Operating Manual

Vacuklav® 23 B+
Vacuklav® 31 B+

Steam sterilizer

from software version 5.15

EN

Dear doctor,

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 treatment 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 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.

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.

Symbols on the device

Manufacturer of the medical device

Date of manufacture of the 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

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 products 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 medical 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. In affixing this symbol, the manufacturer furthermore declares that he has satisfied all the legal requirements pertaining to the release, redemption and environmentally sound disposal of electric and electronic appliances.
MELAG devices are synonymous for long-term quality. When you eventually need to decommission your MELAG device, we offer a special disposal service. Simply contact your stockist.

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 decontamination, the sterilization of instruments and textiles using this steam sterilizer may only be carried out by competent personnel.

Carrying the steam sterilizer

- Two people are necessary to carry the device.
- Use a suitable carrying strap to transport the device.

Malfunctions

- If repeated malfunction messages occur while operating the steam sterilizer, turn the device off and notify your specialist dealer.
- Only have the steam sterilizer repaired by authorised persons.

Set-up, installation and commissioning

- Check the device for any damage suffered during transport after unpacking.
- The device should only be set-up, installed and commissioned by MELAG authorized persons.
- The connections for electrical provision and water supply and effluent must be set-up by trained personnel.
- Use of the optional leak detector (water stop) minimizes the risk of water damage.
- In accordance with current VDE specifications, the device is unsuitable 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 and plug should only be replaced by authorized personnel.
- 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.

Decontamination and sterilization

- Follow the manufacturer instructions of your textile articles and instruments regarding their decontamination and sterilization.
- Observe the relevant standards and directives for the decontamination and sterilization of textiles and instruments, e.g. RKI [Robert Koch Institute] and DGSV [German Society for Sterile Supply].
- Only ever use packaging material and systems which have been approved by their manufacturer for steam sterilization.

Program termination

- 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 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 steam sterilizer. If necessary, sterilize the affected objects after rewrapping.

Removing the sterilized equipment

- Never use force to open the door.
- Use a tray jack to remove the tray. Never touch the sterilized items, the chamber or the door with unprotected hands. The components are hot.
- Check the packaging on the sterilized equipment for damage when removing it from the steam sterilizer. Should the packaging be damaged, re-pack the sterilization material 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

- Have the maintenance done only by authorized persons.
- Maintain the specified servicing intervals.
- Only original MELAG spare parts may be used.

Malfunctions

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.
- Only have the device repaired by authorized persons.

3 Performance specifications

Intended use

This steam sterilizer is designed for application in a medical context, e.g. general practitioners and dental practices. DIN EN 13060 classifies this steam sterilizer is a Class B sterilizer. 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 instruments with narrow lumen and transfer instruments - both wrapped or unwrapped - and large quantities of textiles.

WARNING

Any attempt to sterilize liquids can result in a delay in boiling. This can result in damage of the steam sterilizer and burns.

- Never use this steam sterilizer to sterilize any fluids. It is not licensed for the sterilization of fluids.

Overview of sterilization programs (class B)

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 DIN EN 13060.

Type tests	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Program type in accordance with DIN 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 DIN EN 13060					

