MELAG
competence in hygiene

Technical Manual

Euroklav® 23 VS+
Euroklav® 29 VS+

Steam sterilizer

from software version 5.17



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

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.

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 **Chapter 2**	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 material

The device can be commissioned without installation material. Extra installation material is only required given the connection of a water treatment unit and/or a direct wastewater connection.

The following additional material can be ordered as required:

Qty.	Article	Art. no.
1	Connection set MELAdem 40	09031
1	Connection set MELAdem 47	09032
1	Water outlet hose for steam sterilizer, length 2 m	36585
1	Surface-mounted siphon	37410
1	Double hose grommet for siphon (with a trap for connection to the flush siphon)	37400
1	Mounting set (EN 1717) for MELAdem	49600
1	3/4" water tap with safety combination	37310
1	Additional water inflow tap with safety combination (for connection to a pre-existing angle valve)	58130
1	Water stop (leakage water detector)	01056
1	Filter for MELAdem	48240
1	Double chamber siphon	26635

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	Euroklav 23 VS+	Euroklav 29 VS+
Installation surface	level and horizontal	
Installation location	dry and protected from dust	
Max. Floor loading (hydraulic pressure test)	3.2 kN/m²	2.9 kN/m²
Max. height	2000 m	
Waste heat (with maximum load)	0.9 kWh	0.8 kWh
Ambient temperature	5-40 °C (ideal range 16-26 °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

