

((0197

Technical Manual

Vacuklav[®] 24 B+ Vacuklav[®] 30 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.

Contents

1 General guidelines	
Symbols used	
Formatting rules	
2 Installation requirements	
Installation location	5
Electromagnetic environments	5
Space requirements	6
On-site requirements	7
Protection in accordance with EN 1717	
System and network safety	
3 Setup and installation	11
Removing from the packaging	11
Aligning the door seal sealing lips	11
Connection to the water line	
Installation examples	
Connecting the outlet hose	18
Aligning the steam sterilizer	18
Test runs	18
Instructing the users	18
4 Settings and adjustment	
Settings on the steam sterilizer	
5 Technical tables	
Feed water quality	20
Nominal value tolerances	
Empty chamber test	21
Pressure-time charts	21



1 General guidelines

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

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 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		

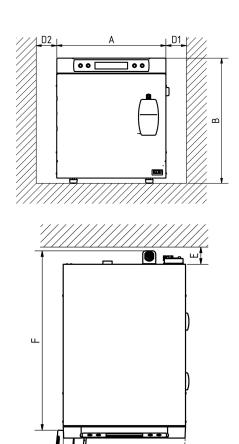
Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.

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



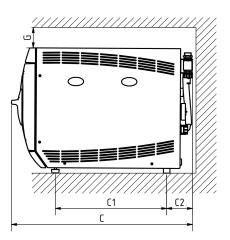


Fig. 1: View from the front, the right and above

D2

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

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.			

7



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 ¹⁾	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.

Protection in accordance with EN 1717

The connection of the steam sterilizer to the water supply is comparable with the connection of a washing machine in a domestic context. In general, the connection of consumers to the drinking water network should be performed in accordance with EN 1717, so that the drinking water supply is protected against contamination through the possible flow back of the water. The steam sterilizer was developed in accordance with all the requirements of EN 1717 and is equipped with a pre-fitted safety combination on its rear

Many buildings are already equipped with a safety combination. Ask your plumber. In practice, it is often advantageous to use a water inflow tap with a pre-fitted safety combination consisting of a back-flow preventer and a pipe aerator. To ensure a standard-conform connection to the steam sterilizer independently of the building installation, we recommend two versions, see section Connecting the cooling water inflow hose.

8

¹⁾ In the Prion program with porous full load.



System and network safety

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

Interfaces and connections



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	Туре	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



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.

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.





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.

Insert the door seal into the groove.



The wide sealing surface points towards the chamber.



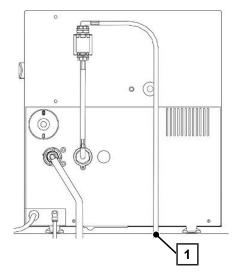
Connection to the water line



▼ PLEASE NOTE

To prevent water damage, MELAG recommends the use of a leakage water detector e.g. the MELAG water stop.

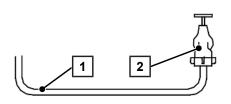
The connection of consumers to the drinking water system must be performed in accordance with EN 1717 so as to protect the drinking water supply from pollution. For this purpose, provide a safety combination located on the rear panel of the steam sterilizer, consisting of a return flow inhibitor and pipe aerator (in accordance with EN 1717 Part 4). In many cases, this is already present on the building side. Ask your plumber!



1 Water inflow hose (2.5 m) (DN16)

In the medical practice, it is a good idea to use taps already containing an integrated safeguard combination of return flow inhibitor and pipe aerator. In order to ensure a standards-compliant connection of the steam sterilizer independent of the installation on the building side, MELAG recommends the following two methods.

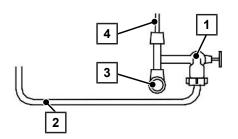
Method 1: Connection to a separate water line



- Tap water supply hose EN 1717, 2.5 m (DN16)
- 3/4" water inflow tap with safety combination
- A separate water pipe (nominal width DN15 with 1/2" coupling) is already available or will be installed.
- Install a water tap with integrated safety combination.
- Check whether the existing water tap is equipped with a return flow inhibitor and pipe aerator. 1.
- 2. If not, replace the existing tap with the intended tap with integrated safety combination from MELAG.
- 3. Install the water stop (optional).
- Connect the water inflow hose (DN16) of the steam sterilizers to the water tap with a 1/2" coupling.



