



User Manual

MELAquick[®] 12+ MELAquick[®] 12+ p

Steam sterilizer

from software version 5.20







Dear customer,

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

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

The MELAG management and team.

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Contents

1 General guidelines	5
Symbols used	5
Formatting rules	5
Disposal	5
2 Safety	6
3 Performance specifications	8
Intended use	8
Sterilization procedure	8
Type of the feed water supply	8
Safety equipment	
Performance characteristics of sterilization programs	9
Program sequences	
Program overview	10
4 Description of the device	12
Scope of delivery	12
Views of the device	12
Symbols on the device	14
Operating panel	15
Accessories	15
5 Installation requirements	17
Installation location	17
Mains connection	19
Water connection	19
Compressed air connection (only MELAquick 12+)	20
System and network safety	21
6 First steps	23
Setup and installation	23
Feed water supply	23
Connections required	23
Switching on the steam sterilizer	27
Opening and closing the door	28
Settings	29
7 Sterilization	31
Preparing the load	31
Loading the steam sterilizer	31
Selecting the program	33
Selecting automatic preheating	33
Selecting additional drying	34
Starting the program	34
Program in progress	35
Manual program abort	35
Program is ended	37
Removing the sterile material	37

MELAG

Storing sterile material	
8 Logging	
Batch documentation	
Output media	
Outputting logs immediately and automatically	
Subsequent log output	
Displaying the log memory	
Deleting logs in the internal log memory	
Reading logs correctly	
9 Function checks	47
Automatic functional checks	
Manual functional checks	
Batch-related checks	
Water quality of the feed water	
Pre-heating temperature of the sterilization chamber	
10 Maintenance	
Maintenance intervals	
Cleaning	
Avoiding staining	50
Replacing the door gasket	50
Maintenance	51
11 Pause times	52
Frequency of sterilization	
Operating pauses	
Decommissioning	
Transport	
Recommissioning after relocation	53
12 System malfunctions	
Notifications	
Warnings	55
Malfunction messages	58
13 Technical tables	
Nominal value tolerances	
Empty chamber test	
Pressure-time charts	
Feed water quality	
14 Technical data	67
15 Accessories and spare parts	
Glossary	
•	

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 <u>www.melag.com</u>.

Symbols used

Symbol	Explanation
\triangle	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
I	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Example	Explanation
Universal-	Words or phrases appearing on the display of the device are marked as display text.
Program	
\checkmark	Prerequisites for the following handling instruction.
	Refer to the glossary or another text section.
	Information for safe handling.

Disposal

MELAG devices are synonymous with high quality and a long life-span. When you eventually need to decommission your MELAG device, the required disposal of the device can take place with MELAG in Berlin. Simply contact your stockist.

Dispose of accessories and consumption media which you no longer require in the appropriate manner. Comply with all relevant disposal specification in terms of possibly contaminated waste.

The packaging protects the device against transport damage. The packaging materials have been selected for their environmentally-friendly disposability and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials.

Dispose of spare parts that are no longer used, e.g. seals, properly.

MELAG draws the operator's attention to the fact that they are responsible for deleting personal data on the device to be disposed of.

MELAG draws the operator's attention to the fact that they may be legally obliged (e.g. in Germany according to ElektroG) to remove used batteries and accumulators non-destructively before handing over the device, provided they are not enclosed in the device.

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 sterilization using this steam sterilizer.
- The operator must ensure that the users are regularly trained in the operation and safe handling of the device.

Carrying the steam sterilizer

Transport the steam sterilizer with the carrying straps included in the scope of delivery (fix them on to the side of the steam sterilizer using e.g. package tape).

Setup, installation and commissioning

- Check the device after unpacking for any damage suffered during transport.
- The device should only be setup, installed and commissioned by MELAG authorised persons.
- The connections for electrical provision and water supply and discharge must be setup by trained personnel.
- The device is not suitable for operation in explosive atmospheres.
- Install and operate the device in a frost-free environment.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
- The documentation media (computer, CF card reader etc.) must be placed in such a way that they cannot come into contact with liquids.

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.
- The power cable or plug should only be replaced by ▶authorised technicians.
- Never damage or alter the power plug or cable.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- 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.

Spring safety valve

The free movement of the valve rod must be guaranteed. For example, the spring safety valve must not be taped or blocked. Install the device in such a way that the proper functioning of the spring safety valve is guaranteed.

Reprocessing and sterilization

- Follow the manufacturer's instructions of your instruments regarding their reprocessing and sterilization.
- Comply with the relevant standards and directives applicable to the reprocessing and sterilization of instruments (in Germany e.g. from the >RKI and >DGSV).
- Only ever use packaging material and systems which have been cleared by their manufacturer for steam sterilization.
- Use only original MELAG accessories or those from other suppliers authorised for use by MELAG.

Program abort

- Please observe that depending on the time of the program abort, opening the door following a program abort can lead to hot steam leaving the sterilization chamber.
- Depending on the time of the program abort, it is possible that the load is unsterile. Observe the clear instructions shown on the display of the device. Sterilize the affected load after re-wrapping again.

Removing the sterile material

- Never use force to open the door.
- Use a basket handle to remove the universal basket and package holder. Never touch the sterile material, the sterilization chamber or the door with unprotected hands. The components are hot.
- After removal, place the universal basket and the package holder on a dry, disinfected surface or use the holder for universal basket or holder for insert baskets.
- Check the packaging on the sterile material for damage when removing it from the steam sterilizer. Should the packaging be damaged, re-pack the load and re-sterilize it.

Maintenance

- Maintenance should only be performed by >authorised technicians.
- Maintain the specified servicing intervals.
- Only original MELAG spare parts may be used.

Repair

■ 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.

Malfunctions

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.
- The device may only be serviced by >authorised technicians.

Notification requirement in the event of serious accidents in the European Economic Area

Please note that all serious accidents which occur in connection with the medical product (e.g. death or serious deterioration in the state of health of a patient) which were presumably caused by the product, must be reported to the manufacturer (MELAG) and the relevant authority of the member state, in which the user and/or patient resides.

3 Performance specifications

Intended use

The steam sterilizer is designed for use in a general medical environment in which the instruments used and their packaging do not require a type B steam sterilizer with cycles.

According to **EN 13060**, this steam sterilizer is a type S cycle sterilizer. As a universal steam sterilizer, it is suitable for sterilization of unwrapped/single-wrapped solid instruments, simple hollow items and dental transmission instruments¹.



WARNING

Any attempt to sterilize liquids can result in a **▶** delay in boiling. This can result in burns and damage to the device.

Never use this device to sterilize fluids. It is not licensed for the sterilization of fluids.



NOTICE

Failure to comply with these safety instructions can result in damage or can compromise safety.

- Only ever use the steam sterilizer for the applications as foreseen in the technical documentation and only in connection with the devices and components as recommended by MELAG.
- Like the preceding instrument reprocessing, the sterilization of instruments with this steam sterilizer (in Germany according to §2 ▶MPBetreibV) may only be carried out by ▶competent personnel.
- Only use instruments and packaging which are suitable for steam sterilization according to the manufacturer's information.

Sterilization procedure

The steam sterilizer sterilizes on the basis of the fractionated flow procedure.

This guarantees the complete and effective wetting/penetration of the **bload** with saturated steam.

The procedure can be used to safely and quickly sterilize single wrapped instruments.

The steam sterilizer uses integrated steam generation to generate sterilizing steam. The sterilization chamber is protected from overheating and you can sterilize instruments in a short time.

Automatic preheating

If preheating is activated, the cold chamber is heated up to the preheating temperature of the particular program before program start, or this temperature is held between two program runs. This reduces program times and the accretion of condensation, thus improving drying results.

Drying

The load is dried with the pulsating overpressure drying method. This way you achieve optimal drying results for wrapped instruments as well.

Type of the feed water supply

The steam sterilzer works with a feed water one-way system. This means that it uses fresh ▶feed water (▶demineralized or ▶distilled water) for every sterilization procedure. The quality of the feed water is subject to permanent monitoring via integrated ▶conductivity measurement. If combined with a proper preparation of the instruments, this serves largely to prevent stain accretion on the instruments and soiling of the steam sterilizer.

¹⁾ Further information is provided in the certificate of suitability (enclosed).

Safety equipment

Internal process monitoring

A **>**process evaluation system is integrated in the electronics of the steam sterilizer. It compares the process parameters (such as temperature, time and pressure) during a program run. It monitors the parameters in terms of their threshold values during control and regulation and guarantees safe and successful sterilization. A monitoring system checks the device components of the steam sterilizer for their functionality and interplay. If one or more parameters exceeds predetermined threshold values, the steam sterilizer issues warning or malfunction messages and if necessary, aborts the program. In the case of a program abort, follow the instructions on the display.

The steam sterilizer uses an electronic parameter control. This enables the steam sterilizer to optimise the total operating time of a program in dependence on the load.

Door mechanism

The steam sterilizer constantly checks pressure and temperature in the sterilization chamber and prevents the door from being opened when over-pressure has built up.

Quantity and quality of the feed water

The quantity and quality of the ▶feed water is automatically checked before every program start.

Performance characteristics of sterilization programs

The results in this table show which inspections were performed on the steam sterilizer. The marked fields demonstrate compliance with all the applicable sections of the standard ►EN 13060.

Type tests	Universal-Program S	Quick-Program S	Prion-Program S	
Program type in accordance with EN 13060	Туре S	Type S	Type S	
Dynamic pressure test of the sterilization chamber	Х	Х	Х	
Empty chamber test	Х	Х	Х	
Solid load	Х	Х	Х	
Simple hollow bodies	Х	Х	Х	
Dental transmission instruments ²⁾	Х	Х	Х	
Single wrapped	Х		Х	
Drying solid load	Х	Х	Х	
Sterilization temperature	134 °C	134 °C	134 °C	
Sterilization temperature range	+ 4 °C	+ 4 °C	+ 4 °C	
Sterilization pressure	2.1 bar	2.1 bar	2.1 bar	
Sterilization time	05:30 min	03:30 min	20:30 min	
X = Complies with all applicable sections of the standard EN 13060				

Program sequences

Regular sterilization program

After program start, you can follow the program run on the display. It shows the chamber temperature and pressure as well as the time until the end of sterilization and drying.

Program phase	Description
1. Air removal phase	The fractionated flow procedure removes the air from the sterilization chamber through pulsing repeated steam injection and removal. Depending on the program selected and the current chamber temperature upon program start, further fractionation can also follow.
2. Heating phase	The heating phase follows the air removal phase. The pressure and temperature increase until the program-specific sterilization parameters have been reached.

²⁾ Further information is provided in the certificate of suitability (enclosed).

Program phase	Description
3. Sterilization phase	The sterilization phase begins as soon as the pressure and temperature correspond to the program-dependent nominal values. The sterilization time is indicated on the display.
4. Pressure release	The end of the sterilization phase is followed by pressure release with simultaneous emptying.
5. Drying phase	The drying phase begins after the pressure release.

Program overview

Main menu



(§+) (§)

Press the 'S' and '+' keys simultaneously

'Start/Stop' key and program abort



SETUP menu: Function



1

4 Description of the device

Scope of delivery

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

Standard scope of delivery

- MELAquick 12+/MELAquick 12+ p
- User manual
- · Warranty certificate
- · Manufacturer's inspection report and declaration of conformity
- Record of installation and setup
- Basket handle
- Sieve tray
- Support plate
- · Feed water container with inlet hose and cable for water level monitoring
- · Wastewater container with outlet hose and cable for water level monitoring
- 2 spare device fuses
- 2 carrying straps

Only MELAquick 12+

- Compressed air hose, 5 m
- Coupling plug for compressed air
- Stopper set for deactivating the drying process

Views of the device

View from the front



- 1 Twist grip
- 2 Operating and display panel
- 3 Suction clip for drying air with insert (only MELAquick 12+ p)
- 4 Power switch

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View from rear



Top view



- 5 Device fuse
- 6 Cable connection for monitoring the water level in the feed water container
- 7 Cable connection for monitoring the water level in the wastewater container
- 8 Connection for wastewater container
- 9 Slot for emergency release
- 10 Spring safety valve
- 11 Connection for feed water container
- 12 Mains supply for IEC plug
- 13 Sterile filter and connection for compressed air (only MELAquick 12+)
- 14 Serial interface (RS232)

- 15 Wiping rubber (under sliding door)
- 16 Door gasket
- 17 Sieve tray

Symbols on the device

Type plate



Warning symbols



This symbol indicates that the marked area becomes hot during operation. Contact with it during or shortly after operation can pose the danger of burns.

