MELAG
competence in hygiene

Operating Manual

Vacuklav® 24 B+
Vacuklav® 30 B+

Steam sterilizer

from software version 5.20

EN

Dear customer,

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

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

The MELAG management and team.

CE 0197

Contents

1 General notes

Please read this operating manual carefully before commissioning the device. This manual contains important safety information. The functionality and value-retention of this device depends on the care accorded to it. Please store this operating manual carefully and in close proximity to the device. It represents a component of the product.

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Symbols used

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

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.

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.

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 have been trained in the operation and safe handling of the device.
- The operator must ensure that users are regularly trained in the operation and safe handling of the device.

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 authorized persons.
- The connections for electrical provision and water supply and discharge must be setup by trained personnel.
- Using the optional electronic leak detector (water stop) minimizes the risk of water damage.
- 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.
- Observe all the information contained in the technical manual during commissioning.

Power cable and power plug

- 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 authorized 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.
- The mains socket must be freely accessible after installation so that the device can be disconnected from the electrical mains at any time if necessary by pulling the mains plug.

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 textile articles and instruments regarding their reprocessing and sterilization.
- Comply with the relevant standards and directives applicable to the reprocessing and sterilization of textiles and 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.

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 tray lifter to remove the tray. Never touch the sterilized equipment, the chamber, the mount or the inside of the door with bare hands. The components are hot.
- 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.

Transport and storage

- Store and transport the device in a frost-free environment.
- The device should always be carried by two people.
- Use suitable carrying straps to carry the device.

Maintenance

- Maintenance should only be performed by authorized 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 (according to VDE 0105-100 or IEC 60050).

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 authorized 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

This steam sterilizer is designed for application in a medical context, e.g. general practitioners and dental practices. According to EN 13060, this steam sterilizer is considered as a steam sterilizer with type B cycles. As a universal steam sterilizer, it is suited to highly-demanding sterilization tasks. It can be used for a range of tasks such as the sterilization of large quantities of instruments with narrow lumen and transmission instruments - both wrapped or unwrapped - and of textiles.

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.

Performance characteristics of sterilization programs

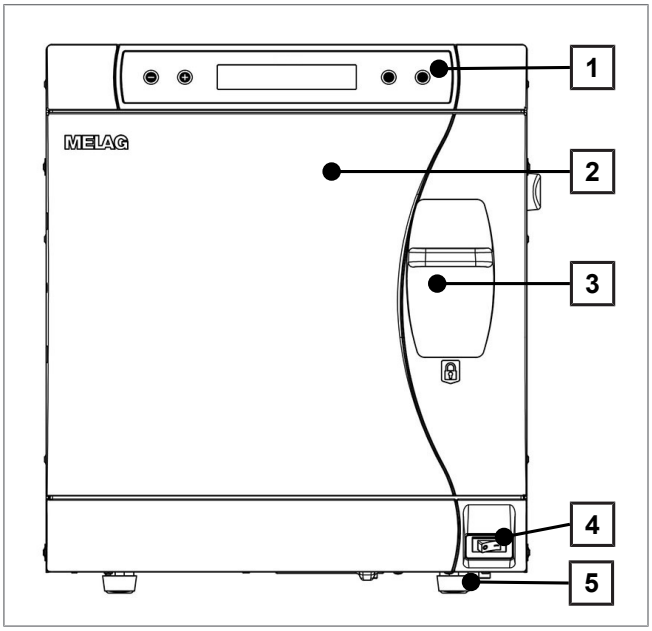
The results in this table show which inspections were performed on the steam sterilizer. The marked field shows compliance with all the applicable sections of the standard EN 13060.

Type tests	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Program type in accordance with EN 13060	Type B	Type B	Type S	Type B	Type B
Dynamic pressure test of the sterilization chamber	X	X	--	X	X
Air leakage	X	X	X	X	X
Empty chamber test	X	X	X	X	X
Solid load	X	X	X	X	X
Porous partial load	X	--	--	X	X
Porous full load	X	--	--	X	X
Simple hollow body (Hollow body B)	--	--	X	--	--
Product with narrow lumen (Hollow body A)	X	X	--	X	X
Single wrapping	X	X	--	X	X
Multiple wrapping	X	--	--	X	X
Drying solid load	X	X	X	X	X
Drying porous load	X	--	--	X	X
Sterilization temperature	134 °C	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2.1 bar	2.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	5:30 min	5:30 min	3:30 min	20:30 min	20:30 min
X = Complies with all applicable sections of the standard EN 13060					