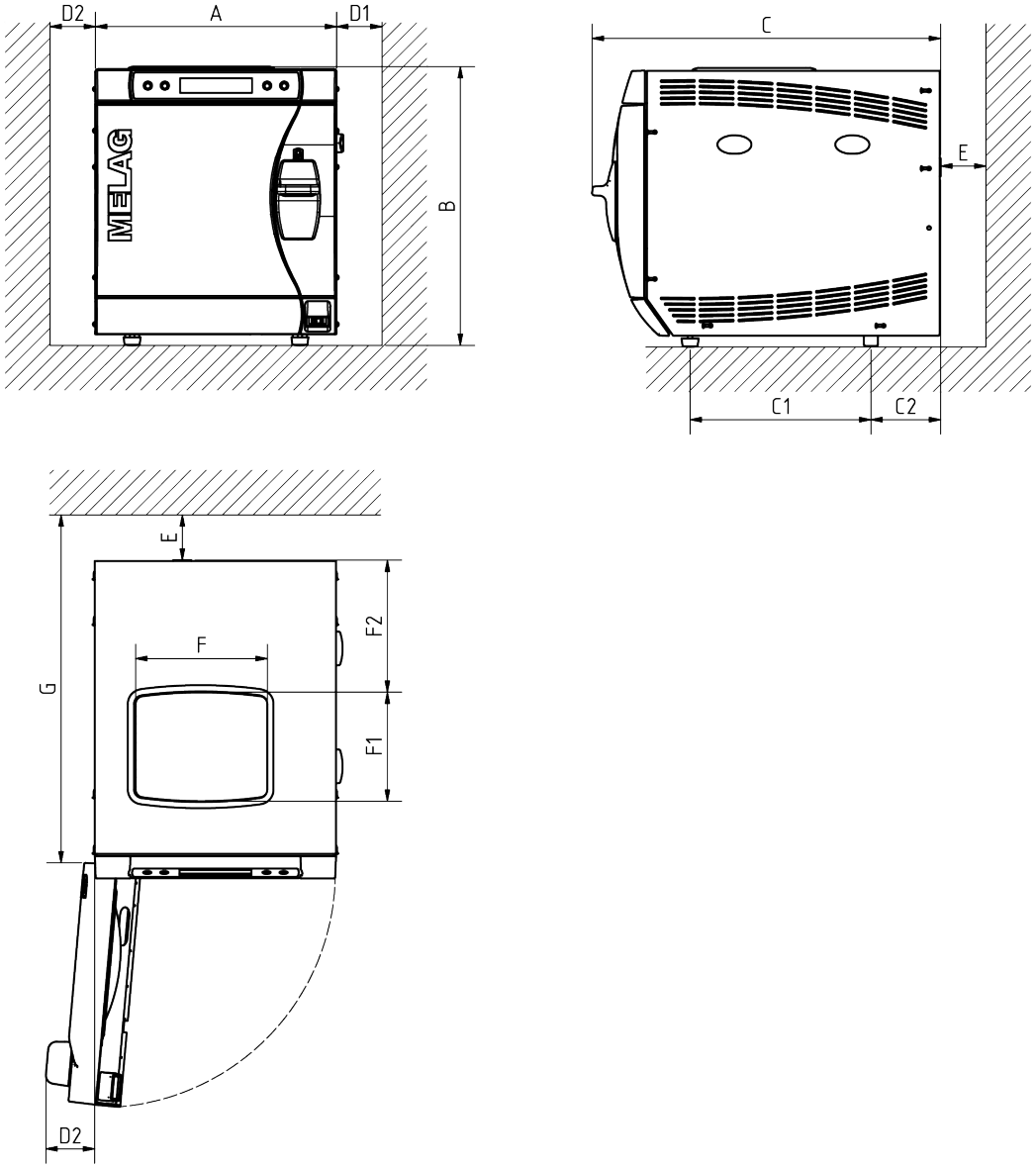


Fig. 1: View from the front, the right and above

Dimensions		Euroklav 23 VS+	Euroklav 29 VS+
Width	A	42.5 cm	
Height	B	49 cm	
Depth, total	C	70 cm	62 cm
Clearance between the device feet	C_1	43.5 cm	32.5 cm
Clearance from rear device foot up to the rear panel	C_2	9.5 cm	12.5 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	27.5 cm	
Free area with a fully-opened door	G	68 cm	63.5 cm

The space requirements of the steam sterilizer corresponds to its dimensions plus an additional 10 cm to the left and rear and an extra 5 cm to the right. The area above the steam sterilizer should be freely accessible in order to enable easy filling of the storage tank and good ventilation.

PLEASE NOTE

The steam sterilizer is not suitable for installation in a cupboard unit.

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	39 cm	--
Height	35 cm	47 cm	51 cm
Depth	15 cm	15 cm	--
Diameter	--	--	Ø 24 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 authorized technicians.

On-site requirements of the mains connection

Property	On-site requirements	
	Euroklav 23 VS+	Euroklav 29 VS+
Electricity supply	220-240 V, 50/60 Hz	
Max. voltage range	207-253 V	
Building fuses	A separate circuit with 16 A, RCD 30 mA (to guarantee continued practice operation during steam sterilizer malfunction)	
Other	Additional socket for the MELAprint 42/44 log printer etc.	
Length of the power cable	1.35 m	

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

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 drain 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
Min. flow pressure	Corresponding to the water treatment unit	--
Recommended flow pressure*)	1.5 bar at 3 l/min	--
Min. water pressure (static)*)	2 bar	--
Max. water pressure (static)*)	10 bar	--
Max. consumption per program cycle	700 ml (Euroklav 23 VS+) 600 ml (Euroklav 29 VS+)	--
Water quality	Distilled or demineralized water in accordance with DIN EN 13060, Appendix C	--
*) Optional when using a water treatment unit		

With connection to a water treatment unit

	MELAdem 40	MELAdem 47
Permissible water pressure	1.5-10 bar	2-6 bar
Measures for protecting the drinking water	We recommend the use of a safety combination consisting of a back-flow preventer and a pipe aerator (e.g. the assembly set in accordance with EN 1717 for MELAdem) in accordance with EN 1717 to protect against backflow into the drinking water supply.	
Leakage water detector	We recommend the installation of a leakage water detector with a cut-off valve (e.g. MELAG water stop).	

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.

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 started up 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 lip

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.