4 Description of the device

Views of the device

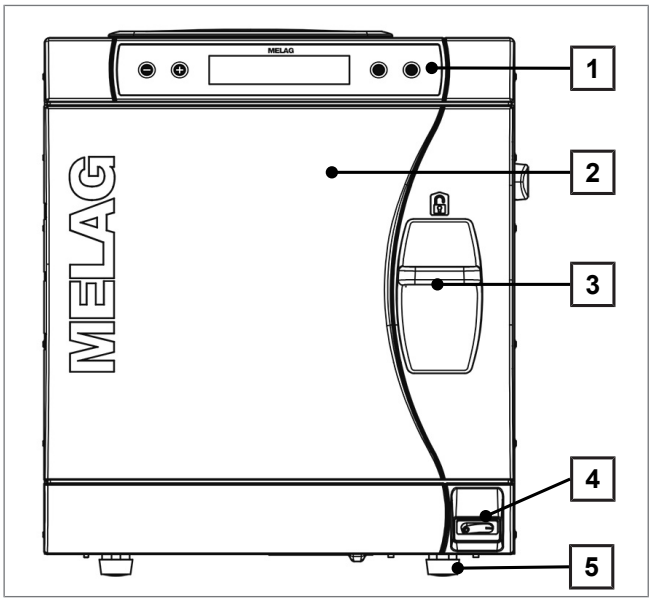


Fig. 1: View from front

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

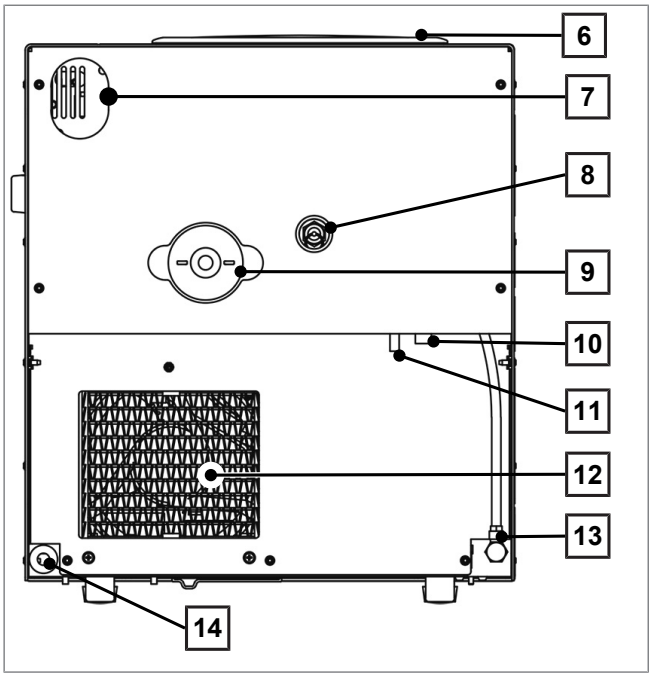


Fig. 2: View from rear

6 Tank lid
7 Slot for optional upgrade with the safety combination EN 1717
8 Spring safety valve
9 Sterile filter
10 Emergency overflow hose
11 One-way drain (optional)
12 Cooler
13 Feed water inflow for the water treatment unit
14 Power cable

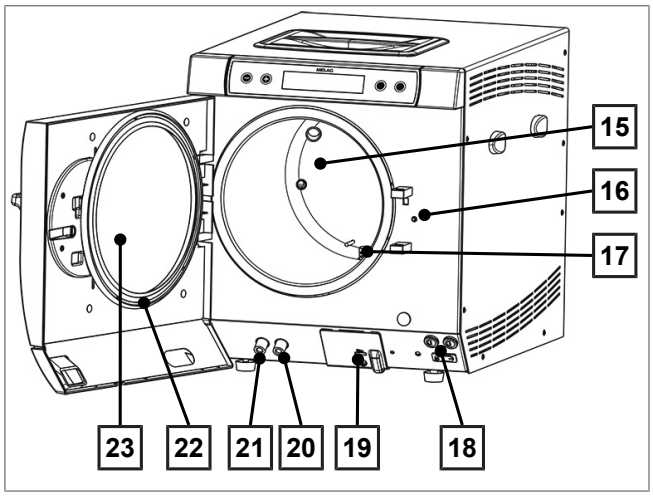
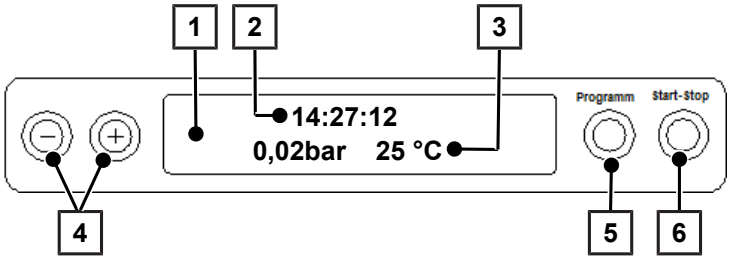


Fig. 3: View of the interior

15 Chamber
16 Door locking pin
17 Chamber sealing face
18 2x Device fuses
19 Serial data and printer connection (RS232)[1)]
20 Connection for emptying the internal storage tank - feed water
21 Connection for emptying the internal storage tank - waste water
22 Door seal
23 Round blank

Operating panel

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



1 **2-row LC display**
for display of 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: printing, date / time, pre-heating, total batches, conductivity, acknowledge malfunction, '+' 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

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

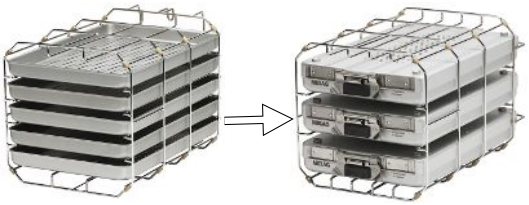
[1)] hidden behind white cover

Load mounts

The steam sterilizer is always delivered with a mount for holding trays or cassettes. Detailed information regarding the various mounts, their combinability with various load holders and their application can be found in the operating manual “Usage instructions for mounts”.