4 Description of the device

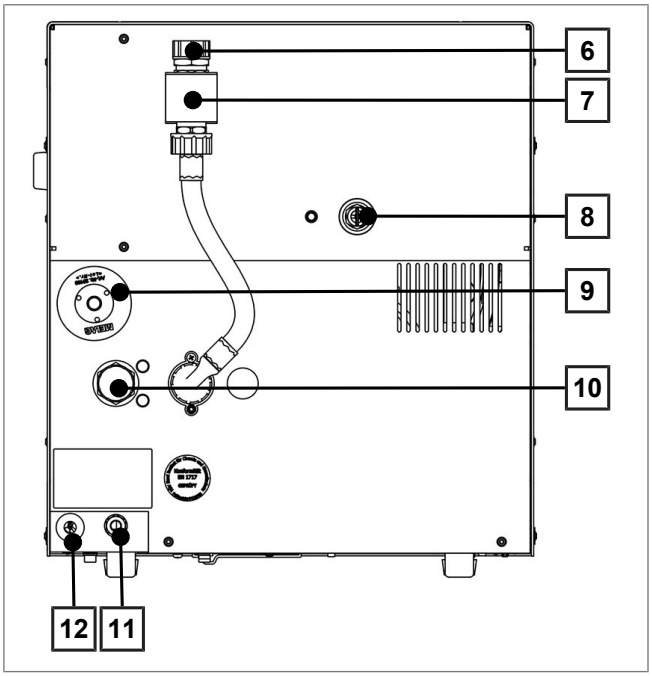
Views of the device

Front



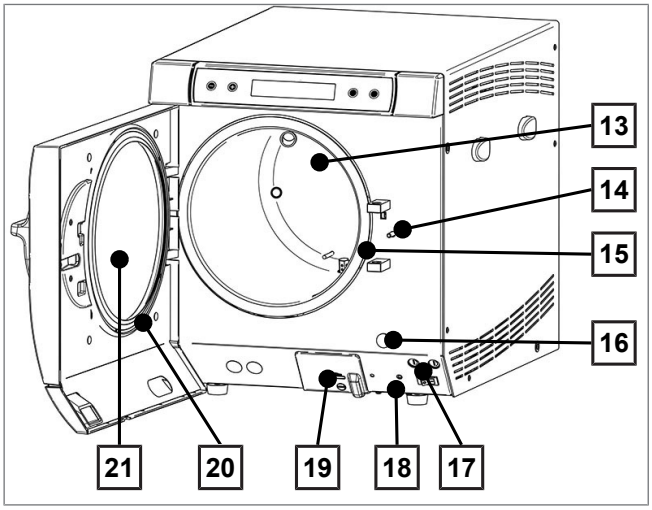
1 Operating and display panel
2 Door, swings open to the left
3 Slide locking grip
4 Power switch
5 Front device foot (adjustable)

Rear panel



6 Cooling water inflow (3/4” external thread)
7 Safety combination in accordance with EN 1717
8 Spring safety valve
9 Sterile filter
10 Cooling water outlet (3/4” external thread)
11 Feed water inflow from external water storage container or MELAdem, swivel screw connection for hose Ø 6x1
12 Mains connection

View of the interior



13 Sterilization chamber
14 Door locking pin
15 Chamber seal face
16 Cap for emergency activation of the vacuum pump
17 2x Device fuse
18 Motor protection switch reset button
19 Serial data and printer connection (RS232)[1)]
20 Door seal
21 Round blank

Symbols on the device


Manufacturer of the medical device


Date of manufacture of the medical device

Identifies a medical device

Medical device serial number from the manufacturer

Article number of the medical device


Information about the chamber volume


Operating temperature of the device


Operating pressure of the device


Internal device fuse, rated in amperes [A]


Electrical connection of the device: AC current

[1)] hidden behind white cover

The operating manual includes important safety information. Failure to comply with these instructions can result in injury and material damage.

Please read this operating manual carefully before commissioning the device.

In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the Medical Device Directive. The four-digit number confirms that this is monitored by an approved certification agency.

In affixing this CE mark, the manufacturer declares that this product fulfils the basic requirements of the Pressure Equipment Directive. The four-digit number confirms that this is monitored by an approved certification agency.

The device may not be disposed as domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of.

Motor protection switch

With the adjacent label, the device manufacturer declares that the medical product corresponds to the basic requirements of the European standard EN 1717 - Protecting Drinking Water from Contamination.

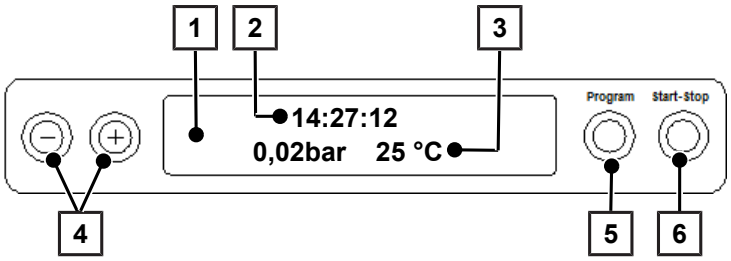
Symbols on the power switch

Switching on device

Switching off device

Operating panel

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



1 **2-row LC display**
for displaying the program status and parameters

2 Time (h:min:s)

3 Chamber pressure (bar) and (steam) temperature (°C)

4 **Function keys '-' and '+'**
for the selection, setting and display of special functions: print, date/time, preheating, total batches, conductivity, acknowledge error, key '+' for unlocking the door

5 **Program selection key 'P'**
for selecting the sterilization program / test program and selection / setting of the options (submenus) of the special functions

6 **Start – Stop key 'S'**
for starting programs, aborting programs / drying and controlling the special functions

Initial state

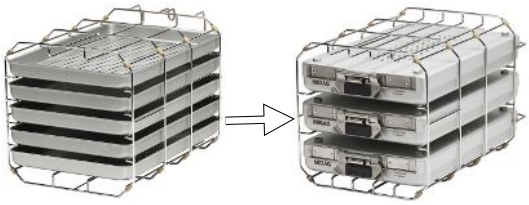
Each time the device is switched on, the display changes to the initial state, showing the current time, the chamber pressure in bar and the (steam) temperature in °C.