Operating panel

The operating panel consists of a two-row alphanumerical LED display and four membrane keys.



- 1 Chamber pressure (bar) and (steam) temperature (°C)
- 2 Time (hh:min:ss)
- 3 **2-row LED display** for displaying the program status and parameters
- 4 **Start Stop key 'S'** for starting programs, aborting programs / drying and controlling the special functions
- 5 **Program selection key 'P'** for selecting the sterilization program / test program and selection / setting of the options (submenus) of the special functions
 - **Function keys '-' and '+'** for the selection, setting and display of special functions: print, date/time, preheating, total batches, conductivity, acknowledge malfunction, '+' key for unlocking the door

Initial state

6

The display switches to the initial state after every activation of the device. It displays the current time, chamber pressure in bar and the (steam) temperature in °C.

Accessories

The accessories are intended for use outside the patient area.

Universal basket with small part(s) insert

The universal basket is used for holding unwrapped instruments with a length of up to 20 cm.

The universal basket can be loaded with the small parts insert for holding endo instruments or dental drills.



Holder for insert baskets

The holder is placed on the work surface.

For cooling the instruments after sterilization, the universal basket or the holder with round mounts/ISO adapters can be placed on this holder.

Package holder for wrapped instruments

The package holder is used to hold up to 3 separately wrapped instruments (packaging according to ►EN 868-5).

The package holder can be removed from the chamber of the steam sterilizer with the basket handle by hooking it into the upper holes.

Holder for universal basket

The holder is hooked into the sideways venting slots of the steam sterilizer and is used to hold the universal basket while cooling down the instruments.

unwrapped handpieces or turbines.

Holder with 7 round mounts

Holder with 7 ISO adapters

Holder with ISO adapters for symmetrical support of up to 7 handpieces or turbines.

Holder with round mounts for conventional support of up to 7











5 Installation requirements

Installation location



WARNING

Failure to comply with the setup conditions can result in injuries and/or damage to the steam sterilizer.

- The steam sterilizer should only be setup, installed and commissioned by persons authorised by MELAG.
- The steam sterilizer is not suitable for operation in explosive atmospheres.
- The steam sterilizer is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

Property	MELAquick 12+/MELAquick 12+ p
Installation surface	level and horizontal
Installation location	interior of a building (dry and protected from dust)
Load-bearing capacity of installation surface	min. 25 kg plus 5 kg feed water container and 5 kg wastewater container
Floor loading (normal operation)	2.5 kN/m ²
Floor loading (hydraulic pressure test)	2.6 kN/m ²
Max. altitude	2000 m
Heat emission (with max. load)	approx. 0.48 kW (1.74 MJ/h)
Ambient temperature	5-40 °C (ideal range 16-26 °C) ³⁾
Relative humidity	max. 80 % at temperatures of up to 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)

Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.

Electromagnetic environments

When assessing the Electromagnetic Compatibility (EMC) of this device, the emitted interference threshold values for Class B devices and the stability for operation in an electromagnetic environment as described in IEC 61326-1 were taken as the basis. The device is thus suitable for operation in all institutions and domestic settings connected to a public mains power supply. The floor should be made of wood or concrete or be tiled with ceramic tiling. If the floor is fitted with synthetic material, the relative humidity must amount to a minimum of 30 %.

³⁾Only MELAquick 12+: The installation location must be selected so that the temperature in the area of the sterile filter an along the compressed air hose cannot exceed 40°C.



Space requirements

NOTICE

Failure to observe the space requirements can result the build-up of heat. This could adversely affect the function of the device and entail the shortening of the components' lifetime and result in extended program times.

Without fail, keep the specified distance free to the surrounding surfaces at the sides and above the device.

The distance to the surrounding surfaces must be at least 5 cm on both sides and 10 cm at the back side. The steam sterilizer should be freely accessible from above, so that you can load it and good ventilation is guaranteed.



Dimensions		MELAquick 12+	MELAquick 12+ p
Width	A	19.5 cm	20.5 cm
Height	В	43 cm	43 cm
Depth	С	47 cm	46 cm
Clearance between the device feet	D	29 cm	29 cm
Clearance from rear device foot up to the rear panel	E	9 cm	8 cm
Min. clearance to the side	F	5 cm	5 cm
Min. clearance to the rear	G	10 cm	10 cm
Min. clearance to the top	Н	22 cm	22 cm

Additional space requirements

In addition to the space required for the steam sterilizer, you need space for the feed water and wastewater containers.

Space requirement Water treatment unit	Width	Height	Depth	Diame- ter	Installation
MELAdem 40	32 cm	35 cm	15 cm		The attachment can be next to the steam sterilizer, above or below the steam sterilizer
MELAdem 47 module housing	39 cm	47 cm	15 cm		Attachment next to the steam sterilizer,
MELAdem 47 storage container		51 cm		24 cm	above or below the steam sterilizer (e.g. lower cabinet)

Mains connection



WARNING

Improper installation may lead to a short-circuit, fire, water damage or electrical shock.

This could result in serious injury.

Only have the device set up, installed and commissioned by people authorised by MELAG.

Comply with the following for safe handling:

- Never damage or alter the power plug or cable.
- Never bend or twist the power cable.
- Never remove the plug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Never run the power cable over areas in which it could become trapped (e.g. doors or windows).
- Never lead the cable along a source of heat.
- Never use any nails, paper fasteners or similar objects to fix the cable.
- Should the power plug or cable suffer damage, switch off the device. The power cable or plug should only be replaced by authorised technicians.

PLEASE NOTE

The IEC plug on the steam sterilizer or the mains socket must be freely accessible after installation so that the steam sterilizer can be taken from the electricity supply at any time.

On-site requirements

Property	MELAquick 12+	MELAquick 12+ p	
Power supply	220-240 V, 50/60 Hz*) 220-240 V, 50 Hz*)		
Building fuse	A separate circuit with 16 A Type B, RCD 30 mA (to guarantee continued practice operation during steam sterilizer malfunction)		
Other	additional socket for the MELAprint 42/44 log printer etc.		
Length of the power cable	2.5 m		
*) Max. voltage range 207-253 V			

Water connection

The steam sterilizer works in the gentle yet effective one-steam way water system. This means that the device uses fresh purified ▶feed water for every sterilization run for the steam generation.

On-site requirements

	Feed water	Wastewater
Connection in the practice	External feed water container	Emptying into the external wastewater
	to a water treatment unit, e.g. MELAdem 40/ 47	container
Installation height		Min. 30 cm under the steam sterilizer
Max. temperature	40 °C	approx. 100 °C (direct in wastewater container)
Recommended flow pressure	0.5 bar at 0.8 l/min (average at least 0.025 l/ min [= 1.5 l/h])	
Min. water pressure (static)	0.5 bar	
Max. water pressure (static)	10 bar	

	Feed water	Wastewater	
Max. consumption per program cycle ⁴⁾	approx. 280 ml		
Water quality	Distilled or ▶demineralised water in accordance with▶ EN 13060, Appendix C		
Measures for protecting the drinking water	none (internal precautions against back-flow i combination consisting of a back-flow prevent with ▶EN 1717)	ernal precautions against back-flow into the drinking water supply via safety ion consisting of a back-flow preventer and pipe aerator; secured in accordance 1717)	

Connection of a water treatment unit

	MELAdem 40	MELAdem 47
Permissible hydraulic pressure	1.5-10 bar	2-6 bar
Water stop	For insurance reasons, MELAG recommends the installation of a water stop with a cut-off valve (e.g. from MELAG), as the MELAdem 40 / MELAdem 47 are under constant hydrau pressure from the domestic water supply.	

Compressed air connection (only MELAquick 12+)

A compressed air connection is provided for MELAquick 12+.

The externally provided compressed air must meet the following conditions:

- Dried, free of condensate and filtered with a filter unit ≤ 2 µm
- Pressure range 3-8 bar (43.5-116 PSI)
- For hose lengths greater than 4 m the minimum pressure must be 4 bar (58 PSI)
- Standard volume flow 10 l/min; this is removed from the supply only during drying

For the connection of the compressed air hose, different manifolds and coupling plugs are available as optional accessories, see Accessories and spare parts [> page 68].



WARNING

If the steam sterilizer is operated without a compressed air supply, it is not conform to EN 13060 because of the missing drying function. The steam sterilizer no longer accords with the intended purpose outlined in the user manual.

If the device is to be operated without a compressed air supply, then have the stopper set included with the device to deactivate drying installed by an authorised customer services / stockist technician before commissioning.

NOTICE

According to EN ISO 7396-1, the steam sterilizer may not be connected to the supply network for medical compressed air, e.g. medical air technology.

⁴⁾ In the Universal-Program S with solid full load.

System and network safety

The device is fitted with multiple external interfaces. Comply with the following information pertaining to the use of these interfaces to ensure safe operation of the device, especially to ensure incorporation in the local network (LAN).

Interfaces and connections



١

Only connect the hardware to the device which is listed in the following table. Only use the software which has been intended for the purpose and approved by the manufacturer.

Interface	Туре	Hardware	Purpose/software
COM port	OM port RS-232 PC		MELAview saving log data and querying device data
			MELAtrace saving log data
		Modem	Data transfer via points of presence
		MELAnet Box	Provides a LAN (Ethernet) interface for the device, see below (Ethernet)
		MELAview/MELAtrace Saving log data	
			FTP server saving log data
		MELAprint 42/44	Log printing
		MELAflash CF-Card-Printer	Writing log data on a CF card

NOTICE

When performing a device software update, use only the update data authorized by MELAG for the corresponding device type.

Operating the device with memory media

To prevent data loss, only use memory media to save the log data with the following characteristics:

- Functional capability (without malware etc.)
- Writeable
- Formatted with a correct file system

Perform regular data backup. Restrict access to the device and systems with access authorization to the necessary circle of persons.

Only use CF cards.

Operating the device in the local network (LAN)

NOTICE

Do not connect the device to a public network (e.g. the internet).

An Ethernet/IP-based network connection (LAN) is required to operate the device in a local network. In its delivery state, the MELAnet Box IP address is 192.168.40.100.

NOTICE

Check the IP address carefully during the conversion for a manual configuration before connecting the device to the LAN.

An incorrectly-entered IP address can cause IP conflicts in the network and thus disturb another device in your network.

In the LAN with a firewall, only permit connections to and from the device which correspond to the intended use of the device. All ports not used are blocked on the device side.

Log	Source port	Destination port	Direction	Aims
TCP	≥ 1025	21	Outgoing	FTP control
TCP	any	≥ 1025	Listening / incoming	FTP (active) data transfer (MELAnet Box set to FTP logging)
TCP	any	80	Listening / incoming	Data transfer to the web browser
TCP	any	65001	Listening / incoming	Data transfer of log data (MELAnet Box set to TCP logging)

The device is able to make the following connections as standard via MELAnet Box:

Network bandwidth / Quality of Service (QoS)

The device does not place any requirements on the LAN bandwidth for data transfer, that exceed the standard time-out times of the respective logs.

Process	Volume max.	Volume normal
Transfer status, program, standby log	2 kB	1.9 kB
Graphic log	110 kB	110 kB

First steps 6

Setup and installation

Record of installation and setup

The responsible stockist is to complete the record of installation and setup as proof of the correct setup, installation and commissioning. A copy is to be sent to MELAG. This is a constituent part of any guarantee claim.

Feed water supply

Steam sterilization requires the use of Idistilled or Idemineralized water, known as Ifeed water. Annex C of IDI 13060 specifies the guideline values to be observed.

The feed water supply is effected either via the external feed water container or via a water treatment unit (e.g. MELAdem 40/MELAdem 47).

The external feed water container has a capacity of 5 l; depending on the program selected, it is sufficient for approx. 20 sterilization cycles. The maximum water requirement of a program run amounts to 280 ml.

A water treatment unit is connected to the domestic water supply. It produces the feed water which the steam sterilizer requires for steam generation. The use of a water treatment unit guarantees the availability of sufficient feed water. You no longer have to manually fill the feed water container.

Connections required

Connecting the feed container and wastewater container

Place the feed water container and wastewater container below the device, in the immediate vicinity and freely accessible.

The length of the inlet and outlet hoses and the cables is 1.5 m. The hoses can be cut to the desired length during installation. If required, hoses as well as cables for the water containers up to max. 5 m can also be ordered and used.



CAUTION Danger of scalding

Hot steam can escape at the rear or, when feed water is drawn in, air can enter the lines and impair the function of the steam sterilizer.

