

# Technical Manual

## Vacuklav<sup>®</sup> 23 B+ Vacuklav<sup>®</sup> 31 B+

Steam sterilizer

from software version 5.20



EN

Read this manual carefully and in the correct order before setting up and commissioning the device. The instructions include important safety information. You also receive a user manual with the device. Please store this manual and the user manual carefully and in close proximity to the device. They represent a component of the product.

CE 0197



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# 1 General guidelines

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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](http://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.

## Formatting rules

Example	Explanation
see <b>Chapter 2</b>	Reference to another text section within this document.
Universal- Program	Words or phrases appearing on the display of the device are marked as display text.

## 2 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 23 B+	Vacuklav 31 B+
Installation surface	level and horizontal	
Installation location	interior of a building (dry and protected from dust)	
Floor loading (normal operation)	2.7 kN/m <sup>2</sup>	3.2 kN/m <sup>2</sup>
Max. floor loading (hydraulic pressure test)	3.4 kN/m <sup>2</sup>	3.9 kN/m <sup>2</sup>
Max. altitude	2000 m	
Waste heat (with max. 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	

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

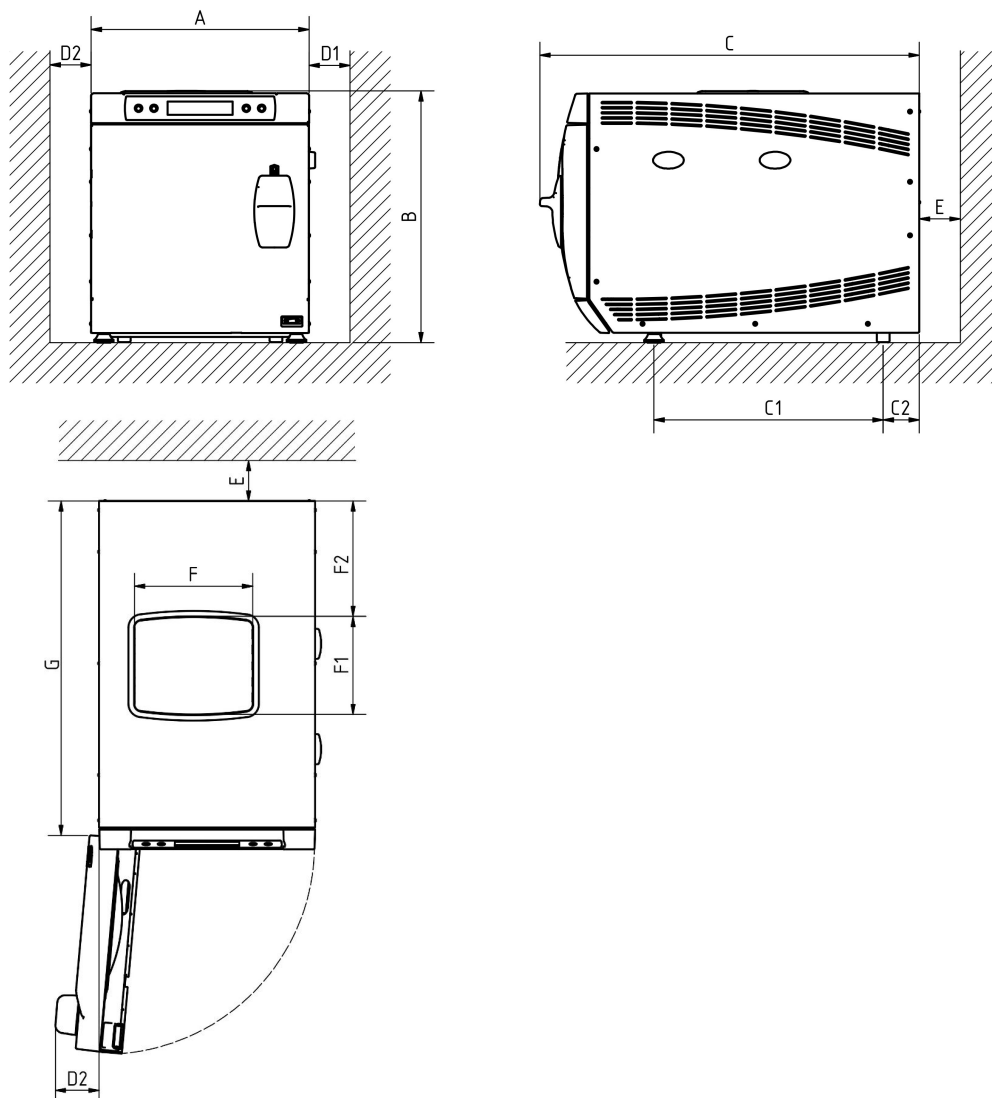


Fig. 1: View from the front, the right and above

Dimensions		Vacuklav 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 <sub>1</sub>	45 cm	37 cm
Clearance from rear device foot up to the rear panel	C <sub>2</sub>	7 cm	8 cm
Min. clearance to the side	D <sub>1</sub>	5 cm	
Min. clearance to the side of the door hinge	D <sub>2</sub>	10 cm	
Min. clearance to the rear	E	10 cm	
Tank lid (width)	F	23 cm	
Tank lid (depth)	F <sub>1</sub>	19.5 cm	
Tank lid (clearance to the rear)	F <sub>2</sub>	23 cm	
Free area with a fully-opened door	G	66 cm	54 cm
Min. clearance to the top (can be pulled out / with exhaust shaft)	--	5/20 cm	