Load mounts

For detailed information about the different mounts, how to combine them with different load holders and how to use them, please refer to the separate document “User manual: Accessories for small steam sterilizers”.

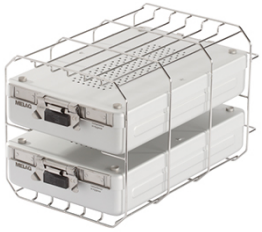
Mount A Plus

The mount (A Plus) is standard and can accommodate either five trays or three MELAstore Boxes 100 when turned 90°.



Mount D

The mount (D) can accommodate two tall sterilization containers (e.g. MELAstore Box 200) or four trays (when turned 90°).



5 Installation requirements

Installation location

WARNING

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

- The steam sterilizer should only be setup, installed and commissioned by persons authorized 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	Vacuklav 24 B+	Vacuklav 30 B+
Installation surface	level and horizontal	
Installation location	interior of a building (dry and protected from dust)	
Floor loading (normal operation)	2.6 kN/m²	3.1 kN/m²
Max. floor loading (hydraulic pressure test)	3.3 kN/m²	3.8 kN/m²
Max. altitude	2000 m	
Waste heat (with max. load)	0.6 kWh	
Ambient temperature	5-40 °C (recommended max. 25 °C)	
Relative humidity	max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative humidity at 40 °C	

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 %.

Space requirements

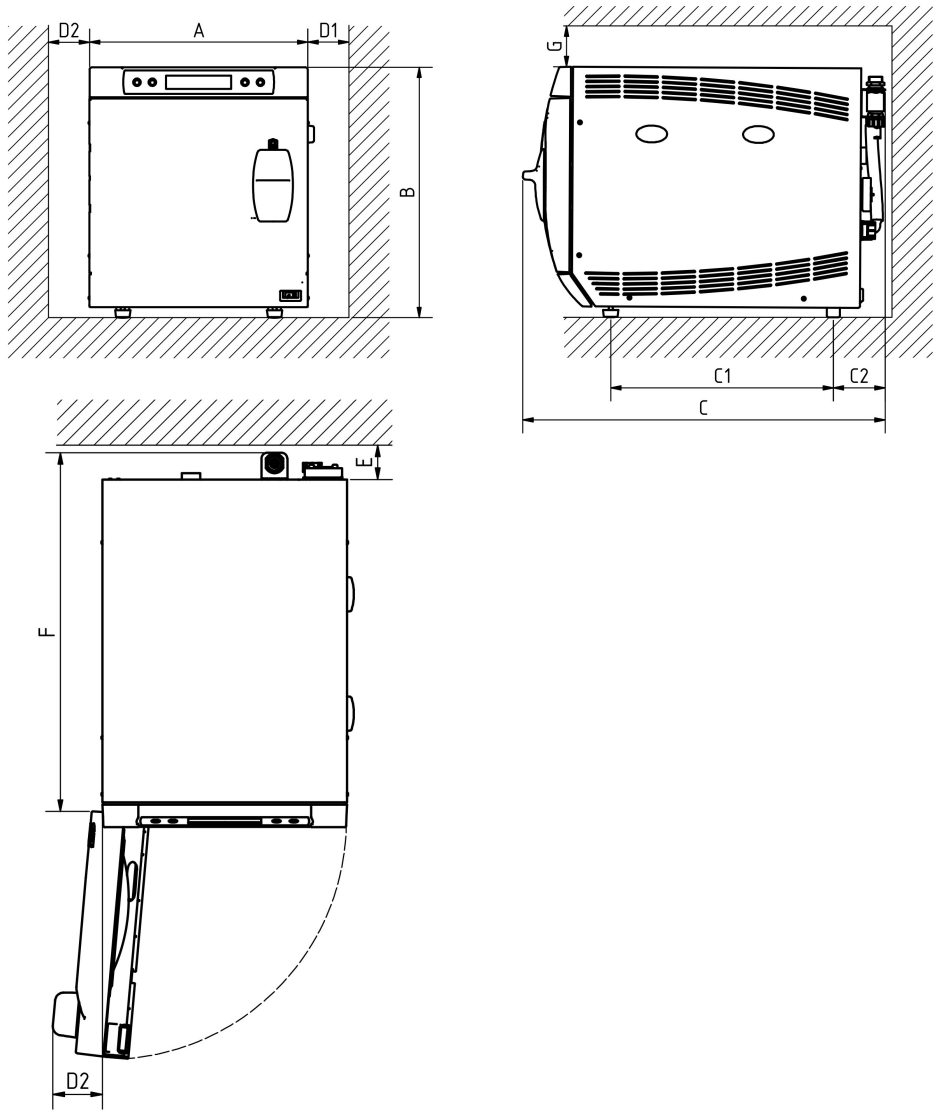


Fig. 1: View from the front, the right and above

Dimensions		Vacuklav 24 B+	Vacuklav 30 B+
Width	A	42.5 cm	
Height	B	49.5 cm	
Depth, total*)	C	70.5 cm	66 cm
Clearance between the device feet	C_1	43.5 cm	32 cm
Clearance from rear device foot up to the rear panel	C_2	10 cm	18 cm
Min. clearance to the side	D_1	5 cm	
Min. clearance to the side of the door hinge	D_2	10 cm	
Min. clearance to the rear	E	5 cm	
Free area with a fully-opened door	F	62.5 cm	58 cm
Min. clearance to the top	G	5 cm	

*) including safety combination in accordance with EN 1717

Maintain the side clearances when installing the steam sterilizer.