Mount A "Plus"

The mount (A "Plus") is standard and can accommodate either five trays or three standard tray cassettes when turned 90˚.

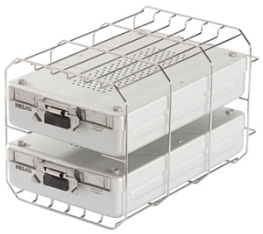


Mount B

The mount (B) can accommodate four standard tray cassettes or four trays.

Mount D

The mount (D) can accommodate two high cassettes (e.g. implant cassettes) or four trays (if turned 90°).



5 Installation requirements

Installation location

WARNING

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

- The steam sterilizer should only be setup, installed and commissioned by persons authorized by MELAG.
- In accordance with current VDE specifications, the steam sterilizer is unsuitable for operation in areas exposed to the danger of explosion.
- 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.

Properties	Vacuklav 23 B+	Vacuklav 31 B+
Set-up surface	level and horizontal	
Installation location	dry and dustproof	
Floor loading (normal operation)	2.3 kN/m²	2.7 kN/m²
Max. height	2000 m	
Waste heat (with maximum load)	0.9 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	

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

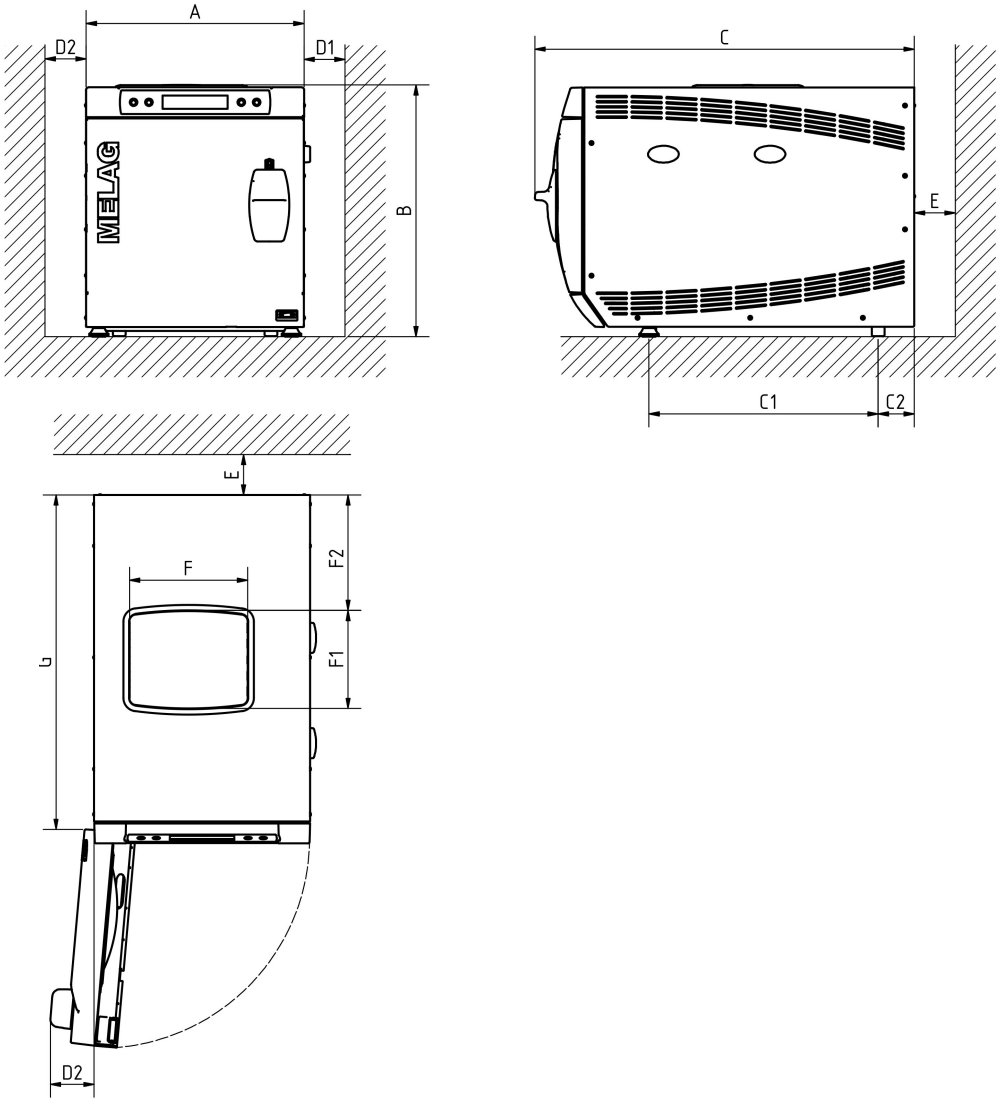


Fig. 4: View from the front, the right and above

Dimensions		Vacuklav 23 B+	Vacuklav 31 B+
Width	A	42.5 cm	
Height	B	49 cm	
Depth, total	C	74 cm	62 cm
Clearance between the device feet	C_1	45 cm	37 cm
Clearance from rear device foot up to the rear panel	C_2	7 cm	8 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	10 cm	
Tank lid (width)	F	23 cm	
Tank lit (depth)	F_1	19.5 cm	
Tank lid (clearance to the rear)	F_2	23 cm	
Free area with a fully-opened door	G	66 cm	54 cm
Chamber diameter/depth	--	Ø 25 cm | 45 cm	Ø 25 cm | 35 cm

The area above the steam sterilizer should be freely accessible in order to enable easy filling of the storage tank and good ventilation.

The steam sterilizer works with a cooler on the rear of the device for the cooling system. The function and life-span of the steam sterilizer can be affected if the heat dissipation above the cooler is restricted in any way. As such, we advise against installation of the steam sterilizer; this is only possible if sufficient air circulation is ensured.

6 Installation

Setup and installation

Record of installation and set-up

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.

Aligning the steam sterilizer

To enable fault-free operation, the steam sterilizer must be setup level using a spirit level placed on the chamber flange. Then extend the fore device feet by five (Vacuklav 23 B+/ 24 B+) or three (Vacuklav 30 B+/ 31 B+) revolutions to effect a slight rearwards slope of the steam sterilizer.