Aligning the steam sterilizer

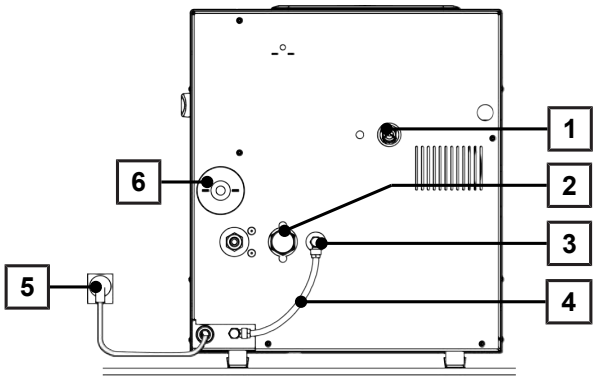
To enable fault-free operation, the steam sterilizer must be setup level using a spirit level placed on the chamber flange. Then extend the fore device feet by five (Euroklav 23 VS+) or three (Euroklav 29 VS+) revolutions to effect a slight rearwards slope of the steam sterilizer.

Installation examples

Example 1 - Standard delivery state

Direct feed water inflow from the internal storage tank. The wastewater will be collected in the wastewater chamber of the storage tank. No water connection required.

The steam sterilizer is supplied with feed water directly from the internal storage tank via a hose bridge. A float switch integrated in the device notifies the absence of feed water. Programs can only be started after feed water has been filled. The used feed water (wastewater) is collected in the wastewater chamber of the internal storage tank and is to be emptied manually at a later point. A float switch also monitors the current water level in the wastewater chamber.

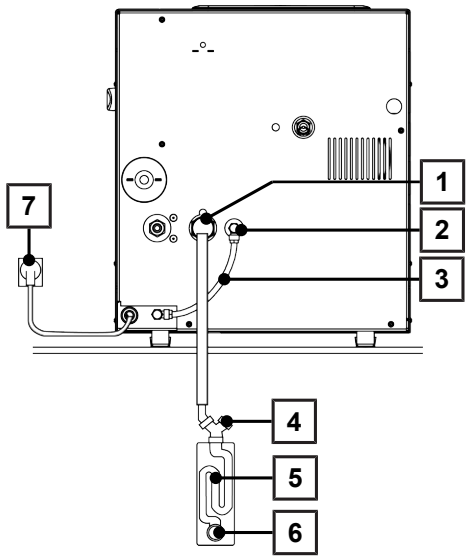


Item	Description
1	Spring safety valve
2	One way drain
3	Feed water inflow
4	Hose bridge for feed water supply
5	Mains connection
6	Sterile filter

Example 2 - one-way drain via siphon

Direct feed water inflow from the internal storage tank. One-way drain via the surface-mounted siphon.

The steam sterilizer is supplied with feed water directly from the internal storage tank via a hose bridge. A float switch integrated in the device notifies the absence of feed water. Programs can only be started after feed water has been filled. The used feed water (wastewater) is discharged via the one-way drain.



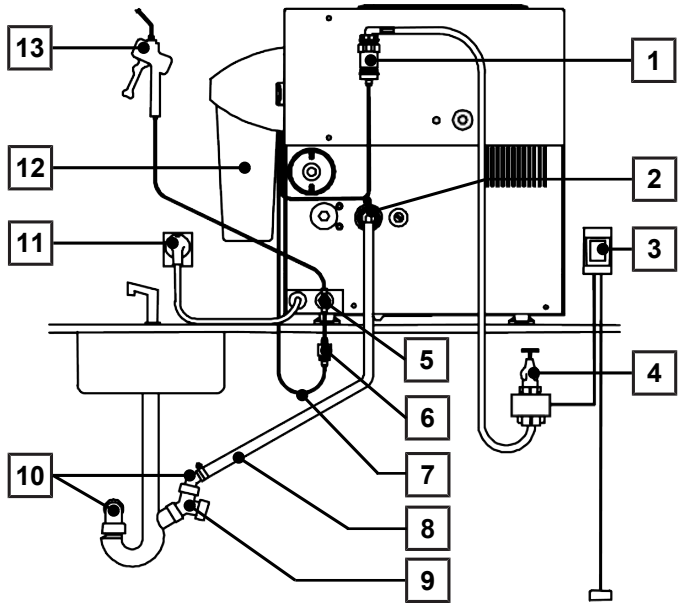
Item	Description
1	One way drain
2	Feed water inflow
3	Hose bridge for feed water supply
4	Double hose nozzle with anti-flooding flap
5	Surface-mounted siphon
6	Wall outlet (NW40 - on site)
7	Mains connection