Insert both hoses into the couplings as far as they will go.



E PLEASE NOTE

Fit the outlet hose at a constant decline without kinks or sagging. In case of deviations to the installation arrangements, consult with MELAG.

Failure to do so can result in malfunctions of the device.

Feed water connection

- Insert the inlet hose (Ø 6 mm, pos. f) into the feed water connection at the rear of the device as far as it will go and secure the hose with the union nut.
- 2. To check the water level in the tank (pos. d), connect the cable (pos. e) to the back of the device.

Wastewater connection

- 3. Insert the outlet hose (Ø 8 mm, pos. a) into the waste water connection on the back of the device as far as it will go and fasten the hose with the union nut.
- 4. To query the water level in the tank (pos. c), connect the cable (pos. b) to the back of the device.
- 5. Fill in tap water (approx. 10 cm high) into the wastewater container in order to cool the condensate coil and add commercially available instrument disinfectant to prevent germ formation in the wastewater container. Use half of the amount recommended by the manufacturer in order to preserve the material of the condensate coil. This is required during initial commissioning and after every emptying of the wastewater container.



If the connections on the feed water and wastewater container for the fill level query are reversed, then the messages on the display for filling or emptying the containers are shown incorrectly.

Connecting the water treatment unit

If the steam sterilizer is to obtain the feed water fully automatically, connect a water treatment unit.

The following must be fulfilled or present:

- PTFE hose with an outer diameter of 6 mm.
- 1. Connect the steam sterilizer to the water treatment unit using a PTFE hose.
- 2. Or connect the steam sterilizer to an existing water treatment unit (if its capacity is sufficient) in parallel with another device via a T-piece.

Installation examples

MELAdem 40

The feed water is fed from the MELAdem 40 ion exchanger. The water is discharged into the wastewater container.



Position	Description	Art. no.	contained in
1	Mounting set EN 1717 for MELAdem	ME49600	
1.1	Safety combination EN 1717 incl. holder	ME82375	ME49600
1.2	Tap water supply hose EN 1717	ME24930	ME49600
2	Cold water adapter 3/4" to 1/4" (direct connection water hose)	ME09037	
3	MELAdem 40 ion exchanger	ME01049	
3.1	Hose PUR (black) 6/4 mm (inlet hose MELAdem 40)	ME28820	MELAdem 40
3.2	Hose PUR (black) 6/4 mm (inlet hose feed water)	ME28820	MELAdem 40
3.3	Filter for MELAdem	ME48240	MELAdem 40
4	Water tap (on site)		
5	MELAquick 12+/12+ p		
5.1	Wastewater container, complete	ME74215	MELAquick
5.1.1	Hose PTFE (8/6 mm, wastewater hose)	ME39180	
5.2	Connecting cable for water container (for water level monitoring)	ME21353	MELAquick
5.3	Connection of feed water		MELAquick
5.4	Wastewater connection		MELAquick
5.5	Connection for water level monitoring in the wastewater container		MELAquick

MELAdem 47

The feed water is fed from the MELAdem 47 reverse osmosis unit. The water is discharged into the wastewater container.



Position	Description	Art. no.	contained in
1	Safety combination EN 1717 incl. holder	ME82375	
2	MELAquick 12+/12+ p		
2.1	Connection for water level monitoring in the wastewater container		MELAquick
2.2	Connection to wastewater container		MELAquick
2.3	Connection of feed water		MELAquick
2.4	Wastewater container, complete	ME74215	MELAquick
2.4.1	Hose PTFE (8/6 mm, wastewater hose)	ME39180	MELAquick
2.5	Connecting cable for water container (for water level monitoring)	ME21353	MELAquick
3	MELAdem 47 reverse osmosis unit	ME01047	
3.1	Hose PUR (black) 6/4 mm (inlet hose feed water)	ME28820	MELAdem 47
3.2	T-piece for hoses	ME38600	MELAdem 47
3.3	Pressure tank MELAdem 47 (with shut-off valve and hose)	ME57065	MELAdem 47
3.4	Filter for MELAdem	ME48240	MELAdem 47
3.5	Water inflow hose	ME37220	MELAdem 47
3.6	Wastewater adapter (G1/4" internal thread)	ME56930	MELAdem 47
3.7	Double support sleeve for an existing trap	ME37400	MELAdem 47
3.8	Y-fitting for water supply with seal	ME37315	MELAdem 47
4	Double-chamber siphon (on site)	ME26635	
5	Wall outlet DN 40 (on site)		
6	Hose for water drain of steam sterilizers	ME36585	
7	Mains connection (on site)		
8	Vacuklav 40 B+ Evolution/Vacuklav 44 B+ Evolution	ME10080/ME10084	
8.1	Cooling water inlet fitting		Vacuklav

Position	Description	Art. no.	contained in
8.2	Cooling water outlet fitting		Vacuklav
8.3	Tap water supply hose EN 1717	ME24930	Vacuklav
9	Water stop (optional)	ME01056	
10	Water tap with safety combination (on site)		

Connecting compressed air (only MELAquick 12+)

NOTICE

- According to EN 13060, the steam sterilizer must not be operated without the sterile filter integrated in the compressed air hose.
- 1. Connect a free end of the compressed air hose (Ø 6 mm) to the quick coupling piece of the sterile filter pre-fitted to the device.
- Connect the other end to the on-site compressed air supply. A coupling connector (NW 7.2) is included in the scope 2. of delivery of the device.

Do not remove the sterile filter pre-fitted to the device.

WARNING

If the steam sterilizer reports the occurrence of event 42 "Drying – pressure pump" or a program is aborted without the compressed air supply having been completed at this point, the program is viewed as not having been completed successfully.

- In such a case, the Universal-Program S must be performed five times without a load (alternatively, three times with activated additional drying). Drying must not be aborted. Only then is the steam sterilizer ready for operation.
- The steam sterilizer can only be operated correctly with permanently connected compressed air supply.
- Before every program start, ensure that the compressed air supply shut-off valve is open.

Switching on the steam sterilizer

The following must be fulfilled or present:

- The feed water container is connected and filled with fresh feed water of appropriate quality. Alternatively, a water treatment unit is connected.
- The wastewater container is connected.
- The compressed air line is connected and any on-site shut-off valve is open.
- \checkmark The steam sterilizer power supply is switched on.
- Switch on the steam sterilizer at the power switch.
 - The display switches between the initial state and the message Unlock door with '+' key, as long as the door is closed.

After switching the steam sterilizer on, it requires approx. 15 min to reach operational readiness, if the Autom. preheating option is activated.



EF PLEASE NOTE

For hose lengths over 1.5 m, event 14 may occur several times during initial commissioning.

Acknowledge this message until it is no longer displayed. In case of insufficiently filled containers or an unconnected water treatment unit, a signal tone sounds and a respective message is shown on the Display.

Opening and closing the door

Opening the door

After the end of a program, the request Acknow. with '+' key is displayed.

- 1. Unlock the door with the '+' key.
 - The door unlocks audibly.

PLEASE NOTE

The door can only be opened when the twist grip is fully turned by 90°.

If it was unintentionally attempted to open the door while the door was still locked, the twist grip must first be turned back until the groove is perpendicular to the longitudinal axis. Only then the door can be opened again using the '+' key. Otherwise the locking mechanism jams.

2. Turn the twist grip 90° counter-clockwise to open the door. A small resistance can be felt just before the stop.



3. Push the door all the way back.

If an output medium is connected and Log output YES is set, there is also a log output.

Close the door

NOTICE

Never push the door down while pulling it closed.

The door seal may fold down or be damaged.

The result may be a leaking sterilization chamber as well as a subsequent malfunction message.

- 1. Pull the door forward by the twist grip as far as it will go.
- To close the door, turn the twist grip 90° clockwise. In correctly locked condition, the groove in the twist grip must be perpendicular to the longitudinal axis as shown.



Manual door emergency-opening



WARNING

The steam sterilizer must be completely pressure free.

Failure to observe this provision can result in scalding/injury.

- No steam may be permitted to leave from between the sterile filter and the rear panel of the steam sterilizer.
- It is imperative that you allow the steam sterilizer to cool. Metal parts such as the door and sterilization chamber can be hot.

If the door cannot be opened, e.g. due to a power failure, proceed as described in the following, observing the safety information provided above.

The following must be fulfilled or present:

- The device is completely pressure-free.
- 1. Switch off the steam sterilizer at the mains and remove the plug from the socket.
- Insert a flat rounded object into the sideways slots of the steam sterilizer and push the object down.
- Hold the object down and unlock the door at the same time by turning the twist grip counter-clockwise by 90° and opening the door towards the back.



Settings

Setting the date and time

Correct batch documentation requires the correct date and time setting on the steam sterilizer. Ensure that you take into account any clock change, as this is not adjusted automatically. Set the date and time as follows:

- Select the menu Function by pressing the '+' and '-' keys simultaneously.
 - The display will show the message Function: Last batch number.
- 2. Navigate with the '+' or '-' key in the Function menu until the display shows Function: Date / Time

				٦		
Function:						
Date / Time						
		Programm	Start-Stop			
\bigcirc	(+)	\bigcirc	\bigcirc			

- 3. Press the 'P' key to confirm.
 - The current hour is displayed.
- Choose one of the following setting possibilities using the '+' or '-' key: Hour, minute, second, day, month, year.
- 5. To e.g. adjust the hours parameter, press the 'P' key to confirm.
 - The current value flashes on the display.

- 6. You can increase or reduce the value using the '+' and '-' keys.
- 7. Confirm with the 'P' key in order to save the value.
 - The current value set no longer flashes on the display.
- 8. Proceed in a similar fashion to alter the other parameters.
- 9. After completing the settings, press the 'S' key to leave the menu.
 - The display will show Function: Date / Time.
- **10.** Repeated pressing of the 'S' key enables you to leave the menu and the display returns to its initial state.

Setting the water treatment unit

In the delivery state, Feed water supply is set to internal. If the feed water is supplied from a water treatment unit, option Feed water supply must be set in menu Function.

- 1. Select the menu Function by pressing the '+' and '-' keys simultaneously.
 - The display shows Function: Last batch number.
- Navigate using the '+' or '-' keys until the display shows Function: Feed water supply.

	Fur Feed wat	nction: ter supply	
\odot	+	Programm	Start-Stop

- 3. Press the 'P' key.
 - The currently set option appears on the display, e.g. Feed water supply internal.
- To set the value to Feed water supply external, press the 'P' key again.
- In order to save the setting and to leave the menu, press the 'S' key.
- 6. Repeated pressing of the 'S' key enables you to leave the menu entirely and return to the display initial state.

7 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 *bload*. The materials used, cleaning agents and reprocessing procedure are of decisive significance.

NOTICE

Only ever operate the steam sterilizer with a sterile filter inserted.

Comply with the following for safe handling:

- Observe both the instrument manufacturer's instructions regarding ▶reprocessing and sterilization as well as the relevant standards and directives (in Germany, for example, ▶DGUV Regulation 1, ▶RKI and ▶DGSV).
- Clean, disinfect and dry the instruments before each sterilization, e.g. using a washer-disinfector.
- Follow the cleaning and care instructions of the manufacturer. Only in this way is it possible to guarantee correct cleaning and disinfection and subsequent sterilization.
- If possible, rinse the instruments with >demineralised or >distilled water at the end of cleaning and disinfection and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- Use only those care agents suitable for steam sterilization. Consult the manufacturer of the care agents. Do not use any water repellent agents or oils impermeable to steam.
- When using the following devices, observe the reprocessing instructions of the instrument manufacturer: Ultrasonic devices, care devices for straight and contra-angle handpieces as well as washer-disinfectors.
- Unwrapped >sterile material looses its sterility upon contact with the ambient air. If you plan to store the instruments in a sterile fashion, wrap them in a suitable packaging before sterilization.

NOTICE

The presence of residual disinfection and cleaning fluids results in corrosion.

This could result in increased maintenance requirements and a restriction of the steam sterilizer function.

Loading the steam sterilizer

Effective sterilization and good drying is only possible if the steam sterilizer has been loaded correctly.

Danger of burns from hot surfaces

Failure to observe these requirements can result in burns.

- Use a basket handle to load the device.
- Only touch the chamber or the door with protected hands. The elements may be hot.

Unwrapped instruments

Comply with the following for safe handling:

- Always use the universal basket for unwrapped instruments, see Accessories [> page 15]. This can hold approx. 12 handpieces, turbines or other instruments up to a length of max. 20 cm.
- Unless the manufacturer specified otherwise, you should place handpieces in the steam sterilizer with their shaft (the drive side) pointing upwards.