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 power 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 and plug should only be replaced by authorized personnel.

Table 1: On-site requirements of the mains connection

Properties	On-site requirements
Electricity supply	Socket with 220-240 V, 50/60 Hz, 2100 W*)
Building fuses	Separate power circuit with 16 A, FI protection 30 mA (to guarantee continued practice operation during steam sterilizer malfunction)
Other	Additional socket for the MELAprint 42/44 log printer etc.
Length of power cable	1.35 m

*) Max. voltage range 207-253 V

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

Water connection

Table 2: Requirements for the water connection

	Feed water	Wastewater
Connection in the practice	To a water treatment unit e.g. MELAdem	Manual emptying via the internal storage tank. Optional: automatically via the one-way discharge with the MELAG upgrade kit for the tank drain. Wall outlet, nominal width DN 40 or to a siphon (flush outflow)
Installation height	--	Min. 30 cm under the steam sterilizer
Max. water temperature	--	70 °C
Recommended flow pressure	1.5 bar at 3 l/min	--
Min. water pressure (static)	Corresponding water treatment unit[2)]	--
Max. water pressure (static)	10 bar	--
Max. consumption per program cycle[3)]	c. 700 ml (23 B+) c. 600 ml (31 B+)	--
Water quality	Distilled or demineralized water in accordance with DIN 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 DIN EN 1717)	

Table 3: When using a water treatment unit

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

PLEASE NOTE

The wastewater hose must be fitted at a constant decline without 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 water, known as feed water. DIN EN 13060 requires that feed water be used in accordance with the guideline values in appendix C.

The feed water supply is effected either via the internal feed storage tank or via a separate water treatment unit (e.g. MELAdem 40 / MELAdem 47). When using the internal storage tank for the feed water supply, it is necessary to refill it periodically. The steam sterilizer will issue notification at the relevant time. The internal storage tank holds 5 l and is sufficient for up to 7 sterilization runs in a one-way system.

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. There is no need to fill the feed water container manually.

[2)] Optional when using a water treatment unit.
[3)] In the Prion-Program a with porous full load.

7 Sterilization

Switching on the steam sterilizer

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

- The steam sterilizer is switched on at the power switch.

The display switches between the initial state and the notification `Unlock door with '+' key`, if the door is closed.