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

The steam sterilizer works with a cooler on the rear of the device. The function and life-span of the steam sterilizer can be compromised if heat dissipation via the cooler is restricted in any way. The steam sterilizer may only be installed if sufficient air circulation can be guaranteed.

**Additional space requirement for the feed water supply**

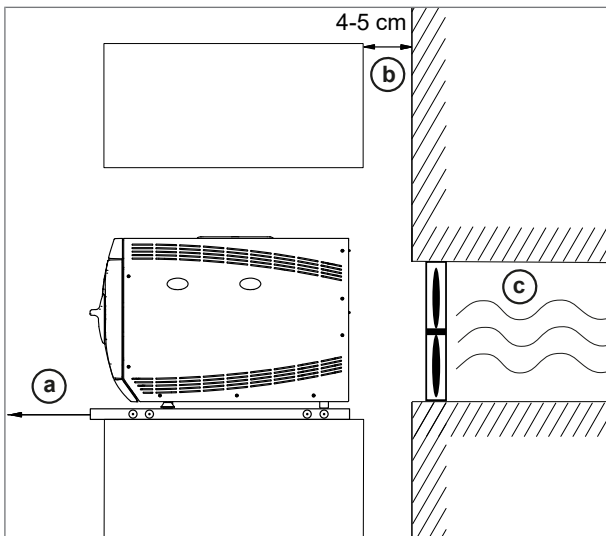
Additional space is required for a storage container or a water treatment unit. It is also necessary to guarantee free access to the hoses and cables leading from the steam sterilizer to the water treatment unit.

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

**Requirements for the installation of a device**

If the installation of the device is mandatory, one of the following measures must be implemented:

1. It must be possible to pull out the device for operation (pos. a).
2. There must be an exhaust air shaft in the rear area of the installation space that discharges the warm air upwards (pos. b).
3. There must be an exhaust air shaft in the rear area of the installation space that discharges the warm air to the rear (pos. c).



## On-site requirements

### 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

	Feed water	Wastewater
Connection in the practice	Manual filling via the internal storage tank  Optional: to a water treatment unit, e.g. MELAdem	Manual emptying via the internal storage tank.  Optional: automatically via the one-way outlet with the MELAG upgrade kit for the tank outlet  Wall outflow, nominal width DN 40 or to a siphon (flush outflow)
Installation height	--	min. 30 cm under the steam sterilizer
Max. water temperature	35 °C	70 °C
Recommended flow pressure	1.5 bar at 3 l/min	--
Min. water pressure (static)	corresponding to the water treatment unit <sup>1)</sup>	--
Max. water pressure (static)	10 bar	--
Max. water consumption <sup>2)</sup>	approx. 700 ml	--
Water quality	Distilled or demineralised water in accordance with EN 13060, Appendix C	--

<sup>1)</sup> Optional when using a water treatment unit

<sup>2)</sup> In the Prion program with porous full load.



**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.

**System and network safety**

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

**Interfaces and connections**



**NOTICE**

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

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



**NOTICE**

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

## Operating the device with memory media

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

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

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

Only use MELAflash CF cards.

## Operating the device in the local network (LAN)



### NOTICE

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

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



### NOTICE

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

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

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

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

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

## Network bandwidth / Quality of Service (QoS)

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

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

## 3 Setup and installation

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### WARNING

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

This could result in serious injury.

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

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### Removing from the packaging



### CAUTION

Danger of injury from incorrect carrying.

Lifting and carrying too heavy a load can result in spinal injury. Failure to comply with these provisions can result in crushing.

- The device should always be carried by two people.
- Use the correct carrying straps to carry the device.
- Comply with the safety regulations issued by your professional association.

1. Remove the steam sterilizer from the box using the carrying straps.
2. Unscrew the four screws from each side of the unit cover to remove the straps.
3. Then re-screw these screws without the flat washers.
4. Store the carrying straps and washers in a safe place.
5. Open the door and remove the trays and accessories immediately after switching on the device.

### Aligning the door seal sealing lips

Long periods of storage with the door closed can result in the sealing lips of the door seal becoming stuck. Align the sealing lips to prevent leaks.