Additional space requirement for the feed water supply

Additional space is required for a storage container or a water treatment unit. It is also necessary to guarantee free access to the hoses and cables leading from the steam sterilizer to the water treatment unit.

Space requirements	**MELAdem 40**	**MELAdem 47**		**Storage container**
		Water treatment unit	Pressure tank	
Width	32 cm	40 cm	--	21 cm
Height	35 cm	46 cm	40 cm	38 cm
Depth	16 cm	18 cm	--	23 cm
Diameter	--	--	approx. 28 cm	--

6 Installation

Setup and installation

PLEASE NOTE

Comply with the specifications of the technical manual during setup and installation. This contains all building-side requirements.

Record of installation and setup

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

Aligning the steam sterilizer

To ensure fault-free operation, the steam sterilizer must be set up horizontally with the aid of a spirit level placed on the chamber seal face. Then extend the fore device feet by five (Vacuklav 24 B+) or three (Vacuklav 30 B+) revolutions to effect a slight rearwards slope of the device.

Mains supply

Implement the following safety measures when dealing with the cable and power plug:

- 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.
- The mains socket must be freely accessible after installation so that the steam sterilizer can be disconnected from the electricity supply at any time.

On-site requirements of the mains connection

Property	
Electricity supply	220-240 V, 50/60 Hz
Max. voltage range	207-253 V
Building fuses	separate power circuit with 16 A fuse, 30 mA RCD protection (to guarantee continued practice operation during steam sterilizer malfunction)
Length of power cable*)	1.35 m
Other	additional socket for the MELAprint 42/44 log printer etc.
*) Comply with the specifications in the connection diagram.	

Water connection

	Cooling water	Feed water	Wastewater
Connection in the practice	To the cooling water cut-off valve (water inflow tap) G3/4“	To a water treatment unit, e.g. MELAdem 40/47	Wall outlet, nominal width DN 40 or to a siphon (flush outflow)
Installation height	--	--	min. 30 cm under the steam sterilizer
Max. water temperature	20 °C (ideal 15 °C)	35 °C	short-term 90 °C
Max. flow rate	--	--	short-term approx. 3.3 l/min
Min. flow pressure	> 1.2 bar at 3 l/min	corresponding to the water treatment unit	--
Recommended flow pressure	2.0-4.0 bar at 3 l/min	1.5 bar at 3 l/min	--
Min. water pressure (static)	--	corresponding to the water treatment unit	--
Max. water pressure (static)	10 bar	10 bar	--
Max. water consumption[2)]	approx. 57.5 l	approx. 720 ml (24 B+) approx. 770 ml (30 B+)	--
Water quality	drinking water	Distilled or demineralised water in accordance with EN 13060, Appendix C	--
Measures for protecting the drinking water	None (internal precautions against back-flow into the drinking water supply via safety combination consisting of a back-flow preventer and pipe aerator; secured in accordance with EN 1717)		

Connection of a water treatment unit

	MELAdem 40	MELAdem 47
Permissible water 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 water pressure from the domestic water supply.	

PLEASE NOTE

The outlet hose must be fitted at a constant decline without kinks or sagging. Deviations to the installation arrangements require consultation with MELAG.

Failure to do so can result in malfunctions of the steam sterilizer.

Feed water supply

Steam sterilization requires the use of distilled or demineralized water, known as feed water. Annex C of EN 13060 specifies the guideline values to be observed.

The supply with feed water is effected either via an external water storage container, which must be filled periodically with water of the corresponding quality, or via a water treatment unit (e.g. MELAdem 40/ MELAdem 47).

[2)] In the Prion program with porous full load.

7 Sterilization

Switching on the steam sterilizer

✓ *The steam sterilizer is connected to the electricity supply.*

✓ *The door is closed.*

▶ The steam sterilizer is switched on 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.

PLEASE NOTE

Remove all accessories from the sterilization chamber directly after switching on for the first time and before initial commissioning.

After device activation, a heating up time of approx. 5 min (Vacuklav 24 B+) or approx. 3 min (Vacuklav 30 B+) is required depending on the device type. A program will be started only after the target temperature has been reached.

PLEASE NOTE

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

Preparing the load

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

NOTICE

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

Reprocessing textiles

WARNING

The incorrect reprocessing of textiles, e.g. a textile package can prevent steam penetration or produce poor drying results.

The textiles could not be sterilized.

Comply with the following points when reprocessing textiles and putting the textiles in sterilization containers:

- Comply with both the manufacturer's instructions of the textiles regarding reprocessing and sterilization as well as the relevant standards and directives (in Germany e.g. from the RKI and DGSV).
- Arrange the folds in the textiles parallel to each other.
- Stack textiles vertically wherever possible and not too closely together in the sterilization container. This enables the development of flow channels.
- If textile packages do not remain together, wrap the textiles in sterilization paper.