PLEASE NOTE

All accessories must be removed from the chamber directly after the steam sterilizer has been switched on for the first time and before initial commissioning.

After device activation, a heating up time of c. 5 minutes 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 three seconds before switching it back on.

Preparing the sterilization material

Cleaning and disinfection must always have been performed before sterilization. Only in this way is it possible to guarantee the subsequent sterilization of the sterilization material. The materials used, the cleaning fluid and treatment procedures used are of decisive significance.

NOTICE

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

Decontaminating textiles

WARNING

The incorrect decontamination of textiles, e.g. a textile package can prevent steam penetration and/or produce poor drying results. The textiles could not be sterilized.

This could endanger the health of patient and practice team.

Please comply with the following points when treating textiles and putting the textiles in sterilization containers:

- Comply with both the manufacturer's instructions of the textiles regarding treatment and sterilization as well as the relevant standards and directives 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.
- Retain the vertical stacking system when packing textiles in the sterilization container.
- 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.

Decontaminating the instruments

WARNING

The incorrect decontamination of instruments could result in any dirt residue being loosened by the steam pressure during sterilization.

The use of unsuitable care agents e.g. water repellent agents or oils impermeable to steam could result in unsterile instruments. This represents a danger to the health of both patients and yourself.

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.

Please ensure the following when treating used and brand-new instruments:

- Follow both the instrument manufacturer's instructions regarding decontamination and sterilization and comply with the relevant standards and directives e.g. from the BGV A1, RKI and DGSV.
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with de-mineralized 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 ultrasound devices, care equipment for handpieces and washer-disinfectors, please comply with the manufacturer's treatment instructions.

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 sterilized equipment, 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 cassettes in the chamber only with their appropriate mount.
- Use perforated trays such as those from MELAG. Only in this way can condensate drain off. The use a non-perforated base or half-shell to accommodate the sterilization material can result in poor drying results.
- The use of paper tray inserts can also result in poor drying results.
- Wherever possible, please 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 DIN 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 such as e.g. standard tray cassettes or soft packaging such as transparent sterilization packaging, paper bags, sterilization paper, textiles or fleece.

Closed sterilization containers

CAUTION

The use of unsuitable sterilization containers results in insufficient steam penetration and even failure of the sterilization. This can also prevent condensate drain-off.

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

CAUTION

Incorrect stacking of the sterilization containers can result in the dripping condensate being unable to drain off to the chamber floor. This can saturate sterilization material directly underneath it.

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

- Do not cover the perforations when stacking the sterilization containers.

Please comply with the following when using closed sterilization containers for sterilization material:

- 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 - optimally the bottom. MELAG sterilization containers fulfil the requirements for successful sterilization and drying.
- The perforations of one-sided perforated sterilization containers should be at the top of any containers such as with MELAstore-Boxes.
- Wherever possible, please 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 DIN 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.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- If the seam seal tears during sterilization, this could be caused by the choice of undersized packaging. Should this not be the case, re-pack the instruments and sterilize them again.
- Should the seam seal rip during sterilization, extend the sealing pulse on the film sealing device or make a double seam.

Multiple wrapping

The steam sterilizer works with a fractionated pre-vacuum procedure. This permits the use of multiple packaging.

Mixed loads

Please 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.
- Place transparent sterilization packages on their edge wherever possible and with the paper side facing downwards.

Selecting the program

You can switch between the initial state and the desired program using the program selection switch ‘P’.

Now select the sterilization program according to how and whether the sterilization material is packed. 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.

Table 4: Overview of the 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 [4)]	c. 30 min.	c. 30 min.	c. 20 min.	c. 45 min.	c. 45 min.
Drying	20 min.	10 min.	c. 5 min.	20 min.	20 min.

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

Table 5: Overview of the use of the respective sterilization programs

Program name	Packaging	Especially suitable for	Load
Universal-Program	Single and multiple wrapping	Mixed loads, transfer instruments, products with narrow lumen, simple hollow bodies	5 kg Instruments 1.8 kg Textiles
Quick-Program B	Single wrapped and unwrapped instruments (no textiles)	Transfer instruments, products with narrow lumen, simple hollow bodies	Single wrapping 1.5 kg Unwrapped 5 kg
Quick-Program S	Only unwrapped (no textiles)	Single massive instruments; simple hollow bodies	5 kg Unwrapped instruments
Gentle-Program	Single and multiple wrapped	Larger quantities of textiles; thermo-unstable equipment (such as plastic, rubber articles); mixed loads; products with narrow lumen, simple hollow bodies	1.8 kg Textiles or Thermo-unstable equipment 5 kg
Prion-Program	Single and multiple wrapped	Instruments under suspicion of carrying the danger of infection through abnormally altered proteins (e.g. Creutzfeld-Jacob, BSE), simple hollow bodies	5 kg Instruments 1.8 kg Textiles