Proceed as follows:

1. Remove the door seal.



2. Press your thumb between the two sealing lips and separate the sealing lips once around with your thumb.

**PLEASE NOTE**

Note the differences in the widths of the sealing surfaces when inserting the door seal. The door can only be shut correctly and the sterilization chamber sealed, if the door seal sits correctly in the groove.

3. Insert the door seal into the groove.



- ↪ The wide sealing surface points towards the chamber.

## Installation examples

The following pages provide examples for the recommended installation types for the feed water supply. The connection of a different water treatment unit producing the same water quality is possible after consultation with MELAG.

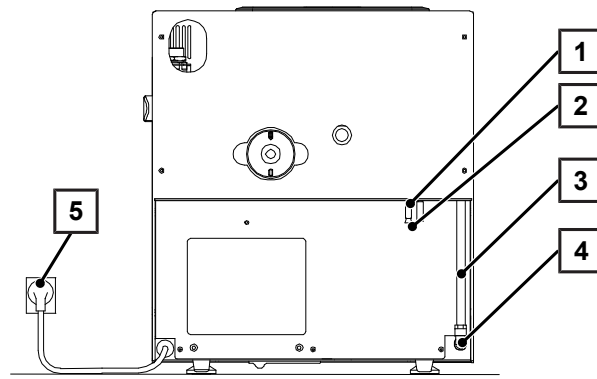
### Example 1 – feed water supply from the internal storage tank (delivery state)

Direct feed water supply from the internal storage tank without an additional water connection.

No further installation is required apart from the electrical connection.

The wastewater is collected in the left-hand side chamber of the storage tank and is to be emptied manually.

A float switch installed in the storage and wastewater tank notifies insufficient feed water or a full wastewater chamber.



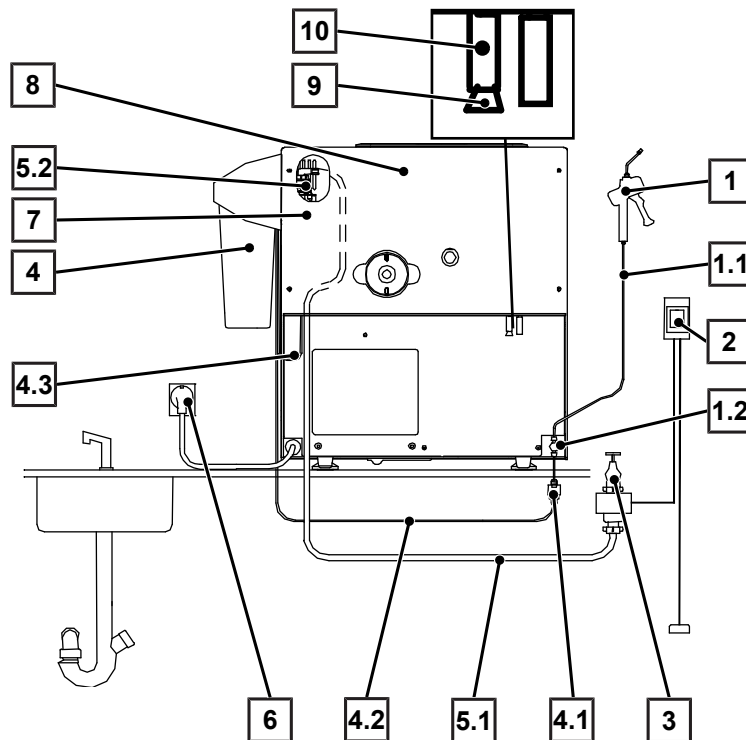
Pos.	Description	Art. no.
1	Silicon hose (9/6 mm, 5 m) <sup>*)</sup>	ME34410
2	Plug for water drain <sup>*)</sup>	ME31140
3	Feed water inlet hose <sup>*)</sup>	ME34410
4	Feed water connection, Vacuklav <sup>*)</sup>	ME21175
5	Mains connection <sup>**)</sup>	--

<sup>\*)</sup> present on the device side

<sup>\*\*)</sup> present on the building side

## Example 2 – feed water supply from the MELAdem 40 ion exchanger

The wastewater is collected in the left-hand side chamber of the internal storage tank and is to be emptied manually. In addition, the wastewater can be automatically discharged via the one-way drain (see [Example 3 – feed water supply from the MELAdem 47 reverse osmosis unit](#) ▶ page 16).