Method 2: Connection to an existing angle valve



- Additional water tap with unit combination (for connection to a pre-existing angle valve)
- Tap water supply hose EN 1717, 2.5 m (DN16)
- B Existing angle valve
- 4 10 mm cold water pipe (to the mixer tap)
- Cold water connection (e.g. of a sink) with angle valve and 10 mm pipe is already available or will be installed.
- ✓ Installation of a water tap with integrated safeguard combination by direct assembly on an available angle valve.
- 1. Install the water stop (optional).
- Connect an additional water tap with integrated securing combination of MELAG directly to the existing angle valve.
- 3. Connect the water inflow hose (DN16) of the autoclave to the water tap.



NOTICE

Do not connect any further devices to the angle valve.

This could result in malfunctions in the cooling water system.



NOTICE

Flow pressure, inflow hose, water stop

- Required flow pressure with a flow rate of 3 l/min: > 1.2 bar
- Length of the cooling water inflow hose: 2.5 m
- The installation of a water stop with shut-off valve is recommended.

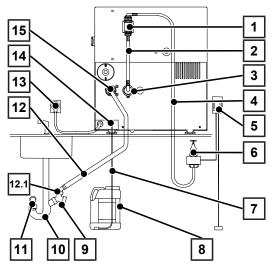


Installation examples

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 storage container

Indirect feed water supply from storage container. The device supplies itself with feed water from the storage container via the suction hose supplied. The max. suction height is 1.5 m. The storage container can also be located to the side of the device. The water outlet hose is connected to the double-chamber siphon via the double hose grommet.



Pos.	Description	Art. no.	contained in
1	Safety combination EN 1717 incl. holder, consisting of return flow inhibitor and pipe aerator*)	ME82375	
2	Hose, safety combination water inlet*)		
	Vacuklav 30 B+	ME25975	
	Vacuklav 24 B+, Vakuclav 24 BL+	ME48475	
3	Solenoid valve cooling water Vacuklav*)	ME57715	
4	Tap water supply hose EN 1717, 2.5 m***)	ME24930	
5	Water stop with cut-off valve and sensor (optional) ¹⁾	ME01056	
6	Water tap with safety combination**		
7	Hose PTFE 6/4 mm (5 m)	ME39310	ME00244
8	Storage container for feed water	ME00244	
9	Double hose fitting for siphon with backflow flaps with non-return flaps (optional)	ME37400	
10	Double chamber siphon***)	ME26635	
11	Wall outlet NW 40**)		
12	Water outlet hose for steam sterilizers, 2 m DN16***)	ME36585	
12.1	Wastewater nozzle for siphon with seal and clamp	ME52615	ME36585
13	Mains connection**)		
14	Feed water connection***)	ME37242	
15	Connecting branch waste water (Pro-Class)	ME57705	

¹⁾ recommended with fixed water connection

^{*)} present on the device side

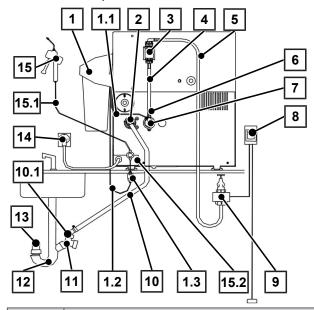
^{**)} present on the building side

^{***)} included in the scope of delivery



Example 2 - feed water supply from the MELAdem 40 ion exchanger

Connection of the MELAdem 40 ion exchanger with MELAjet. The most simple installation is the direct connection of the MELAdem 40 to the steam sterilizer feed water inflow; this generates demineralised water from normal tap water.



Position	Description	Art. no.	contained in	
1	MELAdem 40 ion exchanger	ME01049		
1.1	PUR hose (black) 6/4 mm (inlet hose MELAdem 40)	ME28820	ME01049	
1.2	PUR hose (black) 6/4 mm (inlet hose feed water)	ME28820	ME01049	
1.3	Filter for MELAdem	ME48240	ME01049	
2	Connecting branch waste water (Pro-Class)	ME57705		
3	Safety combination EN 1717 incl. holder*)	ME82375		
4	Hose safety combination to water supply*)			
	Vacuklav 30 B+	ME25975		
	Vacuklav 24 B+, Vacuklav 24 BL+	ME48475		
5	Tap water supply hose EN 1717, 2.5 m**)	ME24930		
6	Water branch set MELAdem 40 / steam sterilizer water drainage	ME37241		
7	Solenoid valve cooling water Vacuklav (cooling water inlet)*)	ME57715		
8	Water stop (Leak water detector with cut-off valve and sensor, optional)	ME01056		
9	Water tap with safety combination***)			
10	Hose for water drain of steam sterilizers, length: 2 m**)	ME36585		
10.1	Wastewater nozzle for siphon with seal and clamp	ME52615	ME36585	
11	Double support sleeve for an existing trap (optional)	ME37400		
12	Double-chamber siphon**)	ME26635		
13	Wall outlet NW 40***)			
14	Mains connection***)			
15	MELAjet spray pistol for MELAdem 40 (optional)	ME27300		
15.1	PUR hose (black) 6/4 mm (hose MELAjet)	ME28820	ME27300	
15.2	Swivel screw connection MELAjet	ME53465	ME27300	