Additional program options

Selecting automatic pre-heating

Automatic pre-heating is activated as standard. This function heats the steam sterilizer chamber to a pre-heating temperature of the respective programme, or holds this temperature between two program runs. This will shorten the cycle times.

PLEASE NOTE

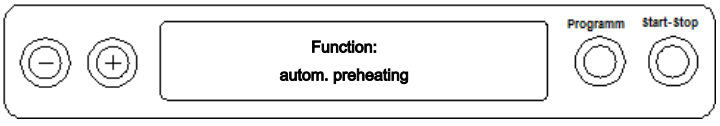
The steam sterilizer must remain continually activated for the automatic preheating.

PLEASE NOTE

MELAG recommends activating the automatic pre-heating function.

To alter this setting proceed as follows:

1. Select SETUP menu **`Function`** by pressing the '+' and '-' keys simultaneously until the display shows **`Function: Last batch number`**.
   Use the '+' or '-' keys to navigate to

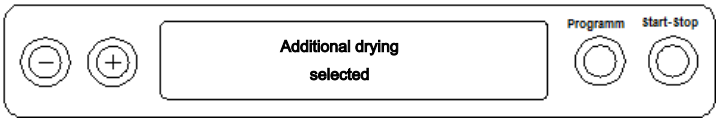


2. Press the ‘P’ key to confirm. The display will show the option currently set e.g. **`Preheating YES`**.
3. Pressing the ‘P’ key again makes the display switch to **`Preheating NO`**. The pre-heating function has been deactivated.
4. To end the **`Function: Autom. preheating`** menu and return to the initial state, press the 'S’ key twice.

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.
  The display will show:



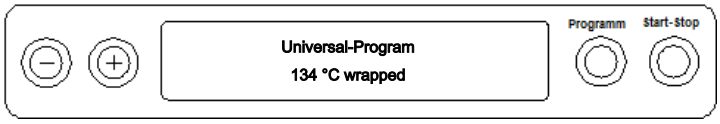
The program run will now begin.

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 sterilization material.



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

PLEASE NOTE

If the Quick-Program S has been started, the warning `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 end the program before drying begins, the sterilization material remains **unsterile**.

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.

WARNING

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

This could result in burns.

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

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.

- If necessary, repack the load and repeat the sterilization for the sterilization material affected.

Proceed as follows to abort the program during 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 shown on the display for approx. 5 seconds. If the ‘S’ key is not pressed repeatedly, 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 clear 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.

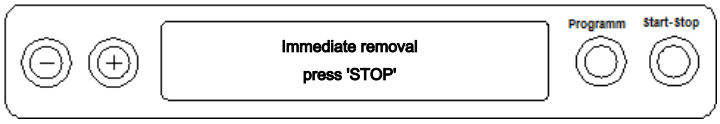
The log will contain: `Program stopped/ Load not sterile!`

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 sterilized equipment and a full load. Sterile storage requires sufficient drying. To ensure this, please allow programs with wrapped sterilized equipment 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:

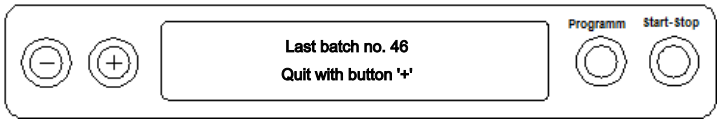
1. Press the ‘S’ key.
2. Confirm the following security query `Immediate removal 'Stop'` by pressing the ‘S’ key repeatedly.

The display confirms the abort with `Drying stopped`.

PLEASE NOTE

The security query will be shown on the display for approx. 5 seconds. If the ‘S’ key is not pressed repeatedly, the program will continue with the usual program run.

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



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

Removing the sterilized equipment

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, re-pack the sterilization material and re-sterilize it.

If you remove the sterilized equipment 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 (AKI; red broschure 11. Edition; p. 57): "In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable."