Position	Description	Art. no.	contained in
1	MELAJet spray pistol for MELAdem 40 (optional)	ME27300	--
1.1	PUR hose (black) 6/4 mm (hose MELAJet)	ME28820	ME27300
1.2	Swivel screw connection MELAJet	ME53465	ME27300
2	Water stop (Leak water detector with cut-off valve and sensor, optional)	ME01056	--
3	Water tap with safety combination**)	--	--
4	MELAdem 40 ion exchanger	ME01049	--
4.1	Filter for MELAdem	ME48240	ME01049
4.2	PUR hose (black) 6/4 mm (inlet hose feed water)	ME28820	ME01049
4.3	PUR hose (black) 6/4 mm (inlet hose MELAdem 40)	ME28820	ME01049
5	Mounting set (EN 1717) for MELAdem (optional)	ME25410	--
5.1	Tap water supply hose EN 1717, 2.5 m	ME24930	ME25410
5.2	Safety combination EN 1717 incl. holder	ME82375	ME25410
6	Mains connection**)	--	--
7	Cold water adapter 3/4" to 1/4" (direct connection water hose)	ME09037	--
8	Back part cover for Vacuklav 23 B+ / 31 B+*)	ME66790	
9	Plug for water drain*)	ME31140	--
10	Silicon hose (9/6 mm, 5 m*)	ME34410	--

\*) present on the device side

\*\*\*) present on the building side

**PLEASE NOTE**

Before converting from the standard version to a water treatment unit, you must first empty the feed water side (right-hand chamber) of the internal storage tank. With automatic one-way outlet, the wastewater side (left-hand chamber) must be emptied as well.

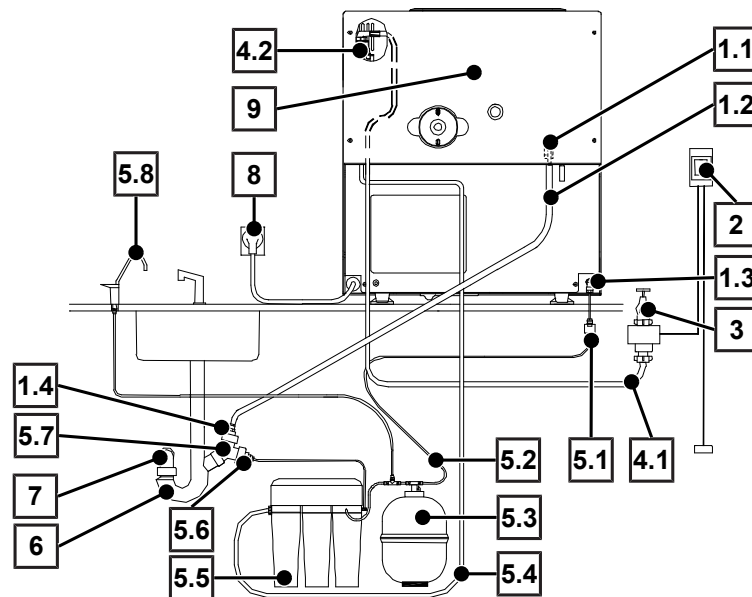
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***Attaching the safety combination in accordance with EN 1717***

1. Unscrew the back panel of the steam sterilizer.
2. Mount the safety combination (art. no. ME82375).
3. Connect the water inflow hose to the upper connection of the safety combination.
4. Connect the MELAdem 40 cold water adapter (art. no. ME09037) to the lower connection of the safety combination.
5. Connect the water inlet hose for the MELAdem 40 to the MELAdem 40 cold water adapter.
6. Guide the hoses through the opening provided at the bottom edge of the back panel.
7. Screw the back panel back on. Guide the hoses through the opening provided at the bottom edge of the back panel.

### Example 3 – feed water supply from the MELAdem 47 reverse osmosis unit

The wastewater is collected on the left chamber of the storage tank and drains automatically via the one-way outlet hose. The one-way outlet hose is connected to the siphon via the double hose grommet.



Position	Description	Art. no.	contained in
1	Water connection set for Pro-Class	ME09033	--
1.1	Add-on kit for wastewater	ME26695	ME09033
1.2			ME09033 / ME26695
1.3	Feed water connection of Euroklav/Vacuklav	ME25655	ME09033
1.4	Wastewater nozzle for siphon with seal and clamp	ME52615	ME09033 / ME26695
2	Water stop (Leak water detector with cut-off valve and sensor, optional)	ME01056	--
3	Water tap with safety combination**)	--	--
4	Mounting set (EN 1717) for MELAdem	ME25410	--
4.1	Tap water supply hose EN 1717, 2.5 m	ME24930	ME25410
4.2	Safety combination EN 1717 incl. holder	ME82375	ME25410
5	MELAdem 47 reverse osmosis unit	ME01047	--
5.1	Filter for MELAdem	ME48240	ME01047
5.2	PUR hose (black) 6/4 mm (inlet hose feed water)	ME28820	ME01047
5.3	Pressure tank MELAdem 47 (with shut-off valve and hose)	ME57065	ME01047
5.4	Water inflow hose (2.5 m) (inlet hose MELAdem 47)	ME37220	ME01047
5.5	MELAdem 47 reverse osmosis unit (without accessories)	ME56740	ME01047
5.6	Wastewater adapter (G1/4" internal thread)	ME56930	ME01047
5.7	Double support sleeve for an existing trap	ME37400	ME01047
5.8	External tap for demineralised water (removal valve)	ME91900	ME01047
6	Double-chamber siphon (optional)	ME26635	--
7	Wall outlet NW 40**)	--	--
8	Mains connection**)	--	--
9	Back part cover for Vacuklav 23 B+ / 31 B+*)	ME66790	

\*) present on the device side

\*\*\*) present on the building side



**PLEASE NOTE**

Before converting from the standard version to a water treatment unit, you must first empty the feed water side (right-hand chamber) of the internal storage tank. With automatic one-way outlet, the wastewater side (left-hand chamber) must be emptied as well.