- For sterilization of very small *loads*, e.g. in the endodontic field (e.g. Hedström files, reamers, K-files), use the semicircular small parts insert. Hang the small parts insert either higher or lower in the universal basket.
- When using the holder with ISO adapters and the holder with round mounts, up to 7 unwrapped straight and contraangle handpieces or turbines can be sterilized.

Packaging

Only ever use packaging materials and systems (*sterile barrier systems*) which fulfil the standard *EN 868-5*. The correct use of suitable packaging is important in achieving successful sterilization results.

You can employ soft packaging such as transparent sterilization packaging, paper bags, sterilization paper or fleece.

Soft sterilization packaging

WARNING

Failure to observe this can result in unsterile instruments and thus endanger the health of patient and the practice team.

Please comply with the following when using soft sterilization packaging e.g. MELAfol 1002:

- Always sterilize soft sterilization packages using the package holder.
- Wrap only one instrument in each sterilization package.
- Arrange soft sterilization packaging standing vertically in the package holder to ensure that the paper side of the outer packaging points to the outside.
- Clamp the sterilization packaging on both sides into the slots of the package holder. Use appropriately wide sterilization packaging (a width of 10 cm is recommended).
- Unless the manufacturer has specified otherwise, the handpieces should be placed in the steam sterilizer with their shaft (the drive side) pointing upwards.
- Sterilization packaging may not be jammed between the door gasket and sliding door. If necessary, fold over the top of the packaging (film side up).
- If the seal seam tears during sterilization, the sterilization packaging may be too small or too full. Re-wrap the instruments and perform sterilization again. The sterilization packaging should be filled to ³/₄ or the spacing for the sealing seam should be 3 cm.
- If the seal seam tears open during sterilization, extend the sealing impulse of the package sealing device or seal the sterilization packaging with a double seam.
- If there is more damage to the sterilization packaging in the Prion-Program S, reinforce the industrial seams of the sterilization packaging by resealing them before sterilization.

Multiple wrapping

The steam sterilizer uses a fractionated flow procedure. The use of I multiple wrapping is not possible.

Mixed loads

Mixed loads may not be sterilized.

Selecting the program

Select by rotating between the initial state and the desired program with the program selection key 'P'.

Select the sterilization program according to whether and how the bload is packed. Also note the temperature resistance of the load.

The following table shows which program is to be selected for which load.

Sterilization programs

	Universal-Program S	Quick-Program S	Prion-Program S		
Sterilization temperature	134 °C	134 °C	134 °C		
Sterilization pressure	2.1 bar	2.1 bar	2.1 bar		
Sterilization time	05:30 min	03:30 min	20:30 min		
Operating time*)	13-15 min	6-8 min	28-30 min		
Drying	8-9 min	approx. 1 min	8-9 min		
*) without drying and depending on load and set-up conditions (e.g. mains voltage, air pressure, feed water supply); can take up to 2 min longer with a cold start					

Use of the respective sterilization programs

Program	Packaging	Especially suitable for	Load
Universal-Program S	single wrapping	Solid instruments, simple hollow bodies, dental transmission instruments*)	1 kg unwrapped/ 270 g wrapped
Quick-Program S	unwrapped only	Simple solid instruments, simple hollow bodies, dental transmission instruments*)	1 kg unwrapped
Prion-Program S	single wrapping	Instruments under suspicion of carrying the danger of infection through abnormally altered proteins (e.g. Creutzfeldt–Jakob, BSE) dental transmission instruments* ⁾	1 kg unwrapped/ 270 g wrapped
*) Europhan information is			

*' Further information is provided in the certificate of suitability (enclosed).

Selecting automatic preheating

Automatic preheating is activated in delivery state.

If preheating is activated, the cold chamber is heated up to the preheating temperature of the particular program before program start, or this temperature is held between two program runs. This reduces program times and the accretion of condensation, thus improving drying results.



PLEASE NOTE

The steam sterilizer must remain continually activated for the automatic preheating. MELAG recommends activating the automatic preheating function.

To alter this setting proceed as follows:

- 1. Select the Function menu by pressing the '+' and '-' keys simultaneously until the display shows Function: Last batch number.
- 2. Navigate using the '+' or '-' keys until the display shows Function: Autom. preheating.



- 3. Press the 'P' key to confirm.
 - The display will show the option currently set e.g. Preheating YES.
- 4. Pressing the 'P' key again makes the display switch to Preheating NO.
 - The preheating function has been deactivated.
- 5. Press the 'S' key twice to leave Function: Autom. preheating and return to the initial state.

Selecting additional drying

The Additional drying function extends the drying time by 50 % to perform difficult drying tasks.

Press the 'S' and '+' keys simultaneously upon starting the program.

Additional drying selected			
\overline{ullet}	+	Programm	Start-Stop

The display shows Additional drying selected The program run then begins.

Starting the program

After selecting a program with the program selection key 'P', in addition to the selected program, the sterilization temperature is displayed and whether the respective program is suitable for a wrapped or unwrapped >load.

Press the 'S' key to start the program. 1.

	Universal	-Program	s
	134°C	wrapped	
		Programm	Start-Stop
\bigcirc	(+)	\bigcirc	\bigcirc

The steam sterilizer checks the >feed water supply and the ▶conductivity.

PLEASE NOTE

When the Quick-Program S is started, the warning message Attention: Unwrapped instruments only is displayed.

2. If the load contains exclusively unwrapped instruments, press the 'S' key again to confirm and to start the program.

Program in progress

After starting the program, you can follow the program run (see Program sequences [) page 9]) on the display. It shows the temperature and pressure of the sterilization chamber as well as the time until the end of sterilization / the drying time which has passed.

Sterilization phase

The display shows whether the sterilization phase has already been completed successfully.

The remaining time of the sterilization phase is displayed in alternation with pressure and temperature specifications.

Sterilization still 2 min, 12 s				
0	+	Programm	Start-Stop	

The sterilization phase is unsuccessful if the user or the system (responding to an malfunction) aborts the program run. A system abort returns the sterilization chamber to a pressureless state.

If the user aborts, a warning appears. If the program is aborted by the system, a malfunction message will be displayed.

Drying phase

The regular drying time is approx. 1 min for the Quick-Program S and approx. 8-9 min for all other programs.

The steam sterilizer provides excellent drying of the bload. If difficultto-dry items require better drying, you can improve drying as follows:

- Always use the package holder for wrapped instruments. 1.
- 2. Activate Additional drying, see Selecting additional drying [> page 34].



Manual program abort

You can abort a current program in all phases. If you abort the program before drying begins, the load remains unsterile.



WARNING

Hot steam can be released from the device when opening the door after a program abort.

This could result in scalding.

- Use a basket handle to remove the universal basket and package holder.
- Never touch the sterile material, the sterilization chamber or the inside of the door with unprotected hands.



PLEASE NOTE

Never abort a program by switching off at the mains.

Non-compliance with this point will result in the display of a malfunction message as soon as the device is reactivated, indicating a power outage.

Order here! PRAXISDIENST



Program abort before the start of drying

\triangle

WARNING

Danger of infection from early program abort

Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and practice team.

- Re-pack the load if necessary.
- Repeat the sterilization of the load.

Proceed as follows to abort the program before drying:

- 1. Press the 'S' key.
- 2. Confirm the following security query **Stop program**? by pressing the 'S' key repeatedly.

	-
- 1	1-

PLEASE NOTE

The security query will be displayed for approx. 5 s. If the 'S' key is not pressed again, the program will continue with the usual program run.

Depending on the time of the abort, pressure will be released or the device will be ventilated. A corresponding display text appears on the display.

After pressure release or ventilation, you will be asked to acknowledge the program abort.

The display will alternate between Stop / End and Acknowledge with '-' key.

- Press the '-' key.
 - The display will alternate between Unlock door with '+' key and the program previously selected.
- 4. You can open the door after pressing the '+' key.
- 5. If the door does not open within 40 s, press the '+' key again.
- The log will contain: Program stopped / Load not sterile!

Program abort after the start of drying

You can abort the program during the drying phase via the 'S' key without the steam sterilizer registering a malfunction.

Should you abort a program after drying has started, the sterilization is having been completed successfully. The steam sterilizer will not issue a malfunction message. You should expect insufficient drying, especially in the case of wrapped >sterile material and a full load. Sterile storage requires sufficient drying. To ensure this, allow programs with wrapped sterile material to continue to the end of the drying phase as far as possible. Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

In the drying phase, the expired drying time is shown in alternation with the message Immediate removal press 'Stop'.

Immediate removal			
$\overline{\bigcirc}$	(+)	Programm	Start-Stop

Proceed as follows to abort the program during drying:

1. Press the 'S' key.

PLEASE NOTE

The security query will be displayed for approx. 5 s. If the 'S' key is not pressed repeatedly, the program will continue with the usual program run.
- 2. Confirm the following security query Immediate removal 'Stop' by pressing the 'S' key again.
 - The display confirms the abort with Drying stopped.

At the end of the program, the message Universal-Program S run successfully alternates with Last batch number XX and Acknow. with '+' key.

Last batch number 7				
Acknow. with '+' key			,	
		Programm	Start-Stop	
igodol	(+)	\bigcirc	\bigcirc	

If a printer or other output medium is connected to the steam sterilizer, and Immediate output is set to YES, the notification Drying stopped is recorded on the log.

Program is ended

Once the program has come to an end, the chamber pressure is adapted to the ambient pressure.

When the program has ended successfully, the corresponding message will be issued on the display.

	Univers run su	al-Program ccessfully	S
\bigcirc		Programm	Start-Stop
\bigcirc	(+)	\bigcirc	\bigcirc

If immediate output is activated, the log of the completed program is issued to the selected output medium, see Logging [> page 39].

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.

CAUTION

Unsterile instruments resulting from damaged or burst packaging. This 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.

If you remove the >sterile material from the device directly after the end of the program, it is possible that the instruments can be partially damp. According to the Arbeitskreis für Instrumentenaufbereitung (MAKI), single drops of water (no puddles) that dry off within 15 min are considered tolerable residual moisture in practice.



PLEASE NOTE

In the warm sterilization chamber, the residual moisture dries especially quickly. Leave the wrapped instruments in the open steam sterilizer for up to three minutes to dry.

Comply with the following specifications when removing the sterile material:

- Never use force to open the door. This could damage the device or result in the emission of hot steam.
- Use a basket handle to remove the universal basket.
- Never touch the sterile material, the sterilization chamber, package holder, the holders or the inside of the door with bare hands. The components are hot.
- Check the packaging of the sterile material for damage when removing it from the device. Should the packaging be damaged, re-pack the load and re-sterilize it.

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:

- Comply with the maximum storage duration in accordance with the packaging type. Comply with the manufacturer's information on the packaging.
- Do not store the sterile material in the reprocessing room.
- Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterile material in an environment protected against moisture.
- Store the sterile material in an environment protected against excess temperature variations.

8 Logging

Batch documentation

The batch documentation serves as proof of the successful conclusion of the program and represents an obligatory part of quality assurance. The device internal log memory saves such data as the program type, **batch** and process parameters of all the programs completed.

To obtain the batch documentation, you can output the internal log memory and transfer its data to various output media. This can be performed immediately at the end of every program or at a later point, such as at the end of the day.

Capacity of the internal log memory

The capacity of the internal log memory is sufficient for 40 logs. If the internal log memory is full, the oldest log will be overwritten automatically at the beginning of the next program.

If a printer is connected and the option Immediate output has been set to NO, a security query will be issued before the saved log is overwritten. For further information about connecting the printer, consult the user manual of the respective device.

Displaying the daily batch counter

The last batch number of the day is shown on the display after every program run.

You can arrange for the batch number to be displayed.

- Select the menu Function by pressing the '+' and '-' keys simultaneously.
 - The display will show the message Function: Last batch number.
- 2. Press the 'P' key to display the current batch number of the day.
- 3. To return to the initial state, press the 'S' key twice.

Displaying the total batch counter

You can display the counter reading of all the batches that have been run so far.

 Select the menu Function by pressing the '+' and '-' keys simultaneously.

The display will show the message Function: Last batch number.

- 2. Navigate with the '+' or '-' key until the corresponding display appears.
- 3. Press the 'P' key to display the current total batch counter.
- 4. To return to the initial state, press the 'S' key twice.