Comply with the following specifications when removing the sterilized equipment:

- Never use force to open the door. This could damage the device and / or result in the emission of hot steam.
- Use a tray lifter to remove the tray.
- Never touch the sterilized equipment, the device interior or the inside of the the door with unprotected hands. The components are hot.
- Check the packaging on the sterilized equipment for damage when removing it from the device. Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

Storing sterile instruments

The maximum storage time is dependent on the packaging and the storage conditions. For standard-conform packaged sterilized equipment – (if protected from dust) it can amount to up to six months. Comply with the provisions of DIN 58953, part 8 and the criteria specified below for the storage of sterilized equipment:

- Comply with the maximum storage duration in accordance with the packaging type.
- Do not store the sterilized equipment in the decontamination room.
- Store the sterilized equipment in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterilized equipment in a moisture-protected environment (e.g. alcohol, disinfectant).
- Store the sterilized equipment in an environment protected against excess temperature variations.

8 Logging

Batch documentation

The batch documentation acts as proof of the successful conclusion of the program and represents an obligatory part of quality assurance (MPBetreibV). 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 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
- MELAprint 42/44 log printer
- MELAnet Box

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 print-outs) is specified in the appendant operating 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 white cover of the serial data and printer connection on the steam sterilizer.
2. To do so, insert a coin in the seal slot (pos. 2) in the white cover and turn a quarter of a revolution.
3. Remove the cover.
4. Push the metal frame downwards slightly until it unlocks and then fold the metal frame (pos. 4) forwards.
5. Connect the s to the RS232 interface (pos. 1) to the computer with a fitting data connection cable.

The data connection cable can be laid in the cable duct (pos. 3) to ensure constant connection of the computer to the steam sterilizer. The metal frame can be folded in and the cover can be closed.

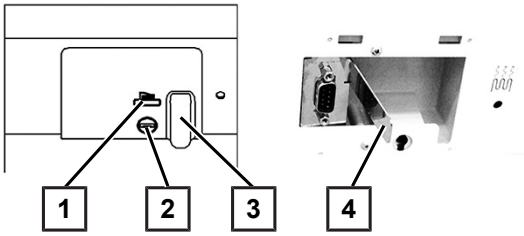
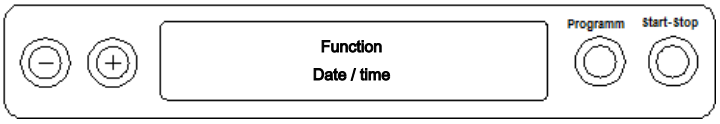


Fig. 5: Steam sterilizer connection

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 the clock change in autumn and summer, as this is not adjusted automatically. Set the date and time as follows:

1. Select SETUP menu **`Function`** by pressing the '+' and '-' keys simultaneously. The display will show **`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 '-' keys: 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 to save.
   The current value set no longer flashes on the display.
   Proceed in a similar fashion to alter the other parameters.
8. After ending the settings, press the 'S' key to leave the menu.
   The display will show **`Function: Date / Time`**.
9. Repeated pressing of the 'S' key enables you to leave the menu and the display returns to its basic state.

9 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. ▪ Push the door to prevent premature wear and the sticking of the door seal. ▪ If present, shut off the water inflow of the water treatment unit.
Longer than two weeks	▪ 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 30] depending on the length of pause.

10 Function tests

Batch-related tests

Helix test body system MELAcontrol / MELAcontrol PRO

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

When sterilizing category "critical B“ instruments, you should add the MELAcontrol / MELAcontrol PRO test body 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 / MELAcontrol PRO.

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

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 measuring times are shown on the display. The chamber will be 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 e.g. over 1.3 mbar, a corresponding message will be issued 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.

11 Maintenance

Servicing intervals

Interval	Measure	Device components
Weekly	Check for soiling, deposits or damage	Chamber inc. door seal and chamber sealing face, 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.

Door seal, chamber, chamber sealing face, mount, trays

Check the chamber, door seal, chamber sealing face and the load mount **once a week** for soiling, deposits or damage.

If you find any impurities, remove the trays or cassettes from the chamber from the front. Clean the soiled components.

When cleaning the chamber, load mount and chamber seal face, please comply with the following:

- Switch off the steam sterilizer before cleaning and remove the power plug from the socket.
- Ensure that the chamber is not hot.
- Use a soft, non-fuzzing cloth.
- First soak the cloth with the cleaning alcohol or spirit and attempt to wipe away impurities.
- Use a chlorine and vinegar-free cleaning fluid.
- Only if the chamber, mount or chamber sealing face has persistent soiling should you use a mild, non-scouring, stainless steel cleaning agent, with a pH value between 5 and 8.
- Use a neutral liquid cleaning agent to clean the door seal.
- You should not allow cleaning fluid to enter the piping coming from the chamber.
- Do not use any hard objects such as a metal saucepan cleaner or a steel brush.