**Attaching the safety combination in accordance with EN 1717**

1. Unscrew the back panel of the steam sterilizer.
2. Mount the safety combination (art. no. ME82375).
3. Connect the water inflow hose to the upper connection of the safety combination.
4. Connect the water inlet hose to the MELAdem 47 reverse osmosis unit to the lower connection of the safety combination.
5. Screw the back panel back on. Guide the hoses through the opening provided at the bottom edge of the back panel.

## 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 23 B+) or three (Vacuklav 31 B+) revolutions to effect a slight rearwards slope of the device.

## Test runs

### Vacuum test with a cold sterilization chamber

Perform a vacuum test with an empty, cold sterilization chamber and record the outcome in accordance with record of installation and setup.

### Universal-Program

If the vacuum test was successful, perform a Universal-Program with 1.5 kg load (instruments) and record the outcome in accordance with record of installation and setup.

## Instructing the users

Explain all the user-typical features for the documentation and setting combinations for the operator.

Hand over the manufacturer's inspection report. The declaration of conformity regarding the pressure equipment directive and the Medical Devices Directive are included in the manufacturer's inspection report.

## 4 Settings and adjustment

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### Settings on the steam sterilizer

#### **Date and time**

Check the date and time and set if necessary. Consult the user manual.

#### **Feed water inflow**

The feed water supply is effected either via the internal storage tank or via a separate water treatment unit (e.g. MELAdem 40 / MELAdem 47). Setup the feed water inflow depending on the installation version to **INTERNAL** or **EXTERNAL**.

Further information is provided in the device user manual.

#### **Additional program options**

The **Autom. preheating** function heats the steam sterilizer chamber to a preheating temperature of the respective program before program start, or holds this temperature between two program runs. This will shorten the cycle times. It also reduces condensate formation on the chamber wall.

The **Additional drying** function increases the program by 50 % for difficult drying tasks.

Further information is provided in the device user manual.

#### **Counter stands**

Working in the **SETUP** menu, you can access counter stands and other technical data of the steam sterilizer.

## 5 Technical tables

### Feed water quality

Minimum requirements placed on the feed water quality based on EN 13060, Appendix C

Substance / property	Feed water
Evaporation residue	≤ 10 mg/l
Silicon oxide, SiO <sub>2</sub>	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metal traces apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 2 mg/l
Phosphate	≤ 0.5 mg/l
pH Value	5 to 7.5
Appearance	≤ colourless, clear, without sediments
Hardness	≤ 0.02 mmol/l

### Nominal value tolerances

Step	Universal-Program		Quick-Program B		Prion-Program		Gentle-Program		Quick-Program S		All values in mbar
	P	T	P	T	P	T	P	T	P	T	
1. Fractionation	80	+50/-20	◀	◀	◀	◀	◀	◀	150	◀	Evacuation
	1400	+50/-30	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake
2. Fractionation	180	+50/-20	◀	◀	◀	◀	◀	◀	250	◀	Evacuation
	1400	+50/-30	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake
3. Fractionation	180	+50/-20	◀	◀	◀	◀	◀	◀	---	---	Evacuation
	1400	+50/-30	◀	◀	◀	◀	◀	◀	---	---	Steam intake
	3050	+70/-30	◀	◀	◀	◀	2060	◀	◀	◀	Pressure increase
	3050	+70/-30	◀	◀	◀	◀	2060	◀	◀	◀	Start of sterilization
	3160	+90/-90	◀	◀	◀	◀	2150	◀	◀	◀	Sterilization
	1200	+30/-90	◀	◀	◀	◀	◀	◀	◀	◀	Pressure release

**Key:**

P = Pressure

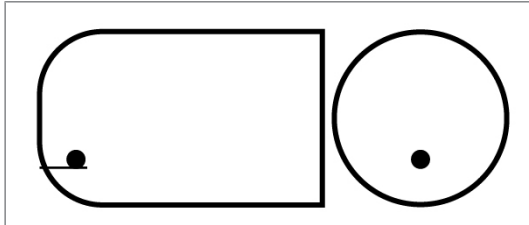
T = Tolerance

◀ as in Universal-Program

## Empty chamber test

The coldest point in the sterilization chamber during the empty chamber test lies directly on the temperature sensor (see circular marking in the following figure). The temperature in the rest of the sterilization chamber is almost the same all over.