^{*)} present on the device side

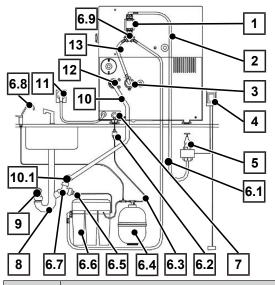
^{**)} not included in the scope of delivery

^{**)} present on the building side



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

Connection of the MELAdem 47 reverse osmosis unit which can be connected directly to the steam sterilizer feed water inflow. The connection of a different water treatment unit with the same water quality is possible after consultation with MELAG.



Position	Description	Art. no.	contained in				
1	Safety combination EN 1717 incl. holder*)	ME82375					
2	Tap water supply hose EN 1717, 2.5 m**)	ME24930					
3	Solenoid valve cooling water Vacuklav*)	ME57715					
4	Water stop (Leak water detector with cut-off valve and sensor, optional)	tor with cut-off valve and sensor, ME01056					
5	Water tap with safety combination***)						
6	MELAdem 47 reverse osmosis unit	ME01047					
6.1	Water inflow hose (2.5 m) (inlet hose MELAdem 47)	ME37220	ME01047				
6.2	Filter for MELAdem	ME48240	ME01047				
6.3	PUR hose (black) 6/4 mm (inlet hose feed water)	ME28820	ME01047				
6.4	Pressure tank MELAdem 47 (with shut-off valve and hose)	ME57065	ME01047				
6.5	Wastewater adapter (G1/4" internal thread)		ME01047				
6.6	MELAdem 47 reverse osmosis unit (without accessories)		ME01047				
6.7	Double support sleeve for an existing trap	ME37400	ME01047				
6.8	External tap for demineralised water (removal valve)	ME91900	ME01047				
6.9	Water inflow distributor Y-piece with seal	ME37315	ME01047				
7	Feed water connection**)	ME37242					
8	Double-chamber siphon***)	ME26635					
9	Wall outlet NW 40***)						
10	Hose for water drain of steam sterilizers, length: 2 m**)	ME36585					
10.1	10.1 Wastewater nozzle for siphon with seal and clamp		ME36585				
11	Mains connection***)						
12	Connecting branch waste water (Pro-Class)*)	ME57705					
13	Hose safety combination to water supply*)						
	Vacuklav 30 B+ Vacuklav 24 B+, Vacuklav 24 BL+	ME25975 ME48475					
	Vacuniav 24 DT, Vacuniav 24 DLT	IVIE40473					

^{*)} present on the device side

^{**)} included in the scope of delivery of the steam sterilizer

^{**)} present on the building side



Connecting the outlet hose

Method 1: Direct wall drain

- ✓ The drain is located at least 30 cm below the steam sterilizer.
- Connect the drain hose supplied to the rear of the steam sterilizer and connect it to the wall drain (DN 40) of the practice, preferably using the surface-mounted siphon from MELAG (art. no. ME37410). Make sure that the hose is installed free of pockets and with a steady slope.

Method 2: Connection to a sink drain

- ✓ The drain is located at least 30 cm below the steam sterilizer.
- Connect the drain hose supplied to the back of the steam sterilizer and connect it to the sink drain (siphon) of the practice. Make sure that the hose is installed free of pockets and with a steady slope.

For a quieter water discharge, it is recommended to replace the double-chamber siphon included in the delivery with the existing siphon.

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.

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

Settings on the steam sterilizer

Date and time

Check the date and time and set if necessary. Consult the 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 ₂	≤ 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
	Р	Т	Р	Т	Р	Т	Р	Т	Р	Т	
1. Frac-	80	+50/-20	•	◀	•	•	•	⋖	150	◀	Evacuation
tionation	1400	+50/-30	•	◀	◀	•	•	⋖	•	◀	Steam intake
2. Frac-	180	+50/-20	•	◀	◀	◀	•	◀	250	◀	Evacuation
tionation	1400	+50/-30	◀	◀	◀	◀	■	◀	•	◀	Steam intake
3. Frac-	180	+50/-20	◀	◀	◀	◀	•	◀			Evacuation
tionation	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

