environment guideline
Émissions of harmonics as per IEC 61000-3-2	class A	The sterilizer is suited for use in all facilities including those containing living areas and those which are directly connected to a public supply system which likewise serves
Emissions of harmonics as per IEC 61000-3-3	Complies	residential buildings.
HF emissions as per CISPR 14-1	Complies	Der Sterilisator ist nicht geeignet, mit anderen Geräten verbunden zu werden.

Table 1: Electromagnetic compatibility - Emitted interference measurements

Interference immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment guideline
Electrostatic discharge (ESD) as per IEC 61000-4-2	±6kV contact discharge ±8kV air discharge	Not applicable**	Not applicable**
Rapid transient electrical disturbances/ bursts as per IEC 61000-4-4	±2kV for mains cables ±1kV for input and output cables	Not applicable**	Not applicable**
Surges as per IEC 61000-4-5	±1kV push-pull voltage ±2kV common-mode voltage	Not applicable**	Not applicable**
Voltage drops, short- term interruptions and fluctuations of the supply voltage as per EC 61000-4-11	<5% UT* (5% sag of the UT) for ½ period <40% UT* (60% sag of the UT) for 5 periods <70% UT* (30% sag of the UT) for 25 periods <5% UT* (95% sag of the UT) for 5 s		Not applicable**
Magnetic fields with he supply frequency 50Hz) as per EC 61000-4-8	3 A/m	Not applicable**	Not applicable**

^{*} The sterilizer is not equipped with electronic controls which could be interrupted.

Table 2: Electromagnetic compatibility - Interference immunity tests 1

Interference immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment guideline"
conducted HF disturbances as per IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	Not applicable**	Not applicable**
radiated HF disturbances as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	-	
*The sterilizer is not	equipped with electronic con	trols which could be interrupted.	

Table 3: Electromagnetic compatibility - Interference immunity tests 2

13.2 Recommended protective distances

13.2.1 Between portable and mobile HF telecommunication devices and the sterilizer

The sterilizer is designed for operation in an electromagnetic environment in which the HF disturbances are monitored. The customer or the user of the sterilizer can thus help to avoid electromagnetic disturbances by complying with the minimum distance required between portable and mobile HF telecommunication devices (transmitters) and the sterilizer, depending on the power output of the communication device, as stated below.

For transmitters whose maximum nominal power is not specified in the following table, the recommended protective distance d in meters (m) can be determined by using the equation in the respective column, whereby P is the maximum nominal power of the transmitter in watt (W) according to the specifications of the transmitter manufacturer.

Nominal power of the transmitter	Protective distance depending on the transmitting frequency [m]			
[w]	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz MHz to 2.5 GHz	
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d=2,3\sqrt{P}$	
	d recommended protective distance in meters P maximum nominal power of the transmitter in watt according to information of the transmitter manufacturer			
0,01	Not applicable**	Not applicable**	Not applicable**	
0,1	Not applicable**	Not applicable**	Not applicable**	
0,1	Not applicable** Not applicable**	Not applicable**		
0,1 1 10	<u> </u>		Not applicable**	

Table 4: Electromagnetic compatibility -Protective distance depending on the transmitting frequency [m]



14 Spare parts _____

Article no.	Designation of article	Article no.	Designation of article
59044	Door seal	59140	Green signal lamp
32890	Temperature controller	59150	White signal lamp
13085	Knob for temperature controller	59120	Heating system
43660	Timer switch	59110	Motor
13095	Knob for timer switch	26960	Fan
33510	Thermometer	59190	Device fuse T 4 A
58980	Adhesive printed scale		

15 Accessories

Article no.	Designation of article	Article no.	Designation of article
59030	Mount 1	00287	Aluminum cassette
59040	Mount 2	28890	Tray handle
02075	Tray	28895	Tray-cassette handle

16 Symbols _____

With this symbol



the manufacturer declares that the medical device corresponds to the basic requirements of the medical product directive. Die vierstellige Nummer besagt, dass eine zugelassene Zertifizierungstelle dieses überwacht.



highlights the need to comply with the operating instructions.

This symbol



means Alternating current.

This symbol



means protection category I.

This symbol



means attention. Hot surface!