*Schematic side and fore view of the sterilization chamber*



## Pressure-time charts

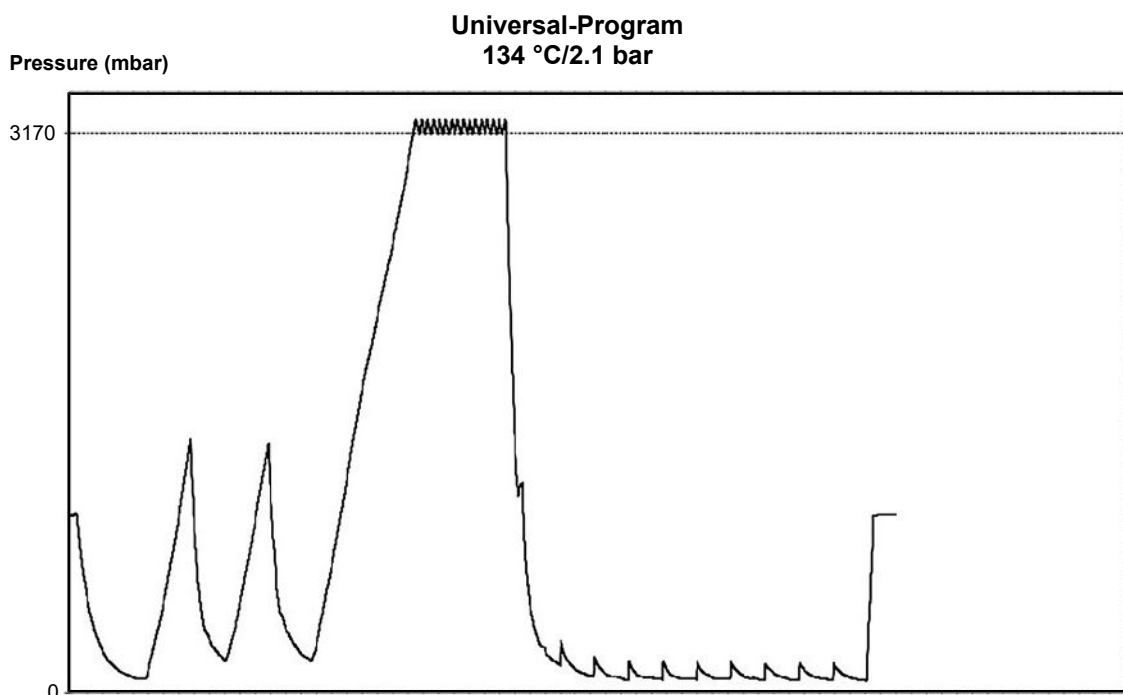


Fig. 2: Pressure-time chart for the Universal-Program, 134 °C and 2.1 bar

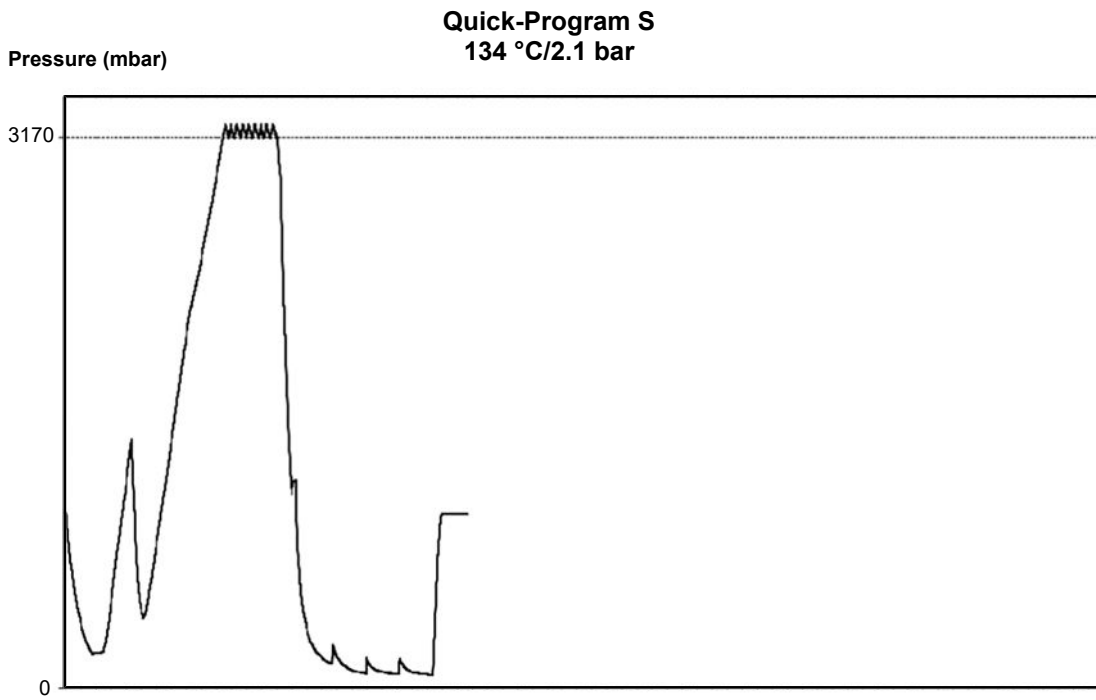


Fig. 3: Pressure-time chart for the Quick-Program S, 134 °C and 2.1 bar

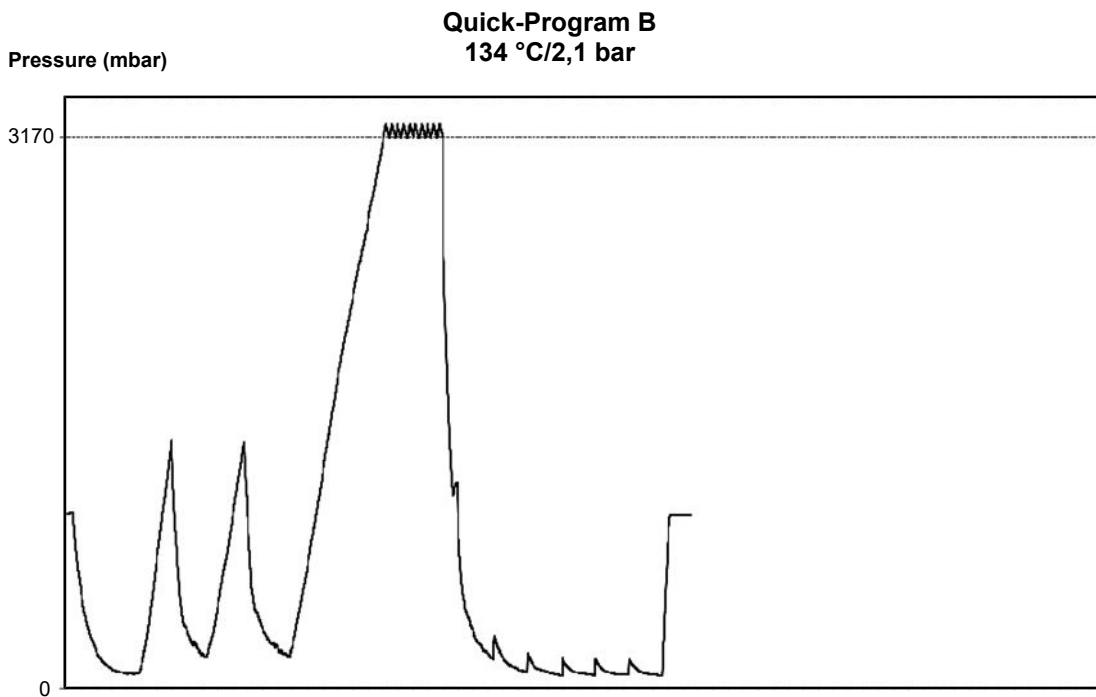


Fig. 4: Pressure-time chart for the Quick-Program B, 134 °C and 2.1 bar

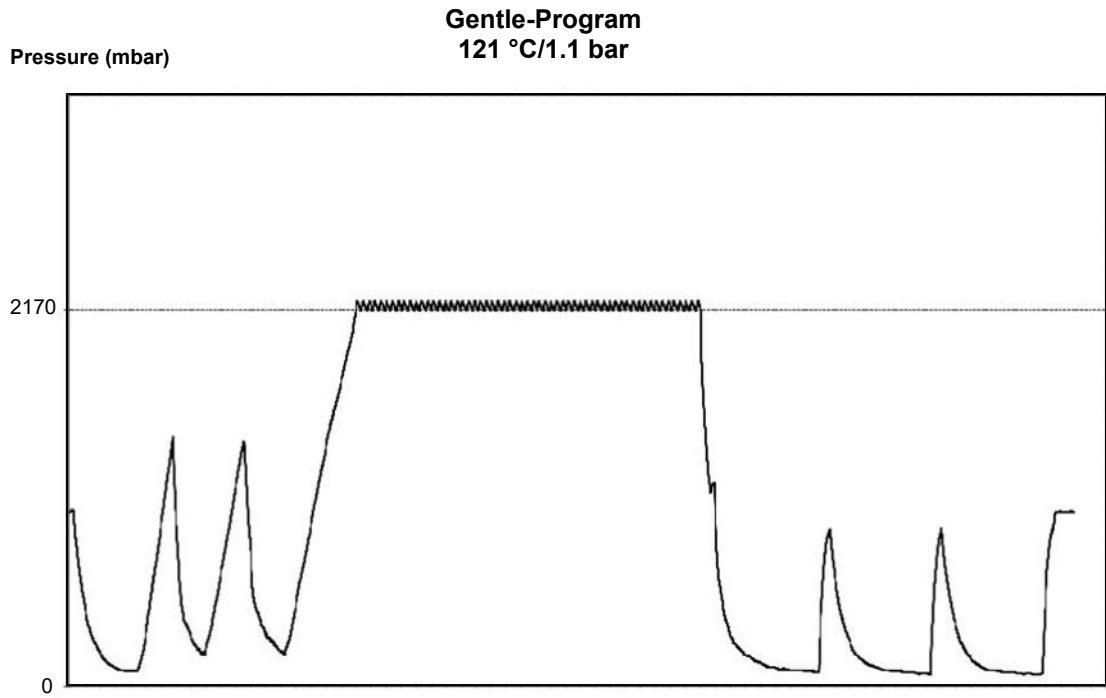


Fig. 5: Pressure-time chart for the Gentle-Program, 121 °C and 1.1 bar

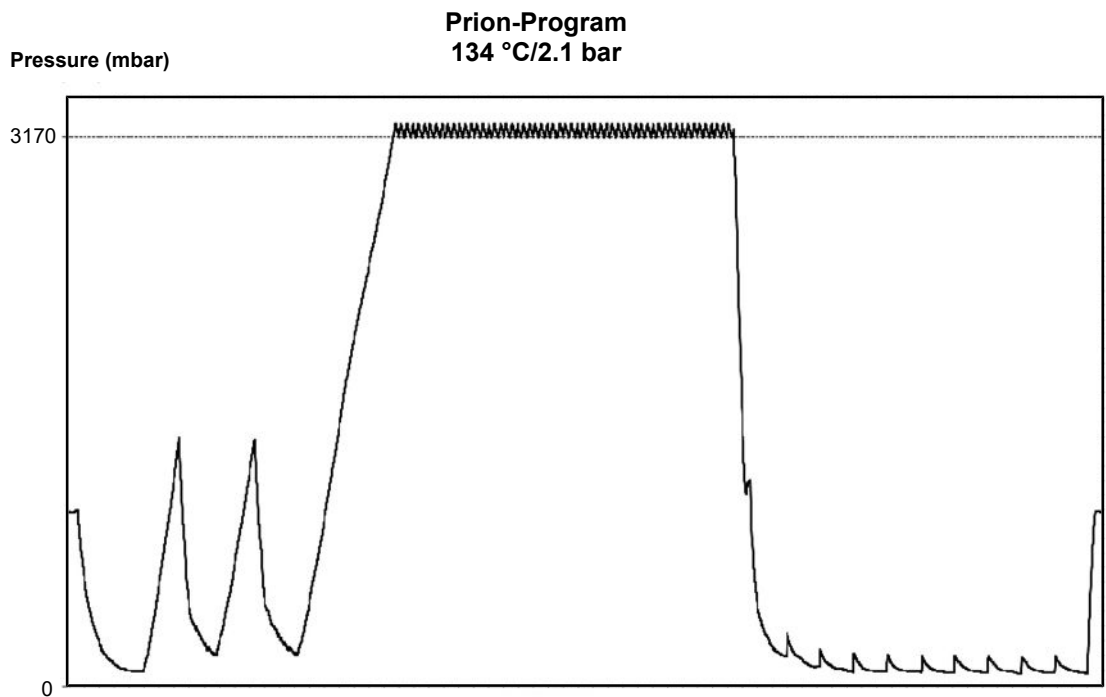


Fig. 6: Pressure-time chart for the Prion-Program, 134 °C and 2.1 bar