- Only ever sterilize dry textiles.
- The textiles may not be permitted to come into direct contact with the sterilization chamber; otherwise they will become saturated with condensate.

Reprocessing the instruments

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

Ensure the following when reprocessing used and brand-new instruments:

- Observe both the instrument manufacturer's instructions regarding reprocessing and sterilization as well as the relevant standards and directives (in Germany, for example, from RKI, DGSV and DGUV Regulation 1).
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after cleaning and disinfecting, where possible with demineralised or distilled water 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 ultrasonic devices, care equipment for handpieces and washer-disinfectors, comply with the manufacturer's reprocessing instructions.

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.

Frequency of sterilization

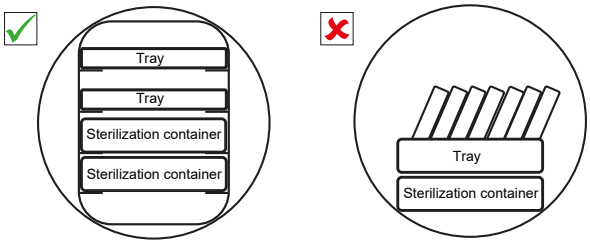
Pause times between the individual programs are not necessary, as the sterilization chamber is maintained permanently at the same temperature. After the end/abort of the drying time and removal of the sterile material, you can load the steam sterilizer again and start a new program.

Loading the steam sterilizer

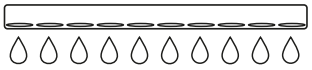
Effective sterilization and good drying is only possible if the steam sterilizer has been loaded correctly.

Ensure the following during loading:

- Insert trays or sterilization containers in the chamber only with their appropriate mount.



- Use perforated trays such as those from MELAG. Only in this way can condensate drain off. Non-perforated bases or half-shells for holding the sterilization material lead to poor drying results.



- The use of paper tray inserts can result in poor drying results.
- Wherever possible, ensure the separate sterilization of textiles and instruments in separate sterilization containers or sterilization packaging. This leads to better drying results.

Packaging

Only ever use packaging materials and systems (sterile barrier systems) which fulfil the standard EN ISO 11607-1. The correct use of suitable packaging is important in achieving successful sterilization results. You can use re-usable rigid packaging systems or soft packaging such as transparent sterilization packaging, paper bags, sterilization paper, textiles or fleece.

Closed sterilization containers

WARNING

Risk of contamination due to insufficient steam penetration or poor drying.

- Use only suitable sterilization containers.
- Do not cover the perforations when stacking the sterilization containers so that the condensate can drain off.

Please comply with the following when using closed sterilization containers:

- Use aluminium sterilization containers. Aluminium retains and conducts heat and thus accelerates drying.
- Closed sterilization containers must be either perforated or have a valve on at least one side. MELAG sterilization containers (e.g. MELAstore Boxes) fulfil the requirements for successful sterilization and drying.
- Wherever possible, ensure that sterilization containers are only stacked on top of those of identical size, so that the condensate can run down their sides.
- Ensure that the perforations are not covered when stacking the containers.

Tip: MELAG sterilization containers fulfil the requirements of EN 868-8 for successful sterilization and drying. They have a perforated lid and base and are fitted with disposable paper filters.

Soft sterilization packaging

Soft sterilization packaging can be used in both sterilization containers and on trays. Please comply with the following when using soft sterilization packaging e.g. MELAfol:

- Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.
- Place transparent sterilization packages on their edge wherever possible and with the paper side facing downwards.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- When loading the steam sterilizer, make sure that either the film or paper sides of different bags are facing each other.
- If the seam seal tears during sterilization, this could be caused by the choice of undersized packaging. Re-pack the instruments with larger packaging and perform sterilization again.
- Should the seam seal rip during sterilization, extend the sealing pulse on the sealing device or make a double seam.

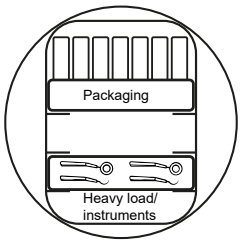
Multiple wrapping

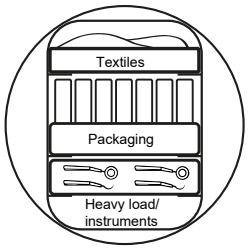
The device works with a fractionated vacuum procedure. This permits the use of multiple wrapping.

Mixed loads

Observe the following when sterilizing mixed loads:

- Always place textiles at the top.
- Place the sterilization containers at the bottom.
- Place unwrapped instruments at the bottom.
- Place the heaviest loads at the bottom.
- Place transparent sterilization packaging and paper bags at the top - except in combination with textiles. In this case, place them at the bottom.





Selecting the program

You can switch between the initial state and the desired program using the program selection key 'P'.

Now select the sterilization program according to how and whether the sterilization material is wrapped. It is also necessary to take into account the temperature resistance of the sterilization material.