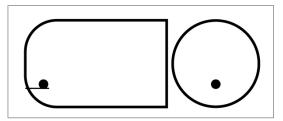
■ as in Universal-Program



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

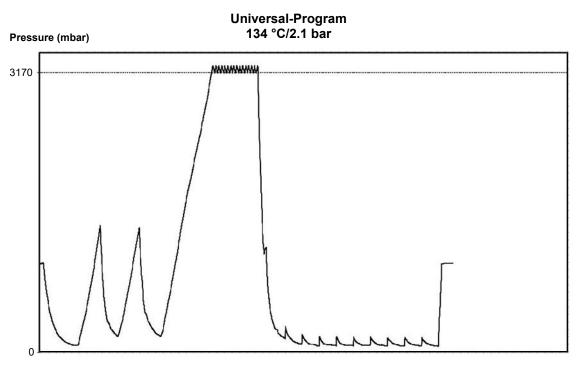


Fig. 2: Pressure-time chart for the Universal-Program, 134 $^{\circ}\text{C}$ and 2.1 bar



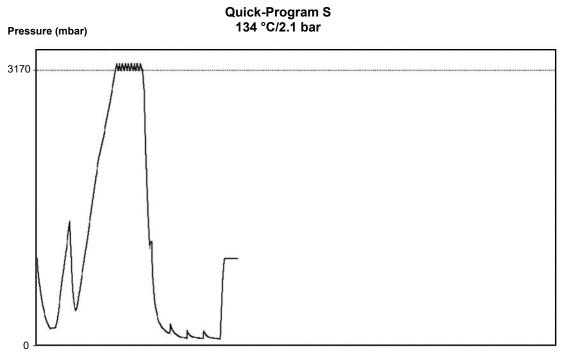


Fig. 3: Pressure-time chart for the Quick-Program S, 134 $^{\circ}\text{C}$ and 2.1 bar

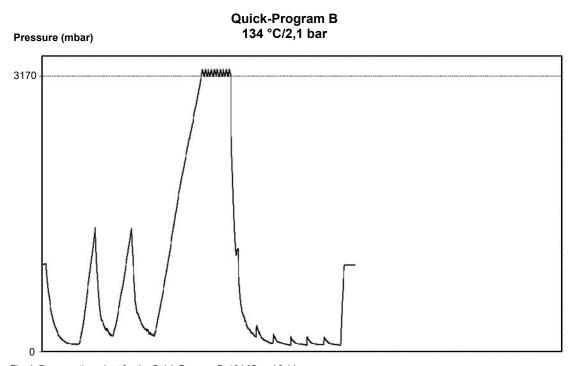


Fig. 4: Pressure-time chart for the Quick-Program B, 134 $^{\circ}\text{C}$ and 2.1 bar



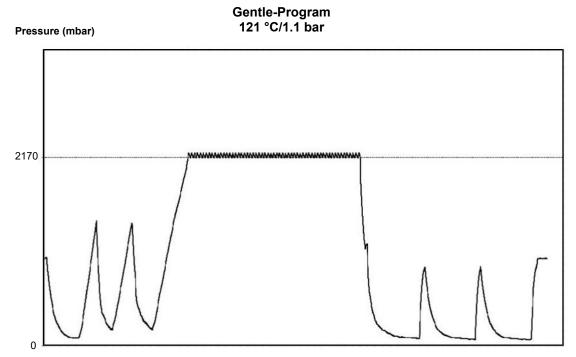


Fig. 5: Pressure-time chart for the Gentle-Program, 121 $^{\circ}\text{C}$ and 1.1 bar

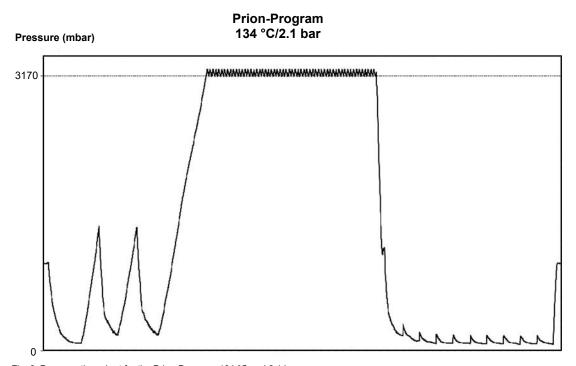


Fig. 6: Pressure-time chart for the Prion-Program, 134 $^{\circ}\text{C}$ and 2.1 bar



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® 24 B+/ Vacuklav® 30 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[®] Helix and MELAcontrol[®] Pro

Berlin, 01.10.2021

Dr. Steffen Gebauer (Management)

MELAG Medizintechnik GmbH & Co. KG

Geneststraße 6-10 10829 Berlin Germany

Email: info@melag.com Web: www.melag.com

Original instructions

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