Example 3 - MELAdem 40

Feed water inflow 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 demineralized water from normal tap water. The MELAjet spray pistol is used to perform the final rinse of the instruments with demineralized water before sterilization.

The used feed water (wastewater) is discharged into the double chamber siphon via the one-way drain.



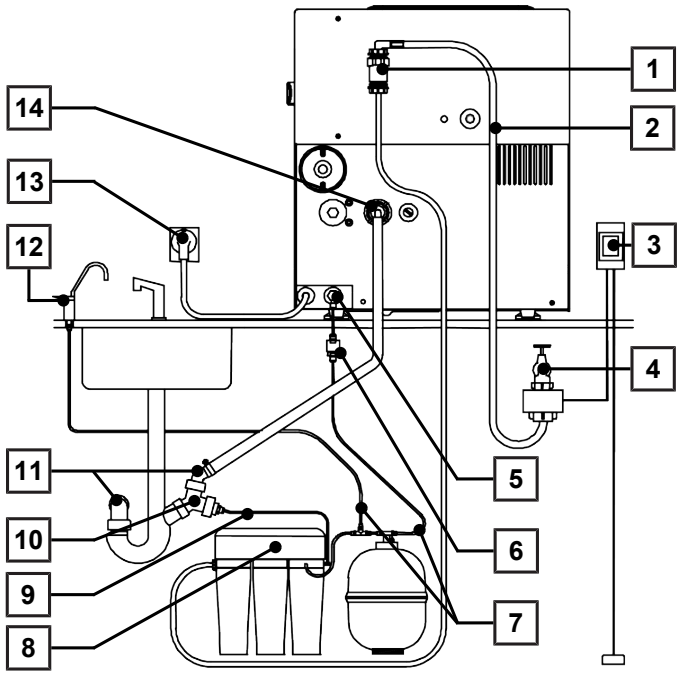
Item	Description
1	Safety combination consisting of a backflow preventer and a pipe aerator in accordance with EN 1717 (optional)
2	One way drain
3	Leakage water detector (water stop) with cut-off valve and sensor (optional) recommended with a fixed water connection
4	Water inflow tap with safety combination (on site)
5	Feed water inflow fitting
6	MELAdem 40 feed water filter
7	Feed water inflow hose
8	One-way drain hose (DN16)
9	Double hose nozzle with anti-flooding flap (optional)
10	Double chamber siphon (optional)
11	Mains connection
12	MELAdem 40
13	MELAjet (optional)

Example 4 - MELAdem 47

Feed water inflow 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.

The used feed water (wastewater) is discharged into the double chamber siphon via the one-way drain.



Item	Description
1	Safety combination consisting of a backflow preventer and a pipe aerator in accordance with EN 1717 (optional)
2	Tap water inflow hose for MELAdem 47
3	Leakage water detector (water stop) with cut-off valve and sensor (optional)
4	Water inflow tap with safety combination (on site)
5	Feed water inflow fitting
6	MELAdem 47 feed water filter
7	Feed water inflow hose
8	MELAdem 47
9	Concentrate outflow MELAdem 47
10	Double hose nozzle with anti-flooding flap (optional)
11	Double chamber siphon (optional)
12	Water tap for feed water
13	Mains connection
14	One way drain

Instructing the users

- Explain all the user-typical features for the documentation and setting combinations for the operator.
- Hand over the user manual, the technical manual and the manufacturer's inspection report. The declaration of conformity regarding the pressure equipment directive and the Medical Devices Act 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.