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

Overview of sterilization programs

	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Sterilization temperature	134 °C	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2.1 bar	2.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	5:30 min	5:30 min	3:30 min	20:30 min	20:30 min
Operating time[3)]	approx. 30 min	approx. 30 min	approx. 15 min	approx. 40 min	approx. 45 min
Drying	approx. 20 min	approx. 10 min	approx. 5 min	approx. 20 min	approx. 20 min

Overview of the use of the respective sterilization programs

Program name	Packaging	Especially suitable for	Load 24 B+/30 B+
Universal-Program	Single and multiple wrapping	Mixed load, long narrow-bore hollow bodies	7 kg / 5 kg
Quick-Program B	Single wrapped and unwrapped instruments (no textiles)	Long narrow-bore hollow bodies	single wrapped max. 1.5 kg unwrapped 7 kg / 5 kg
Quick-Program S	Only unwrapped (no textiles)	single massive instruments; simple hollow bodies	7 kg / 5 kg
Gentle-Program	Single and multiple wrapped	Textiles, thermo-unstable items (e.g. plastic, rubber articles); mixed loads	Textiles 2.5 kg / 2 kg Thermo-unstable equipment 7 kg / 5 kg

[3)] without drying, with a full load and dependent on the load and set-up conditions (e.g. cooling water temperature, if a fixed water connection is present, and mains voltage)

Program name	Packaging	Especially suitable for	Load 24 B+/30 B+
Prion-Program	Single and multiple wrapped	Instruments under suspicion of carrying the danger of infection through abnormally altered proteins (e.g. Creutzfeld-Jacob, BSE)	7 kg / 5 kg

Additional program options

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.

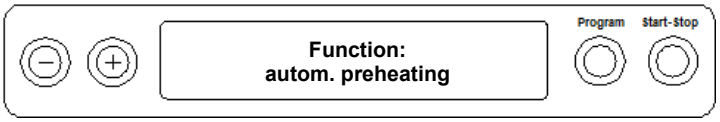
PLEASE NOTE

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 `Function` menu by pressing the '+' and '-' keys simultaneously until the display shows `Function: Last batch number`.
2. Navigate using the '+' or '-' key until the display shows:

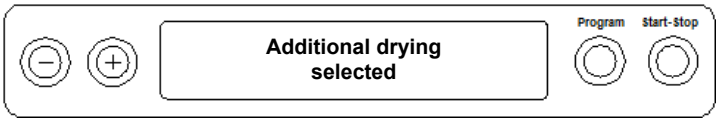


3. Press the 'P' key to confirm.
   ➥ The display will show the option currently set e.g. `Preheating YES`.
4. Pressing the 'P' key again makes the display switch to `Preheating NO`.
   ➥ The preheating function has been deactivated.
5. Press the 'S' key twice to leave `Function: Autom. preheating` and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



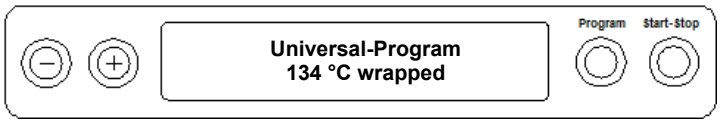
The program run will now begin.

Starting the program

NOTICE

Unsupervised operation of electrical devices, including this steam sterilizer at the operator's risk. MELAG accepts no liability what so ever for any damage resulting from unsupervised operation.

After having selected a program via the program selection key 'P', the display will show both the selected program and sterilization temperature as well as whether the program is suitable for wrapped or unwrapped loads.



- Press the 'S' key to start the program.
  The steam sterilizer checks the feed water supply and its conductivity.

PLEASE NOTE

When the Quick-Program S is started, the warning message `Attention: Unwrapped instruments only` appears on the display.

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

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 tray lifter to remove the tray.
- Never touch the sterile material, the sterilization chamber or the door with unprotected hands. The components are hot.

NOTICE

Aborting a running program by switching off the power switch can result in the egress of hot steam from the sterile filter and will cause the soiling of the sterile filter.

- Never abort a program by switching off at the mains.

Program abort before the start of drying

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.

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`**.

3. 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.

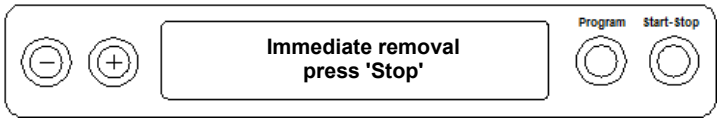
➥ The log will contain: **`Program stopped`** / **`Load not sterile!`**

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 fault.

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 is possible. Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

The drying time completed thus far is indicated on the display during the drying phase. This will alternate with the display of:



Proceed as follows to abort the program during drying:

1. Press the 'S' key.

PLEASE NOTE

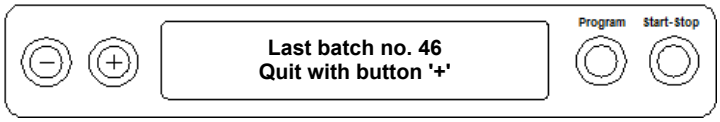
The security query will be displayed for approx. 5 s. If the 'S' key is not pressed repeatedly, the program will continue with the usual program run.

---

2. Confirm the following security query **`Immediate removal 'Stop'`** by pressing the 'S' key again.

   ➥ The display confirms the abort with **`Drying stopped`**.

After ventilation of the chamber, the display will show: **`Universal-Program run successfully`** in alternation with:



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.