Total batches 367			
0	+	Programm	Start-Stop

Last batch number

6

(-`

(+)

Programm

Start-Stop

Output media

You are able to output and archive the logs of the completed programs on the following output media:

- MELAflash CF-Card-Printer on the ▶CF card
- Computer, e.g. with MELAtrace/MELAview software (optionally with MELAnet Box)
- MELAprint 42/44 log printer

In its delivery state, an option for log output is not set on the steam sterilizer.



PLEASE NOTE

Further information about the log printer (e.g. the duration of the readability of the log printouts) is specified in the appendant user manual.

Using a computer as an output medium (without a network connection)

In order to be able to use a computer as an output medium, the computer must be connected to the steam sterilizer via the serial interface.

You can connect the steam sterilizer to a computer if the following conditions are fulfilled:

- The computer is either fitted with a serial interface or a USB serial adapter is connected. \checkmark
- \checkmark The documentation software MELAview/MELAtrace is installed on the computer.

PLEASE NOTE

The MELAnet Box is required for integration in the (practice) network.

Connect the steam sterilizer to the RS232 interface to the computer with a fitting data connection cable.

Reading out logs on the computer

You can use the MELAtrace/MELAview software to read out the logs.

To register the computer with the steam sterilizer, you must make the following setting once on the steam sterilizer:

- 1. Switch on the steam sterilizer.
- 2. Wait until the display shows the initial state.
- 3. Select the menu Function by pressing the '+' and '-' keys simultaneously.
 - The display will show the message Function: Last batch number.
- Navigate with the '+' or '-' key in the Function menu until the 4. display shows Function: Log output.



5. Press the 'P' key to select the submenu Log output: Output medium



6. Press the 'P' key again.

If an output medium has yet to be chosen, the display will show the Log output - No output medium notification.

 Navigate using the '+' or '-' key until the display shows Output medium Computer.

	Output medium				
	Computer				
		Programm	Start-Stop		
\bigcirc	(+)	\bigcirc	\bigcirc		

8. Press the 'P' key to confirm.

The display switches back to the submenu Log output: Output medium.

- 9. Press the 'S' key to return to the menu Function: Log output.
- **10.** After repeated pressing of the 'S' key, the display returns to its initial state.

Opening text logs on the computer

All text logs can be opened and printed using a text editor, a word processing program or a spreadsheet program.

PLEASE NOTE

Graphic logs can only be displayed with the MELAtrace/MELAview (from MELAview 3) documentation software.

Each text log (e.g. .PRO, .STR, .STB etc.) must be linked with the text editor to enable the operating system of your computer to open them automatically with a text editor. The meanings of the endings are outlined in the section Subsequent log output [▶ page 43]. The following examples show how you can link the Windows 10 editor with a specific text log.

- 1. In Windows Explorer double click on the log file.
- 2. If the file ending is unfamiliar, Windows 10 will display the following message:

Windows can't c (.MTK)	open this type of file
Try an app on this PC	*
	OK

3. Select "Try an app on this PC".

4. Mark the editor and confirm with "OK".



You can then open files with this ending via a double-click in Windows Editor.

Alternatively, you can open all text logs with the documentation software MELAtrace/MELAview (from MELAview 3).

Outputting logs immediately and automatically

Text logs

If you want to output the associated text log automatically after the end of a program on an output medium, use the function Immediate output YES. This is not set in the delivery state.

The following requirements must be fulfilled in order to issue logs immediately after the end of a program:

- In the menu Function: Log output, immediate output is set to YES.
- ✓ At least one output medium must be selected (computer, log printer MELAprint 42/44).
- The activated output medium must be connected and initialised.
- 1. Switch on the steam sterilizer at the power switch.
- Select the menu Function by pressing the '+' and '-' keys simultaneously. The display shows the message Function: Last batch number.
- Navigate using the '+' or '-' key until the display shows: Function: Log output and press the 'P' key.
- 4. Navigate using the '+' or '-' key until the display shows:

Immediate output YES			
\overline{ullet}	+	Programm	Start-Stop

- Press the 'P' key to change between Immediate output NO / YES.
- 6. Press the 'S' key to save the setting and to leave the menu. The display will show Function: Log output.

MELAG

7. Pressing the 'S' key once again enables you to leave the menu and return to the display initial state.



If immediate output is unable to issue a log, for example, because the output medium activated is not connected, a warning will appear. MELAG recommends using the immediate log output function.

Graphic logs

For log output immediately after program end, comply with the following:

- In Function: Log output, MELAnet+graphic data must be selected as the output medium.
- The computer or another medium must be connected and initialised.

Subsequent log output

It is possible to issue logs subsequently and independently of the time of a program end. You can choose whether selected or all saved logs (up to 40) are to be output. Use the output medium connected for this task e.g. the log printer.

Printing selected logs

To print the subsequently selected logs of a particular program proceed as follows:

- 1. Select the menu Function by pressing the '+' and '-' keys simultaneously. The display will show the message Function: Last batch number.
- 2. Navigate using the '+' or '-' key until the display shows: Function: Log output and press the 'P' key. The Log output - Output medium menu will be displayed.
- 3. Navigate using the '+' or '-' key until the display shows: Last cycle output: no. 40 (as example no. 40).
- 4. Press the 'P' key. The current log number flashes.
- 5. To output a log or another cycle, navigate to the desired number using the '+' or '-' keys until you have reached the desired number, e.g. 25.
- 6. Press the 'P' key in order to start the output of the selected program. The display will show the message Output.

After a successful output, the display changes back to its previous setting with the display indication.

Repeat the last three steps in order to output further logs.



- 7. Press the 'S' key to leave the submenu without outputting the log.
- 8. Press the 'S' key to leave the menu after outputting the log. The display will show the message Function: Log output.
- 9. Repeated pressing of the 'S' key enables you to leave the menu entirely and return to the display initial state.

Outputting all saved logs

Proceed as follows to output all the saved logs subsequently:

- Select the menu Function by pressing the '+' and '-' keys simultaneously. The display will show the message Function: Last batch number.
- Navigate using the '+' or '-' key until the display shows Function: Log output and press the 'P' key.

Navigate using the '+' or '-' key until the display shows: 3.



- 4. Press the 'P' key in order to start the output of the selected program. During the output the message Output will be displayed.
 - If output has been performed, the display will show: Output stored cycles.
- 5. Press the 'S' key to leave the submenu without outputting the log.



EF PLEASE NOTE

An abort during log output on the log printer is only possible through deactivation of the device using the power switch or by interrupting the power supply to the printer.

When switching off the device via the power switch, wait 3 s before switching it back on.

- 6. Press the 'S' key to leave the menu. The display will show the message Function: Log output.
- 7. Repeated pressing of the 'S' key enables you to leave the menu entirely and return to the display initial state.

Displaying the log memory

If a printer or other output medium is connected and initialised, you can check how many logs have already been saved in the steam sterilizer log memory.

Proceed as follows:

- 1. Select the menu Function by pressing the '+' and '-' keys simultaneously. The display will show the message Function: Last batch number.
- 2. Navigate using the '+' or '-' key until the display shows Function: Log output and press the 'P' key.
- 3. Navigate using the '+' or '-' key until the display shows the number of logs saved.

	Allocated: 40		
	Free:	0	
\bigcirc	+	Programm	Start-Stop

4. Press the 'S' key twice to leave the menu.

Deleting logs in the internal log memory

Delete the saved logs manually to suppress warnings, e.g. Log memory full, while the option Immediate output is set to NO. The following example shows how to delete all the logs saved.

- Select the menu Function by pressing the '+' and '-' keys simultaneously. The display will show the message Function: Last batch number.
- Navigate using the '+' or '-' key until the display shows Function: Log output and press the 'P' key.
- 3. Navigate using the '+' or '-' key until the display shows:



- 4. Press the 'P' key to delete all logs.
- 5. To cancel the sub-menu without deleting, press the 'S' key.
- 6. Press the 'P' key to leave the menu after deletion. The display will show the message Function: Log output.
- 7. Repeated pressing of the 'S' key enables you to leave the menu entirely and return to the display initial state.

Reading logs correctly

Log type	File ending	Explanation
Text log	.PRO	Log of a completed program
Malfunction log	.STR	Log of an unsuccessfully finished program
Graphic log	.GPD	Program run displayed as a graphic curve
Standby log	.STB	Log for malfunctions in idle mode
Demo log	.DEM	Log of a simulated program run. No real sterilization will be performed!
Demo graphic log	.DEG	Simulated program run displayed as a graphic curve. No real sterilization will be performed!

Log header

The header of the program log comprises the general basic information regarding the program run. This includes e.g. date, the selected program, the daily batch number and the device type.

Program step values

The phases of the program run are recorded whilst it runs and the values for steam pressure, temperature and time (related to the program start) are recorded.

Summary

The summary states whether the program has been completed successfully. The values of the sterilization time required, the sterilization temperature and the pressure (including the maximum deviation) are also displayed.

Example for a text log of a successfully completed program

			1
MELAG	MELAquick 12	+	Device type
Program : Univ 134° Date : 13.0 Time : 07:0 Batch number: 16 SN : 2022	versal-Program C wrapped 03.2022 02:16 (Star 212+1017	s t)	Program started Current date Time at program start Batch number of the day Serial number
Preheating AIN6: Conductivity Program step	133.3 °C 25 µS/cm Press. Temp bar °C	. Time min	Preheating temperature Feed water conductivity
Start 1.Fractionation Steam intake Press. Release 2.Fractionation	0.03 127. 1.77 127. 0.22 116.	1 00:00 6 01:02 6 01:08	VALUES OF THE PROGRAM STEPS
3.Fractionation 4.Fractionation 5.Fractionation 6.Fractionation 			Program run phases with the associated values for pressure,
7.Fractionation 8.Fractionation 9.Fractionation Press. build-up	2.06 134.	0 10:12	
Steriliz. begin. Steriliz. end Press. release Flow drying Drying begin. Drying flow Drying flow Drying pumping Drying end End	2.06 134. 2.19 135. 0.17 106. 0.12 101. 1.22 105. 1.21 117. 0.03 117.	0 10:12 7 13:42 3 14:00 3 14:00 7 14:12 3 14:24 6 21:48 8 21:53	
PROGRAM SUCCE Temperature : Pressure : Steril.time :	SSFULLY COMPL 135.6 +0.2 / 2.18 +0.02/ 3 min 30 5	STED! -0.2 °C -0.02 bar	SUMMARY - Control message Median sterilization temperature with max. deviations Median sterilization pressure with max. deviations Sterilization time maintained Time at program end
Time : 42 201501	U/:24:09 (End .017 5.20 5.05) 	Information with total batch counter, factory number and device software number / version no.

9 Function checks

Automatic functional checks

The electronic parameter control subjects the interaction of the sterilization-relevant parameters pressure, temperature and time to constant automatic monitoring. The steam sterilizer **>**process evaluation system compares the process parameters during the program with each other and monitors them in terms of their threshold values. The steam sterilizer monitoring system checks the device components for their functionality and their plausible interaction. Should the parameters exceed pre-set threshold values, the steam sterilizer emits warning or malfunction messages. If necessary, it interrupts the program with appropriate information. When the program has ended successfully, the corresponding message will be shown on the display.

Manual functional checks

You can follow the program run on the display via the values displayed there. You can also use the log recorded for every program to determine its success, see Logging [> page 39].

Batch-related checks

Helix test body system

MELAG recommends testing the functional reliability of the steam sterilizer using a Helix test body system at least once a month.

For this purpose, stockists offer specific dental test body systems as indicator and batch monitoring systems, e.g. Dental BMS (batch monitoring system) by GKE. This system consists of a test body, the Helix, and an indicator strip, and is used in the Universal-Program S at MELAquick.

- 1. Clean the door gasket before the program start.
- 2. Carry out this function check in the Universal-Program S.

Water quality of the feed water

You can access the water quality on the display at any time during a running program when the steam sterilizer is switched on.

Press and hold the '-' key until the display shows Conductivity. The >conductivity is displayed in µS/cm. As soon as you have released the '-' key, the display returns to its previous state (e.g. initial state).



Pre-heating temperature of the sterilization chamber

Press the '-' key twice. When pressing the first time, press shortly. When pressing the second time, hold the key depressed. The conductivity display disappears and the preheating temperature in the sterilization chamber will be displayed.