Housing parts

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

Internal storage tank

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

Interval	
Upon every refill	Check the storage tank for soiling. If necessary, use a cloth and fresh feed water to clean the storage tank before filling.
Every 2 weeks	Clean the left-hand chamber of the storage tank (waste water).

PLEASE NOTE

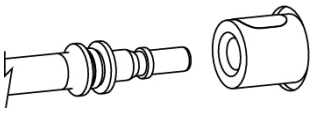
Keep the storage tank free of impurities.

Should you decide upon manual supply of the feed water via the internal storage tank, check the feed water side (the right-hand side) for soiling whilst refilling. If necessary, use a cloth and fresh feed water to clean the storage tank before filling.

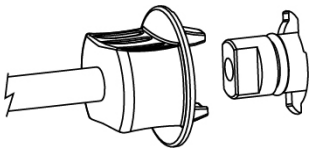
Empty both chambers of the storage tank as follows:

1. Remove the filling funnel underneath the tank lid.
2. Open the device door. Connect the drain hose to the bottom left-hand connection on the device (left-hand wastewater tank, right-hand feed water tank). The device is fitted with either two quick couplings or two bleed valves.

   Quick coupling:
   the drain hose clicks touch-perceptibly.

   Bleed valve:
   turn the drain hose anti-clockwise to its fullest extent.

3. Discharge the water into a container with min. volume of 5 litres.
4. Repeat the procedure for the other chamber if necessary.
5. Replace the filling funnel.
6. Comply with the following specifications to remove the drain hose:

CAUTION

Quick coupling: danger of injury when removing the drain hose

- To empty the storage tank, stand in front of the connection to one side.
- Press the grey release knob on the quick coupling. Hold the hose with one hand whilst pressing the release knob with the other. This dampens the spring force of the seal. The hose will free itself from the coupling on its own.

CAUTION

Bleed valve: danger of injury from knocking against the door when removing the drain hose

- Turn the hose connection back to the vertical position.
- Remove the drain hose with both hands by pulling the drain hose downwards lightly away from the device.

Maintenance

NOTICE

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

- Maintenance should only be performed by trained and authorized customer services 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 months intervals or after 1000 program cycles. The steam sterilizer will issue a maintenance message at the relevant time.

12 Malfunctions

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.

- If necessary, repack the load and repeat the sterilization for the sterilization material affected.

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 23 B+	Vacuklav 31 B+
Device dimensions (H x W x D)	49 x 42.5 x 74 cm	49 x 42.5 x 62 cm
Chamber diameter/depth	Ø 25 cm | 45 cm	Ø 25 cm | 35 cm
Chamber volume	22.6 l	17 l
Empty weight	50 kg	45 kg
Operating weight	60 kg	55 kg
Electricity supply	220-240 V, 50/60 Hz, 2100 W	
Building fuses	16 A, FI protection 30 mA	
Waste heat (with maximum load)	0.9 kWh	
Noise emission	65 dB(A)	
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	
Max. height	2000 m	
Length of the power cable	1.35 m	
Degree of protection (following IEC 60529)	IP20	
CE marking	CE 0197, CE 0035	
Feed water connection		
Water quality	distilled or demineralized feed water in accordance with DIN EN 13060, Appendix C. (with central demineralization system max. conductivity 5 µS/cm)	
Recommended flow pressure	1.5 bar at 3 l/min	
Min. water pressure (static)	corresponding water treatment unit[5)]	
Max. water pressure (static)	10 bar	
Max. water consumption[6)]	c. 700 ml	c. 600 ml
Waste water connection		
Max. water temperature	70 °C[7)]	
Volume storage tank	Feed water (right-hand chamber) 5 l (c. 7 cycles) Waste water side (left-hand chamber) 3 l	

[5)] Optional when using a water treatment unit.
[6)] In Prion-Program with porous full load.
[7)] Optional: automatically via the one-way discharge with the MELAG upgrade kit for the tank drain.

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Your stockist

KBA_23B+_31B+_10053_10051_EN.pdf | Rev. 8 - 18/2620 | Modification date: 2019-01-11