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 **`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`** 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 DIN 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

	Universal-Program		Quick-Program S		Gentle-Program		Prion-Program		
Step	Pressure P	Tole-rance	P	Tol.	P	Tol.	P	Tol.	*All values in mbar*
Pre-vacuum	250	+ 50/- 20	**500**	◀	◀	◀	◀	◀	Evacuation
	2000	+ 50/- 30	◀	◀	◀	◀	◀	◀	Steam intake
1. Fractionation	1200	+ 30/- 50	◀	◀	◀	◀	◀	◀	Steam off-flow
	2000	+ 50/- 30	◀	◀	◀	◀	◀	◀	Steam intake
2. Fractionation	1200	+ 30/- 50	◀	◀	◀	◀	◀	◀	Steam off-flow
	2000	+ 50/- 30	◀	◀	◀	◀	◀	◀	Steam intake
3. Fractionation	1200	+ 30/- 50	◀	◀	◀	◀	◀	◀	Steam off-flow
	2000	+ 50/- 30	◀	◀	◀	◀	◀	◀	Steam intake
4. Fractionation	1200	+ 30/- 50	◀*) ---**)	◀*) ---**)	◀	◀	◀	◀	Steam off-flow
	2000	+ 50/- 30	◀*) ---**)	◀*) ---**)	◀	◀	◀	◀	Steam intake
5. Fractionation	1200	+ 30/- 50	---	---	◀	◀	◀	◀	Steam off-flow
	2000	+ 50/- 30	---	---	◀	◀	◀	◀	Steam intake
	3050	+ 70/- 30	◀	◀	2060	◀	◀	◀	Pressure increase
	3050	+ 70/- 30	◀	◀	2060	◀	◀	◀	Sterilization entry
	3170	+ 90/- 90	◀	◀	2142*)/ 2149**)	◀	◀	◀	Sterilization
	1500	+ 30/- 50	◀	◀	◀	◀	◀	◀	Pressure release

*) Euroklav 23 VS+
**) Euroklav 29 VS+

Key:

◀ As in Universal-Program

Pressure-time chart

Universal-Program

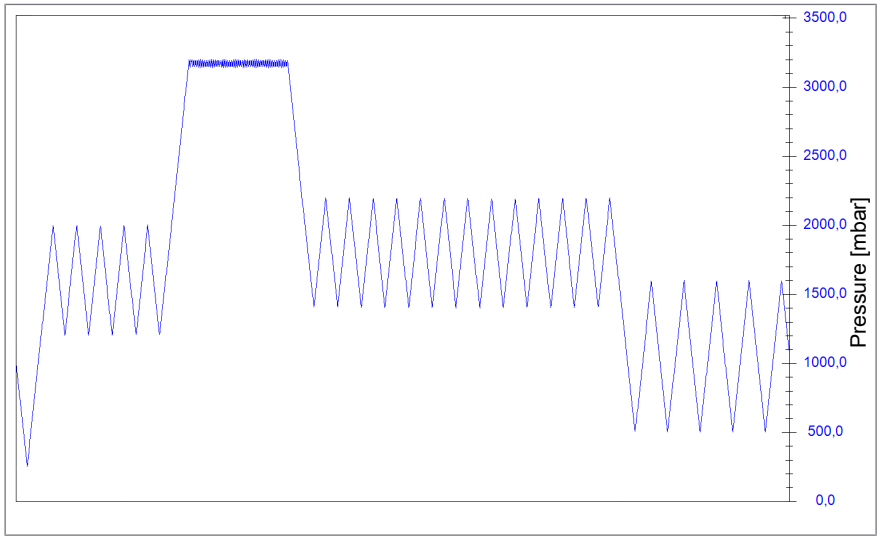


Fig. 2: Pressure-time chart for the Universal-Program, 134 °C and 2.1 bar

Quick-Program S

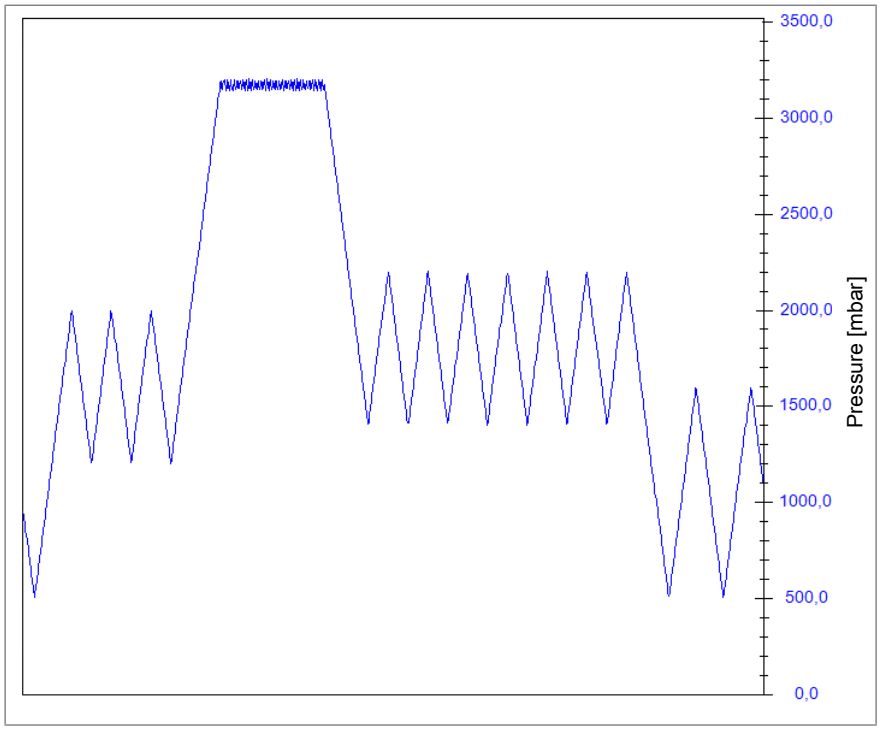


Fig. 3: Pressure-time chart for the Quick-Program S, 134 °C and 2.1 bar

Euroklav 23 VS+: Program contains an additional fractionation

Gentle-Program

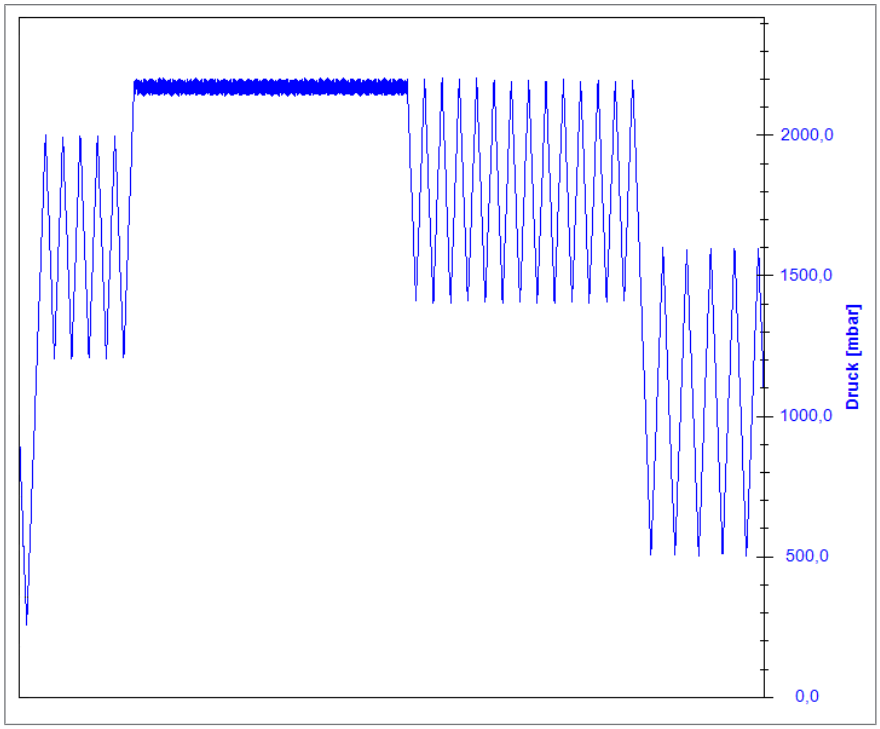


Fig. 4: Pressure-time chart for the Gentle-Program, 121 °C and 1.1 bar

Prion-Program

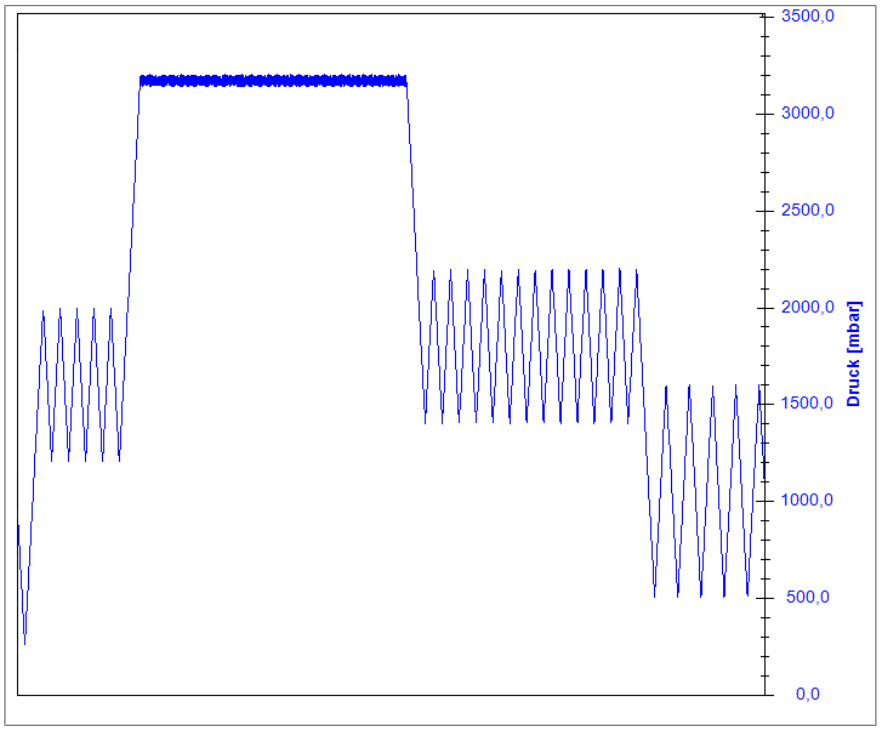


Fig. 5: Pressure-time chart for the Prion-Program, 134 °C and 2.1 bar

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.

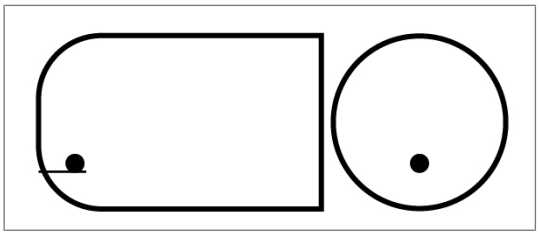


Fig. 6: Schematic side and fore view of the sterilization chamber

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:	Euroklav® 23 VS+/ Euroklav® 29 VS+
Type of device:	Steam sterilizer (steam sterilizer)
Classification:	Class IIb
Device type acc. to DIN EN 13060:	Type S

We herewith declare that the above designated sterilizer is suited for sterilization of

- **Solid instruments (wrapped and unwrapped)**
- **Porous goods (wrapped and unwrapped)**
- **Simple hollow items (wrapped and unwrapped)**

Instructions on load quantities and loading variants are set forth in the User Manual and must be observed.

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

We herewith declare that the following test system is suited for testing the above cited steam sterilizer.

- **Type 5 Indicator according to DIN EN ISO 11140-1**

Berlin, 01.02.2020

Dr. Steffen Gebauer
(Management)

MELAG Medizintechnik GmbH & Co. KG

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Original instructions

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

Your stockist

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