10 Maintenance

Maintenance intervals

Interval	Measure	Device component	
With every filling of the feed water container	Check the container for soiling and clean it if necessary before filling	External feed water container	
Weekly Check for soiling, deposits or damage		Sterilization chamber including door gasket and wiping rubber, universal basket for load	
	Check for discolouration	Sterile filter (MELAquick 12+)	
Every 4 weeks	Check for soiling	Insulating plug on the sterile filter (MELAquick 12+ p)	
As required	Cleaning the surfaces	Housing parts, sieve tray of the sterilization chamber, external wastewater container	
After 24 months or 3000 cycles	Maintenance	by the authorised customer services working in accordance with the maintenance instructions	

Cleaning

NOTICE

Inappropriately performed cleaning can lead to the scratching of and damage to surfaces and the development of leaks in sealing surfaces.

This also favours the development of soiling deposits and **>**corrosion in the **>**sterilization chamber.

- Comply with all information regarding cleaning of the part affected.
- Do not use any hard objects for cleaning such as a metal saucepan cleaner or a steel brush.

Door gasket and sterilization chamber

To maintain the value of your device and to avoid persistent soiling and deposits, MELAG recommends weekly cleaning of the surfaces such as the sterilization chamber including the door gasket and wiping rubber (e.g. with the MELAG chamber cleaning set).

The following must be fulfilled or present:

- The device has been switched off and the power plug has been unplugged from the socket.
- The device has been completely cooled.
- The sterilization chamber is empty.
- 1. Wet the surfaces to be cleaned completely with the cleaning fluid. **PLEASE NOTE:** You should not allow cleaning fluid to enter the piping coming from the sterilization chamber.
- 2. Spread the cleaning fluid evenly with a non-fuzzing cloth.
- 3. Allow the cleaning fluid to act and evaporate for a sufficient time.
- 4. Using a new non-fuzzing cloth, spread ample amounts of demineralised water over the cleaned surfaces.
- 5. Wipe the surfaces thoroughly to remove cleaning residues. Repeat this process as necessary after wringing out the cloth.

Residues of cleaning fluids can ignite or cause deposits on the instruments.

- 6. Allow the cleaned areas to dry completely. This may take a few minutes.
- 7. Finally, wipe the cleaned surfaces with a dry, non-fuzzing microfibre cloth.
- 8. Clean the wiping rubber and the door seal using a commercially available, gentle liquid cleaning agent.

- 9. Check if the entire door gasket is properly inserted in the groove. The door gasket may not show any waves, otherwise push it back into the groove using a rounded object.
- **10.** Next, start a sterilization program without a load.

Sieve tray of the sterilization chamber

A heavily soiled sieve tray can trigger malfunction messages.

Only remove and clean the sieve tray if it is very dirty. The sieve tray prevents dirt particles from depositing in the bores of the sterilization chamber and clogging them.

- 1. Make sure the sterilization chamber is clean before removing the sieve tray.
- 2. Use adhesive strips or the like to remove the sieve tray.

Housing parts

Where necessary, clean the housing parts with a neutral fluid cleaner or spirit.

Comply with the following specifications when disinfecting the housing parts:

- Use wipe disinfectants and not spray disinfectants. This prevents disinfectant from getting into inaccessible places or ventilation slots.
- Only use alcohol-based surface disinfectants (ethanol or isopropanol) or alcohol-free disinfectants based on quaternary ammonium compounds.
- Do not use disinfectants containing secondary and tertiary alkylamines or butanone.

Feed water container

- 1. If you use the feed water container to supply feed water, check the container for soiling before filling it with feed water.
- 2. If necessary, clean the container with a cloth and fresh feed water.

Wastewater container

Empty the wastewater container completely only for cleaning.

During operation, drain only enough water so that the cooling coil is still covered with water.

Sterile filter (only MELAquick 12+)

- 1. Use a pH-neutral and chlorine-free cleaning fluid to remove soiling (e.g. dust) from the sterile filter and the compressed air hose.
- 2. Check the filter medium regularly for discolouration. A light grey colouring of the filter medium does not influence the filter performance.

NOTICE

- Other colourings or dampness in the filter housing points to insufficient reprocessing of the compressed air.
 - Have the sterile filter replaced immediately and check that the quality of the compressed air available meets the requirements, see Compressed air connection (only MELAquick 12+) [> page 20].

Insulating plug on the sterile filter (only MELAquick 12+ p)

- 1. Check the insulating plugs on the sterile filter every four weeks.
- 2. Pull out the insulating plug on the plastic bracket and remove it from the bracket.
- 3. If necessary, clean the insulating plug in the sterile filter with clean water and allow it to dry before inserting.
- 4. Push the insulating plug some 2 mm over the rim of the passage into the plastic bracket while rotating it slightly.
- 5. Place the plastic bracket in the opening in the side wall and turn it by a full rotation so that the insulating plug sits securely in the opening of the sterile filter.

Avoiding staining

Only proper cleaning of the instruments prior to sterilization enables you to avoid residue from being released from the load under steam pressure during sterilization. Loosened dirt residue can clog the filter, fittings and valves of the device and deposit themselves on the instruments and in the sterilization chamber as deposits and stains.

All steam-conducting parts of the device consist of non-rusting material. This rules out the possibility of stain or rust development being caused by the steam sterilizer. Any rust which develops is always extraneous rust.

Incorrect instrument reprocessing can result in the accretion of rust even on stainless steel instruments of leading manufacturers. Often, a single instrument which drops rust can suffice to cause the development of rust on other instruments or in the device. Remove foreign rust from the instruments using chlorine-free stainless steel cleaning fluid (see Cleaning [> page 48]) or send the damaged instruments to the manufacturer.

The extent of stain accretion on the instruments is also dependent on the ▶feed water used for steam generation.

Replacing the door gasket

Replace the door gasket in good time if it shrinks, becomes very wavy or has cracks in the sealing lip. The consequence can be leaks which can lead to the leakage of steam. Safe and successful sterilization may be impacted.

- 1. Remove the worn door gasket from the groove.
- 2. Check the groove (pos. b) for soiling and deposits.
- 3. If necessary, clean the groove with methylated spirit.

A ventilation hole (pos. a) is located in the base of the groove (pos. b) in the chamber opening on the opposite side to the operating panel through which the air underneath the gasket can escape.

- 4. Spread a little washing-up liquid solution (1 part commercial dishwashing detergent + 4 parts water) on the new door gasket (pos. c) to make it easier to insert. NOTICE! Do not move the door gasket in the groove.
- Place the door gasket loosely on the groove and press it into the groove at a point about 45° (position 1) offset from the ventilation hole.
- 6. First press the door gasket into the groove on the opposite side and then press it crosswise at points.
- 7. Press down the locations between these points already inserted into the groove in a cross-wise fashion etc.
- Finally, starting from position 5 on the left, press the door gasket into the groove in short intervals working clockwise in the direction of the ventilation hole.
- Perform a trial run and then check the stability and position of the door gasket. If necessary, press down any bulges with a blunt instrument up to position 8 and then press the gasket into the groove in this position as well.





Maintenance



- Continuing operation beyond the maintenance interval can result in malfunctions in the device!
 - Maintenance should only be performed by trained and authorised technicians.
- Maintain the specified maintenance intervals.

Regular maintenance is vital to ensure reliable operation and value retention of the steam sterilizer. All function and safety-relevant components and electrical units must be checked during maintenance and replaced where necessary. Maintenance is performed in accordance with the maintenance instructions pertinent to this steam sterilizer.

Arrange for regular maintenance in 24 months intervals or after 3000 program cycles. The steam sterilizer will issue a maintenance message at the relevant time.

11 Pause times

Frequency of sterilization

Pause times between individual programs are not necessary. After the end/abort of the drying time and removal of the *sterile material*, you can load the steam sterilizer again and start a new program.

Operating pauses

Depending on the duration of the operating pauses, the following measures must be maintained:

Duration of the operating pause	Measure
Short pauses between two sterilization processes	 Keep the door closed to save energy
Pauses which last longer than an hour	Switch off the steam sterilizer
Longer pauses e.g. over night or the	Switch off the steam sterilizer
weekend	 Push the door closed but do not lock it (by turning the twist grip 90°) to protect the door gasket.
	 If present, shut off the water inflow of the water treatment unit
	 Shut off the compressed air supply, if available
Longer than two weeks	Switch off the steam sterilizer
	 If present, shut off the water inflow of the water treatment unit
	 Shut off the compressed air supply, if available
	Upon re-commissioning:
	 Perform an empty sterilization run in Quick-Program S

After pauses, perform the checks described in chapter Function checks [> page 47] depending on the length of pause.

Decommissioning

When decommissioning the steam sterilizer for a long pause (e.g. due to holiday or planned transport), proceed as follows:

- 1. Switch off the device at the power switch.
- 2. Disconnect the power plug from the socket.
- 3. Empty the feed water and wastewater containers
- 4. Close the water inflow if you are using a water treatment unit.
- 5. Shut off the compressed air supply, if available.
- 6. Disconnect all connection hoses on the rear of the device.

Transport

Comply with the following for safe handling:

- Transport the steam sterilizer with the carrying straps included in the scope of delivery (fix them on to the side of the steam sterilizer using e.g. package tape).
- Never lift the steam sterilizer on the twist grip. Otherwise the locking mechanism will be damaged and functionality is not ensured any more.
- Please observe that the distance between the bottom of the housing base plate of the steam sterilizer and the setup surface is low.

Recommissioning after relocation

When recommissioning after changing the location of the device, proceed as for initial commissioning, see First steps [> page 23].

12 System malfunctions

Troubleshooting online

All messages with current descriptions can be found in the Troubleshooting portal on the MELAG website (https://www.melag.com/en/service/troubleshooting).

Warnings

Warning messages are not malfunction messages. They help to ensure malfunction-free operation and to recognise undesirable situations. Comply with these warning messages early in order to avoid malfunctions.

Malfunction messages

Malfunction messages are issued on the display with an event number. This number serves identification purposes. Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after activating the steam sterilizer or during a program run.

If a malfunction occurs during a program run, the program will be aborted.



WARNING

Danger of infection from early program abort

Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and practice team.

- Re-pack the load if necessary.
- Repeat the sterilization of the load.

Before contacting customer services

Ensure that you have complied with all instructions relating to a warning or malfunction message issued by the display of the device. The following table contains a summary of the most important events. The events contain possible causes and the corresponding operator information.

Should the following table not contain the relevant event, or your efforts do not redress the problem, you can contact your nearest stockist or a local authorised MELAG customer service provider. Please have the serial number of your device and a detailed description of the message ready.

Notifications

Event	Possible causes	Wł	nat you can do
Empty display	Insufficient power supply.	1.	Check the power plug for its correct position in the socket.
		2.	Check the mains voltage at the socket.
		3.	WARNING! Failure to observe this may result in electric shock. This could result in serious injury. Before replacing the device fuses, disconnect the power cable from the power connector on the rear of the device. If necessary, replace the device fuses on the rear of the steam sterilizer, see Views of the device [> page 12].

Event	Possible causes	What you can do		
Poor drying results	The steam sterilizer is overloaded.	In a dry set	addition to an orderly device function, the ring depends to a large extent on the correct up and loading of the steam sterilizer.	
		 Comply with the maximum permissible lo quantities, see <u>Selecting the program</u> [> page 33]. 		
		2.	Activate pre-heating, see Selecting auto- matic preheating [▶ page 33].	
		3.	Use the additional drying function, see Se- lecting additional drying [▶ page 34].	

Warnings

Event	Possible causes	What you can do		
Attention: Door open and Start not possible	The door contact is not closed during the starting process.	Set the correct position of the twist grip – 90° across the longitudinal axis of the steam sterilizer. The display shows Door closed.		
Attention: No feed	When using the feed water container:			
water / Feed water Please refill – Start not possible	There is not enough feed water in the container or the inlet hose/cable is not connected correctly.	1.	Check the water level in the feed water con- tainer and top up with feed water if neces- sary.	
		2.	Check that the hose/cable connector is cor- rectly connected to the feed water contain- er.	
	The float switch is blocked.		Check if the float switch in the feed water container is blocked or jammed.	
			Check the screen insert in the feed water container for blockages.	