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 red brochure of the Arbeitskreis für Instrumentenaufbereitung (AKI), the tolerable residual moisture is – in practice – a few drops of water capable of evaporating within 15 min, but actual pools of water are not acceptable.

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 tray lifter to remove the tray.
- Never touch the sterile material, the sterilization chamber, the mount or the inside of the door with bare hands. The components are hot.
- Check the packaging of the sterilized equipment 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 approx. 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 operating manual of the respective device.

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.*

✓ *The documentation software MELAview/MELAtrace is installed on the computer.*

PLEASE NOTE

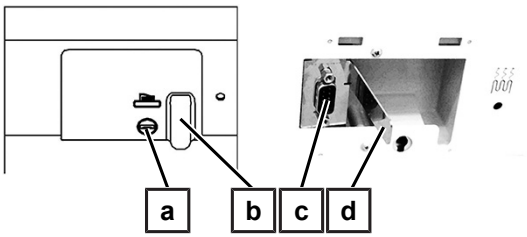
The MELAnet Box is required for integration in the (practice) network.

1. Open the door of the steam sterilizer.
2. Open the white cover of the serial data and printer connection on the steam sterilizer: To do this, use a coin to turn the locking slot (pos. a) on the white cover a quarter of a turn.
3. Remove the cover.
4. Push the metal frame (pos. d) downwards slightly until it unlocks and then fold the metal frame forwards.

5. Push the metal frame (pos. d) downwards slightly until it snaps into place and can no longer fold back independently.
6. Connect the steam sterilizer to the RS232 interface (pos. c) to the computer with a fitting data connection cable.

PLEASE NOTE

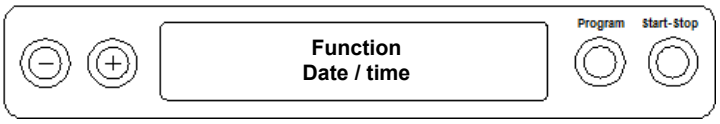
If the computer is constantly connected to the steam sterilizer, you can insert the serial cable in the cable guide (pos. b), fold in the metal strap and replace the cover.



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:

1. Select the menu **`Function`** by pressing the '+' and '-' keys simultaneously.
   ➥ The display will show the message **`Function: Last batch number`**.
2. Navigate in the **`Function`** menu using the '+' or '-' keys until the display shows:



3. Press the 'P' key to confirm.
   ➥ The current hour is displayed.
4. 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.

9 Function tests

Batch-related tests

Test body system MELAcontrol helix and MELAcontrol Pro

The test body system MELAcontrol Helix is an indicator and batch control system fulfilling the requirements of EN 867-5. It consists of a test body and an indicator strip.

When sterilizing category “critical B” instruments, you should add the MELAcontrol Helix or MELAcontrol Pro test body system to every sterilization cycle as a batch control.

Regardless of this, you can perform a steam penetration test in the Universal-Program at any time using MELAcontrol Helix or MELAcontrol Pro.

Intended use of the test body system can result in the colouration of the plastic surface. This colouration exercises no influence on the functionality of the test body system.

Vacuum test

The test detects leaks in the steam sterilizer. This determines the leakage rate at the same time.

Perform a vacuum test in the following circumstances:

- Once a week in routine operation
- During commissioning
- Following longer operating pauses
- In the case of a corresponding malfunction (e.g. in the vacuum system).

Perform the vacuum test with the steam sterilizer in a cold and dry state as follows:

1. Switch on the device at the power switch. The display switches to its initial state.
2. Press the 'P' key until the display shows **`Vacuum test`**.
3. Close the door.
4. Press the 'S' key to start the vacuum test.

➥ The evacuation pressure and the equilibration time or measurement time are shown on the display. The chamber is ventilated after the end of the measuring time. Then the message will be shown on the display with an indication of the leakage rate. Should the leakage rate be too high i.e. over 1.3 mbar, a corresponding message will be shown on the display.

Bowie & Dick test

The Bowie & Dick test serves as proof of steam penetration of porous materials such as e.g. textiles. We recommend this test for the sterilization of large quantities of textiles.

Specialist stockists provide various test systems for the Bowie & Dick test. Perform the test according to the test system manufacturer's specifications.

Starting the Bowie & Dick test program:

1. Switch on the device at the power switch.
2. Select the **`Bowie & Dick Test`** by repeated depression of the 'P' key.
3. Press the 'S' key to start the Bowie & Dick test.

Checking the 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 **`Conductivity`** appears. The conductivity is displayed in µS/cm.

10 Maintenance

Servicing intervals

Interval	Measure	Device components
Daily	Check for soiling, deposits or damage	Chamber inc. door seal and chamber sealing face, door lock, mount for the load
After 24 months or 1000 cycles	Maintenance	By the authorized customer services working in accordance with the maintenance instructions
As required	Cleaning the surfaces	Housing parts

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.

Sterilization chamber, chamber sealing face, mount, trays

To maintain the value of your device and to avoid persistent contamination and deposits, MELAG recommends weekly cleaning of the surfaces (e.g. with the MELAG chamber cleaning set).

Cleaning the sterilization chamber, chamber sealing face, mount and trays

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.*
- ✓ *Trays or sterilization containers and the associated mount have been removed from the sterilization chamber.*

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 door seal with neutral liquid detergent.