# Certificate of Suitability

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

Manufacturer:	MELAG Medizintechnik GmbH & Co. KG
Address:	Geneststraße 6-10 10829 Berlin
Country:	Germany
Product:	Vacuklav <sup>®</sup> 23 B+/ Vacuklav <sup>®</sup> 31 B+
Type of device:	Steam sterilizer
Classification:	Class IIb
Device type acc. to EN 13060:	Type B

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

- **Solid instruments (wrapped and unwrapped)**
- **Porous goods (wrapped and unwrapped)**
- **Instruments with narrow lumen (wrapped and unwrapped)**
- **Simple hollow bodies (wrapped and unwrapped)**

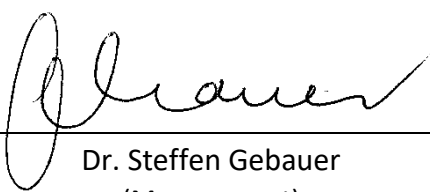
References to loading quantities and loading variations are outlined in the user manual and must be observed.

Be sure to observe the manufacturer's instructions for medical devices intended for sterilization according to EN ISO 17664.

We declare that the following test system is suited for testing the product specified above:

- **Helix test body according to EN 867-5:  
MELAcontrol<sup>®</sup> Helix and MELAcontrol<sup>®</sup> Pro**

Berlin, 01.10.2021



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Dr. Steffen Gebauer  
(Management)

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Original instructions

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

Your stockist