Event	Possible causes	What you can do			
Attention: No feed water / Check feed water supply	PLEASE NOTE: This message can occur once during initial commissioning/ re-commissioning because the pipe system is not yet completely filled.	Start the program again.			
	When using a MELAG water treatment				
	The message will be displayed after a program start. The installed flow monitor does not close.		MELAdem 40: Check the water treatment unit and if necessary, open the inflow to the system.		
		Upon repeated incidence, contact an authorised customer services / stockist technician.			
			MELAdem 47: Check the water treatment unit and if necessary, open the inflow to the system. Perform a new start with an empty pressure storage after approx. 1 h.		
			Upon repeated incidence, contact an authorised customer services / stockist technician.		
		PLEASE NOTE: This message can be issued following commissioning/recommissioning, as the pipe system has not been filled completely. Repeat the start.			
	When using the feed water container:				
	The message will be displayed after a program start. The installed flow monitor does not close.		Upon repeated incidence, contact an authorised customer services / stockist technician.		
	The inlet hose has not been connected correctly.	1.	Check that the hose is correctly connected to the steam sterilizer and the feed water container.		
		2.	Check that the connections are kink-free.		
Attention: Please empty wastewater tank / Start not possible	The wastewater container is full.	1.	Empty the wastewater container to the extent that residual water (approx. 10 cm high) remains in the container, see Cleaning [▶ page 48].		
		2.	If the steam sterilizer does not start after the acknowledgement, switch the device off and on again.		

MELAG

Event	Possible causes	What you can do			
Feed water quality bad / Replace cartridge/	The conductivity of the feed water is too high.	Start through repeated pressing of the 'S' key still possible.			
modulo	Conductivity ≥ 40 µS/cm				
	When using the feed water container:				
		Empty the feed water container, clean, rinse with fresh feed water and fill completely with feed water of the appropriate quality, see Feed water supply [> page 23].			
	When using a MELAG water treatment	unit:			
	The mixed-bed resin is exhausted.	MELAdem 40: Replace the mixed-bed resin (art. no. ME61026), see the user manual of the MELAdem 40 water treatment unit.			
	The mixed-bed resin in the ion exchanger (3rd cartridge) is exhausted.	MELAdem 47: Replace the mixed-bed resin (art. no. ME37470), see the user manual of the MELAdem 47 water treatment unit and check the treatment unit.			
		Following repeated incidence, arrange for maintenance to be performed by the authorised customer services / stockist technician. The pre- filter and activated carbon filter may require changing.			
	When using a different water treatment unit:				
	The mixed-bed resin in the reverse osmosis unit is exhausted.	Replace the module / resin cartridge in accordance with the manufacturer's user manual. Maintenance is required following repeated incidence.			
		PLEASE NOTE: Perform a program start after completing the work outlined above. This warning can be issued upon the initial start after maintenance of the water treatment unit, as the inlet hose / the measurement cell have not been completely rinsed with fresh water.			
Feed water quality insufficient / Start not possible	Feed water conductivity too high. Conductivity ≥ 65 µS/cm	Start no longer possible. See event: Feed water quality bad / Replace cartridge/module.			
Please wait / Preheating chamber	This message appears during the program start phase. The steam sterilizer has not yet reached the starting temperature.	The steam sterilizer starts automatically after the starting temperature has been reached.			
Output medium is not ready	The steam sterilizer is operating without an output medium, but one has been registered.	Working in the Log output menu, set the option No output medium.			
	The output medium has not been connected properly.	Check that the data cable has been connected to the steam sterilizer and output medium correctly.			
	The electricity supply to the printer has been interrupted.	Make sure that the power supply is connected. The red LED "P" on the MELAprint 42/44 log printer must illuminate red.			
	The printer is offline.	Set the printer online (press the 'SEL' key on MELAprint 42/44, the "SEL" LED must illuminate green).			

Event	Possible causes	What you can do		
Log memory full	The internal log memory of the device is	The message is displayed upon program start.		
	full (max. 40 logs possible).	Repeated pressing of the 'S' key removes the message and the program starts. The oldest log will be deleted in the process.		
	An output medium has been registered. In the Log output menu, the option Immediate output NO has been set.	1. Set the steam sterilizer to Immediate output YES, see Outputting logs immedi- ately and automatically [▶ page 42].		
		 Delete the internal device memory, see Deleting logs in the internal log memory [▶ page 45]. If necessary, output all previously saved logs, see Subsequent log output [▶ page 43]. 		
		 Working in the Log output menu, deselect the output medium and set the option No output medium. 		
Please carry out maintenance	The maintenance message is activated. The device has reached 3000 program	The message is displayed upon every program start.		
	cycles or the running time of 24 months.	Repeated pressing of the 'S' key removes the message and the program starts.		
		Retain the message: Press the 'S' key twice to start.		
		Arrange for maintenance by the authorised customer services / stockist technician.		
		PLEASE NOTE: The maintenance counter is reset by the customer services.		
Attention: Battery empty	Monitoring of the internal battery voltage has returned a low value.	The battery is to be replaced by the authorised customer services/stockist technician.		

Malfunction messages

Event	Possible causes	What you can do		
F02	The steam sterilizer is overloaded.	Comply with the maximum permissible load quantities, see Selecting the program [> page 33].		
	The door does not close tightly, possibly the	1. Check whether the door gasket is soiled or worn.		
	door gasket is soiled or worn.	 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 		
	The steam generator is overheated.	Switch off the steam sterilizer and allow it to cool for approx. 15 min.		
	Insufficient mains voltage. The on-site power supply is poor (e.g. undersized installation, defective socket, multiple devices on a single socket/fuse) so that the steam generator cannot heat up.	er Check the building-side socket or test the steam sterilize using a different socket or circuit.		
F04	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean it and replace it, see Sieve tray of the sterilization chamber [> page 49].		
	The outlet hose is kinked or crushed.	Check the hose for kinks and crushing.		
F08	The internal device time monitoring is defective.	Check the building-side socket / test the steam sterilizer using a different socket or circuit or connect to a mains filter. Upon repeated incidence, arrange for an electrician to check the electricity supply for electromagnetic disruption.		

Event	Possible causes	What you can do				
F09	The door has not been locked correctly upon program start.	Lock the door by pushing it forward as far as it will go and turning the grip 90° clockwise. The groove in the grip must be at right angles to the longitudinal axis of the steam sterilizer, see Close the door [▶ page 28].				
F10	A program was started again immediately after a program abort.	Wait approx. 2 min before starting a new program after a program abort.				
	The feed water inlet hose is kinked or has come loose.	Check the hose for kinks and that it is correctly connected to the steam sterilizer and feed water container.				
	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean and replace it, see Sieve tray of the sterilization chamber [▶ page 49].				
	When using a MELAG water treatment unit	When using a MELAG water treatment unit:				
	Residual air is in the feed system of the water treatment unit after initial commissioning or after replacing the mixed- bed resin cartridge.	Acknowledge the malfunction message and start the program repeatedly until the message is no longer displayed.				
F12	The door is not locked correctly.	Lock the door by pushing it forward as far as it will go and turning the grip 90° clockwise. The groove in the grip must be at right angles to the longitudinal axis of the steam sterilizer, see Close the door [▶ page 28].				
	The front door hinge is damaged. The door can be pushed forward a little too far as a result.	Contact an authorised customer services / stockist technician and have the door hinge repaired. To bridge the gap, you can push the door back a little after locking it. The door lock must audibly engage.				

Event	Possible causes	What you can do			
F14	When using the feed water container:				
	There is not enough feed water in the feed water container.	 Check whether sufficient feed water is in the feed water container; the end of the intake hose is sub- merged in water and that no air is being drawn in. 			
		2. If necessary, top up the feed water.			
	The suction height from the feed water container to the steam sterilizer is more than 1.5 m.	Please note that the container stands max. 1.5 m deeper than the steam sterilizer, otherwise no water is drawn in.			
	The suction filter in the feed water container is blocked.	Check the filter in the feed water container for soiling and clean it if necessary.			
	The feed water inlet hose is kinked or has come loose.	Check the hose for kinks and that it is correctly connected to the steam sterilizer and feed water container.			
	The float switch in the feed water container is stuck.	Check that the float switch is working properly. 1. Unscrew and remove the lid of the feed water contain-			
		er.2. Move the float switch up and down and try to make it move smoothly again.			
	When using a MELAG water treatment unit	:			
	The feed water supply is set to internal.	Set the feed water supply to external in the Function menu, see Setting the water treatment unit [> page 30].			
	Residual air is in the feed system of the water treatment unit after initial commissioning or after replacing the mixed- bed resin cartridge.	Acknowledge the malfunction message and start the program repeatedly until the message is no longer displayed.			
	The pressure tank of the MELAdem 47 is not sufficiently filled.	Please note that after initial commissioning of a MELAdem 47 it takes approx. 1 h until the pressure tank is sufficiently full with water.			
	The water inflow tap is not open or the pressure tank of the MELAdem 47 is closed.	1. Check whether the water inflow tap for the water treat- ment unit is open.			
		2. Check whether the tap on the pressure tank is open.			
	When using a central water treatment unit:				
	The central water supply has been interrupted or the flow pressure is insufficient	1. Check whether all inflow valves from the central sys- tem to the steam sterilizer are open.			
		 If necessary, arrange for an inspection of the flow pressure of the central water treatment unit using a flow pressure gauge (min. 0.5 bar at 0.8 l/min). 			
F18	Malfunction on the specified sensor input	Upon repeated incidence, contact an authorised customer services / stockist technician.			
	With "Malfunction 18 Sensor: 6 Input: 6" an excessively high conductivity of the feed water supply can be measured.	Check whether the water used as feed water actually corresponds to the required quality or e.g. tap water has been used. The feed water must fulfil the quality requirements of EN 13060, Appendix C. If tap water has been used, restart the steam sterilizer two to three times so as to flush out the tap water from the system.			
F21	The door is open during the heating phase.	Close the door during the heating phase (standby).			
	Insufficient mains voltage. The mains voltage is too low, poor building voltage supply (e.g. undersized installation, defective socket, multiple devices on a single socket/ fuse) so that the steam generator cannot heat up.	Check the building-side socket / test the steam sterilizer using a different socket or circuit.			
F23	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean and replace it, see Sieve tray of the sterilization chamber [> page 49].			
	The outlet hose is kinked or crushed.	Check the outlet hose for kinks.			

Event	Possible causes	What you can do			
F25	The quality of the feed water is very poor (conductivity $\ge 65 \ \mu$ S/cm).				
	When using the feed water container:				
	Water of insufficient quality (e.g. tap water)	1. Empty and clean the container.			
	was used.	 Fill the container with water of appropriate quality (EN 13060, Appendix C). 			
	When using a MELAG water treatment unit	:			
	MELAdem 40: The mixed-bed resin cartridge is exhausted.	Replace the mixed-bed resin (art. no. ME61026), see the user manual of the MELAdem 40 water treatment unit.			
	MELAdem 47: The mixed-bed resin cartridge, the pre-filter or the activated coal filter is exhausted.	 Replace the mixed-bed resin (art. no. ME37470) and, if necessary, the pre-filter and activated charcoal filter, see the user manual of the MELAdem 47 water treat- ment unit. 			
		 Empty the pressure tank (if possible until it is half full) and wait until it has been filled again. An empty pres- sure tank requires approx. 1 h to fill. 			
		PLEASE NOTE: The message may also continue to be shown after the filter has been replaced until the water remaining in the pressure tank has been consumed.			
F26 F27	Electromagnetic malfunctions in the power supply.	 Check the building-side socket / test the steam sterilizer using a different socket or circuit or connect to a mains filter. 			
		 Upon repeated incidence, arrange for an electrician to check the electricity supply for electromagnetic mal- functions. 			
F32	The steam sterilizer was switched off at the power switch during a program run.	Never switch off the steam sterilizer at the power switch during a program run. Always abort a program with the 'Start-Stop' key.			
	The power plug has been disconnected or has not been connected correctly in the socket.	 Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. 			
		2. Plug the power plug back into the mains socket.			
	Power failure in the building supply.	1. Have the on-site installation checked (e.g. circuit breakers).			
		2. Test the steam sterilizer on another socket or circuit.			
F33	The pressure in the sterilization chamber	1. Check whether the door gasket is soiled or worn.			
	The door does not close tightly, possibly because the door gasket is soiled or worn.	 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 			
F34	The sterilization temperature on temperature sensor 1 was undercut.	Comply with the maximum permissible load quantities, see Selecting the program [▶ page 33].			
	The steam sterilizer is overloaded.				
	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean and replace it, see Sieve tray of the sterilization chamber [> page 49].			
	The door does not close tightly, possibly	1. Check whether the door gasket is soiled or worn.			
	because the door gasket is soiled or worn.	 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 			
	Electromagnetic malfunctions in the power supply.	 Check the building-side socket / test the steam sterilizer using a different socket or circuit or connect to a mains filter. 			
		 Upon repeated incidence, arrange for an electrician to check the electricity supply for electromagnetic mal- functions. 			