Housing parts

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

External water storage container

Should you use the external water storage container for the feed water supply, perform regular checks and cleaning as follows:

Interval	
Upon every refill	Check the storage container for soiling. Clean any soiling before refilling the storage container.
At least once a month	Depending on the light, ambient temperature and consumption, clean the external water storage container to prevent the development of germs and algae. To do so, empty the container and clean it with approx. 3 l of warm tap water with a neutral cleaning agent and a suitable brush. Rinse with a large quantity of tap water at least twice. Always rinse the storage container with a litre of feed water after completing the cleaning.

Maintenance

NOTICE

Continuing operation beyond the maintenance interval can result in malfunctions in the device.

- Maintenance should only be performed by trained and authorized service technicians or stockist technicians.
- Maintain the specified servicing 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 month intervals or after 1000 program cycles. The steam sterilizer will issue a maintenance message at the relevant time.

11 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 weekend	▪ Switch off the steam sterilizer ▪ Leave the door ajar to prevent premature wear and the sticking of the door seal ▪ Shut off the cooling water inflow and if present, the water inflow to the water treatment unit
Longer than two weeks	▪ Switch off the steam sterilizer ▪ Leave the door ajar to prevent premature wear and the sticking of the door seal ▪ Shut off the cooling water inflow and if present, the water inflow to the water treatment unit Upon re-commissioning: ▪ Perform a vacuum test ▪ After a successful vacuum test, perform an empty sterilization run in Quick-Program B

After pauses, perform the checks described in chapter Function tests [▸ page 28] depending on the length of pause.

Transport

Transport within the practice

NOTICE

Failure to observe these provisions can result in damage to the device and malfunction.

Comply with the following provisions when transporting within a room or the practice:

- ▶ When using a water treatment unit and/or an outlet hose, close the water inflow and remove the hose connections on the rear of the device.
- ▶ Should you wish to leave the mount and trays or sterilization containers in the sterilization chamber during transport, protect the surface of the round blank. To do so, place e.g. some foam or bubble wrap between the round blank and mount.
- ▶ Close the device door before moving the device.

Transport over long distances

NOTICE

Damage to the housing and the device interior as a result of using unsuitable transport packaging.

- ■ Only transport the device in its original packaging or other suitable packaging.

Comply with the following provisions when transporting the steam sterilizer (e.g. a move or dispatch):

- Before transporting the steam sterilizer over long distances, before dispatch or given the danger of frost, an authorized technician must prepare the device in accordance with the instructions and empty the storage tank entirely.

12 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

Warnings are not malfunction messages. They help to ensure malfunction-free operation and to recognize undesirable situations. Comply with these warnings 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.

Ensure that you have complied with all instructions relating to a warning or malfunction message issued by the display of the device. Should your efforts do not redress the problem, you can contact your nearest stockist or a local authorized MELAG customer service provider. Please have your device serial number and a detailed description of the malfunction contained in the notification to hand.

13 Technical data

Device type	Vacuklav 24 B+	Vacuklav 30 B+
Device dimensions (H x W x D)	49.5 x 42.5 x 70.5 cm	49.5 x 42.5 x 66 cm
Empty weight	48 kg	45 kg
Operating weight	55 kg	50 kg
Sterilization chamber		
Diameter	25 cm	
Depth	45 cm	35 cm
Volume	22.6 l	17 l
Electrical connection		
Electricity supply	220-240 V, 50/60 Hz	
Max. voltage range	207-253 V	
Electrical power	2100 W	
Building fuses	separate power circuit with 16 A fuse, 30 mA RCD protection	
Overvoltage category	transient overvoltage up to the values of overvoltage category II	
Degree of air pollution (acc. to EN 61010-1)	category 2	
Length of power cable	1.35 m	
Ambient conditions		
Installation location	interior of a building	
Noise emission	63 dB(A)	
Waste heat (with max. load)	0.6 kWh	
Ambient temperature	5-40 °C (recommended max. 25 °C)	
Relative humidity	max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative humidity at 40 °C	
Degree of protection (acc. to IEC 60529)	IP20	
Max. altitude	2000 m	
Cold water connection		
Water quality	drinking water	
Recommended flow pressure	2.0-4.0 bar at 3 l/min	
Min. flow pressure	> 1.2 bar at 3 l/min	
Max. water pressure (static)	10 bar	
Max. water consumption[4)]	approx. 57.5 l	
Max. water temperature	20 °C (ideal 15 °C)	
Feed water connection		
Water quality	distilled or demineralised feed water in accordance with EN 13060, Appendix C (with central demineralisation system max. conductivity 5 µS/cm)	
Recommended flow pressure	1.5 bar at 3 l/min	
Min. flow pressure	corresponding to the water treatment unit	
Min. water pressure (static)	corresponding to the water treatment unit	
Max. water pressure (static)	10 bar	
Max. water consumption[4)]	approx. 720 ml	approx. 770 ml
Wastewater connection		
Max. water temperature	short-term 90 °C	
Max. flow rate	short-term approx. 3.3 l/min	

[4)] In the Prion program with porous full load.

MELAG Medizintechnik GmbH & Co. KG

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Original instructions

Your stockist

KBA_24B+_30B+_EN.pdf | Rev. 9 - 21/4787 | Modification date: 2022-03-18