Event	Possible causes	What you can do		
F35	see event F26/F27			
F36	The required chamber pressure was exceeded during sterilization.	Comply with the maximum permissible load quantities, see Selecting the program [> page 33].		
	The steam sterilizer is overloaded.			
	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean and replace it, see Sieve tray of the sterilization chamber [▶ page 49].		
	The door does not close tightly, possibly	1. Check whether the door gasket is soiled or worn.		
	because the door gasket is soiled or worn.	 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 		
	Electromagnetic malfunctions in the power supply.	 Check the building-side socket / test the steam sterilizer using a different socket or circuit or connect to a mains filter. 		
		 Upon repeated incidence, arrange for an electrician to check the electricity supply for electromagnetic mal- functions. 		
F37	see event F26/F27			
F38				
F39	The internal memory (EEPROM) has suffered data inconsistency or data loss.	 Acknowledge the malfunction message and then reset the date and time, see Setting the date and time [> page 29]. 		
		2. Start the program again.		
F41	see event F04			
F42	The door does not close tightly, possibly	1. Check whether the door gasket is soiled or worn.		
	because the door gasket is soiled or worn.	 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 		
	MELAquick 12+: The compressed air supply is not connected	1. Check the compressed air hose for kinks and correct connection.		
	or interrupted.	2. Check whether the shut-off valve is open.		
	The shut-off valve for compressed air is closed.	 After the compressed air supply has been restored, the Universal-Program S must be carried out 5x without load (or 3x with activated additional drying). 		
	MELAquick 12+ p: The insulating plug in the sterile filter is soiled.	Check the insulating plug in the sterile filter for soiling and clean it, see Insulating plug on the sterile filter (only MELAquick 12+ p) [> page 49].		
		The device may also be operated without an insulating plug (louder operating noise).		
F48	Parameter malfunction	1. Switch off the steam sterilizer and back on again.		
		2. Restart the program.		

Event	Possible causes	What you can do		
F51	The sterilization temperature on temperature sensor 2 was undercut.	Comply with the maximum permissible load quantities, se Selecting the program [> page 33].		
	The steam sterilizer is overloaded.			
	The sieve tray in the sterilization chamber is soiled.	Remove the sieve tray from the sterilization chamber, clean and replace it, see Sieve tray of the sterilization chamber [> page 49].		
	The door does not close tightly, possibly because the door gasket is soiled or worn.	1. Check whether the door gasket is soiled or worn.		
		 Clean or, if necessary, replace the door gasket, see Replacing the door gasket [▶ page 50]. 		
	Electromagnetic malfunctions in the power supply.	 Check the building-side socket / test the steam sterilizer using a different socket or circuit or connect to a mains filter. 		
		2. Upon repeated incidence, arrange for an electrician to check the electricity supply for electromagnetic mal- functions.		
F52	see event F26/F27			
F53				

13 Technical tables

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Step	Quick- Program S		Universal-Pro- gram S		Prion- Program S		All values in mbar	
	Р	Т	Р	Т	Р	Т		
1. fractionation	2700	-30/+160					Steam intake	Fractionation
	1250	-390/+30	•		•	•	Steam off-flow	_
x. fractionation	2700	-50/+110	•		•		Steam intake	_
	1250	-160/+50	•		•	•	Steam off-flow	
	3050	-50/+70	•	•	•	•	Pressure increase	
	3050	-50/+70			•	•	Sterilization entry	
	3170	-90/+90	•		•		Sterilization	_
	1200	-140/+50			•		Pressure release	

Key:

P = Pressure

T = Tolerance

◄ as in the Quick-Program S

Empty chamber test

The blue marking in the schematic diagram indicates the coldest point (directly at the temperature sensor) in the sterilization chamber during the **>**empty chamber test.

The red marking in the schematic diagram indicates the point with the highest temperature in the sterilization chamber during the empty chamber test.



Pressure-time charts





Quick-Program S (134 °C and 2.1 bar)





Prion-Program S (134 °C and 2.1 bar)



Feed water quality

Minimum requirements to the *bfeed water* following *EN 13060*, Appendix C

Substance/property	Feed water
Evaporation residue	≤ 10 mg/l
Silicon oxide, SiO ₂	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Traces of heavy metal apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 2 mg/l
Phosphate	≤ 0.5 mg/l
▶pH value	5 - 7.5
Appearance	≤ colourless, clear, without sediments
Hardness	≤ 0.02 mmol/l

14 Technical data

Device type	MELAquick 12+	MELAquick 12+ p
Device dimensions (W x H x D):	19.5 x 43 x 47 cm	20.5 x 43 x 46 cm
Empty weight	23 kg	24 kg
Operating weight	approx. 25 kg	
Sterilization chamber		
Diameter	9 cm	
Depth	20 cm	
Volume	1.35 I	
Electrical connection		
Power supply	220-240 V, 50/60 Hz	220-240 V, 50 Hz
Max. voltage range	207-253 V	
Electrical power	2050 W	
Building fuse	16 A Type B, RCD 30 mA	
Overvoltage category	Transient overvoltages up to the value	s of overvoltage category II
Air pollution degree (in accordance with EN 61010-1)	Category 2	
Length of the power cable	2.5 m	
Ambient conditions		
Installation location	interior of a building	
Noise emission	66 dB(A)	69 dB(A)
Heat emission (with max. load)	approx. 0.48 kW (1.74 MJ/h)	
Ambient temperature	5-40 °C (ideal range 16-26 °C)	
Relative humidity	max. 80 % at temperatures of up to 31 in linear fashion in-between)	°C, max. 50 % at 40 °C (decreasing
Protection class (in accordance with IEC 60529)	IP20	
Max. altitude	2000 m	
Feed water connection		
Water quality	demineralised and/or distilled water ac (with central demineralisation system i	cording to EN 13060, Appendix C max. conductivity 5 µS/cm)
Recommended flow pressure	0.5 bar at 0.8 l/min	
Min. water pressure (static)	0.5 bar	
Max. water pressure (static)	10 bar	
Max. water consumption	approx. 280 ml	
Volume feed water container	51	
Number cycles feed water container	approx. 20	
Feed water volume initial commissioning	min. 1.5-2 l	
Max. temperature	40 °C	
Wastewater connection		
Max. temperature	approx. 100 °C (direct in wastewater c	ontainer)

15 Accessories and spare parts

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

Article		Art. no.		
		MELAquick 12+	MELAquick 12+ p	
Accessories	Holder with ISO adapters for 7 instruments	ME0	ME00122	
	Holder with round mounts for 7 instruments	ME00123		
	Universal basket with small part(s) insert	ME0	ME00125	
	Package holder	ME00126		
	Holder for universal basket	ME00127		
	Holder for insert baskets	ME00128		
	Basket handle	ME10003		
Water treatment	MELAdem 47 reverse osmosis unit	ME01047		
	MELAdem 40 ion exchanger	ME01049		
	Holder for wall mounting (2 pcs.) (for MELAdem 40)	ME15856		
	T-piece for hoses	ME38600		
	PE hose (2 m) with T-piece (metal, 6/4 mm)	ME3	8605	
Documentation	MELAflash CF-Card-Printer incl. CF card and card reader	ME0	ME01039	
	MELAprint 44 log printer	ME01144		
	MELAnet Box	ME40296		
Other	Connecting cable for water container, 5 m	ME2	1353	
Compressed air	Compressed air distributor (2-way)	ME80220		
connection	Coupling plug for compressed air to hose 6 mm for compressed air on 6 mm hose	ME80230		
Spare parts	Door seal with double lip	ME1	2550	
	Fuse 20 A gRL, set à 4 pcs.	ME2	1481	

Glossary

AKI

AKI is the abbreviation for "Arbeitskreis Instrumentenaufbereitung" (Instrument Reprocessing Working Group)

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.

Batch

The batch is the composition of items which has been subject to the same reprocessing procedure.

CF card

The CF card is a memory medium for digital data; Compact Flash is an official standard, i.e. these memory cards can be used in every device fitted with the corresponding slot. The CF card can be read by every device that supports the standard and where necessary, written on.

Competent personnel

Trained personnel in accordance with national specifications for the respective area of application (dentistry, medicine, podiatry, veterinary medicine, cosmetics, piercing, tattoo) with the following contents: knowledge of instruments, hygiene and microbiology, risk assessment and classification of medical devices and instrument reprocessing.

Conductivity

is the ability of a conductive chemical substance or mixture of substances to conduct or transfer energy or other substances or particles in space.

Corrosion

The chemical alteration or destruction of metal materials by water and chemicals

Delay in boiling

This refers to the phenomenon that it is possible under certain circumstances to heat a fluid beyond its boiling point without them boiling. This represents an unstable state; even low-level agitation can produce a large bubble within the shortest period, which expands explosively.

Demineralised water

Water without the minerals usually found in normal spring or tap water; is produced through ion exchange of normal tap water. It is used here as feed water.

DGSV

Abb.: "Deutsche Gesellschaft für Sterilgutverordnung" (German Association for the Sterilized Equipment Ordinance). The DSGV training centres are specified in DIN 58946, part 6 as "Requirements of 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 - sterilization, sterile equipment supply

Distilled water

From the Latin aqua destillata; also referred to as aqua dest; water which to a great extent is free from salts, organic material and micro-organisms, is produced from normal tap water or pre-cleaned water through the process of distillation (evaporation and subsequent condensation). Distilled water is used, for example, as feed water for steam sterilizers.

Empty chamber test

Test run without a load, performed to assess the performance of a sterilizer without the influence of a load; facilitating verification of the temperatures maintained in comparison to the temperatures set. [see EN 13060]

EN 13060

Standard - small steam sterilizers

EN 1717

Standard - protection of drinking water from soiling in drinking water installations and general requirements for safety devices to prevent drinking water contamination through backflow.

EN 868

Standard – packaging materials and systems for medical products requiring sterilization

Feed water

Feed water is required to produce steam for sterilization. Guide values for water quality in accordance with EN 285 / EN 13060 – Appendix C

Load

Products, devices or materials that are reprocessed together in one operating cycle.

Mixed loads

wrapped and unwrapped load within a single batch

MPBetreibV

Abbreviation for "Medizinprodukte-Betreiberverordnung" [Medical Product Operator Ordinance]. Ordinance covering the installation, operation, application and maintenance of medical products according to §3 of the Medical Devices Directive with the exception of medical products for clinical evaluation or performance evaluation.

Multiple wrapping

e.g. wrapped instruments sealed in a double layer of film or wrapped in film and placed in an additional container or a container wrapped in textiles.

pH Value

The pH value is a measure of the strength of the acid or alkali effect of a watery solution.

Process evaluation system

Also known as the self-monitoring system – this observes itself and compares the various sensors during a current program.

Qualified electrician

Person with suitable technical training, knowledge and experience so that he or she can 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

Abbreviation for "Robert Koch Institute". It is one of the most important bodies for the safeguarding of public health in Germany.

Sterile barrier system

A closed minimum packaging which prevents the entrance of micro-organisms e.g. through sealing bags, sealed and re-usable containers and folded sterilization towels etc.

Sterile material

Also referred to as a batch: a load which has already been sterilized, i.e. is sterile

Sterilization chamber

The interior of a sterilizer accommodates the load



According to the recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute

Manufacturer:	MELAG Medizintechnik GmbH & Co. KG
Address:	Geneststraße 6-10 10829 Berlin
Country:	Germany
Product:	MELAquick [®] 12+/MELAquick [®] 12+ p
Type of device:	Steam sterilizer (autoclave)
Classification:	Class IIb
Device type acc. to EN 13060:	Туре S

We declare that the product specified above is suitable for the steam sterilization of

- W & H Synea WA-99LT
- W & H Alegra WE-99 LED G
- KaVo GentleSilence LUX 8000B
- KaVo IntraCompact 25 LHC
- Sirona T1 Line
- Sirona T1 Control
- Handpieces with comparable qualities (material, weight, geometry)

In accordance with the Robert Koch Institute directive "Hygiene requirements for the reprocessing of medical products" (2012), MELA*quick*[®] 12+ is suitable for the sterilization of dental instruments with the risk assessment

- Semi-critical A and B (unwrapped and wrapped sterilization)
- Critical A and B (wrapped sterilization)

References to loading quantities and loading variations are outlined in the user manual and must be observed.

Manufacturer instructions regarding the medical devices stipulated for sterilization in accordance with EN ISO 17664 must be observed.

Berlin, 01.06.2022

Dr. Steffen Gebauer

(General Management)

Quality - made in Germany





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Original instructions

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

Your stockist