

Technical manual

Vacuklav[®] 41 B+ *Evolution*

Vacuklav[®] 43 B+ *Evolution*

Steam sterilizer

from software version 3.218

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.

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	Description
	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	Description
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 location



WARNING

Failure to comply with the setup conditions can result in injuries and/or damage to the device.

- The steam sterilizer should only be setup, installed and commissioned by persons authorised by MELAG.
- The steam sterilizer is not suitable for operation in explosive atmospheres.
- The steam sterilizer is conceived for use outside the patient care area. The device should be located a minimum of 1.5 m radius away from the treatment area.

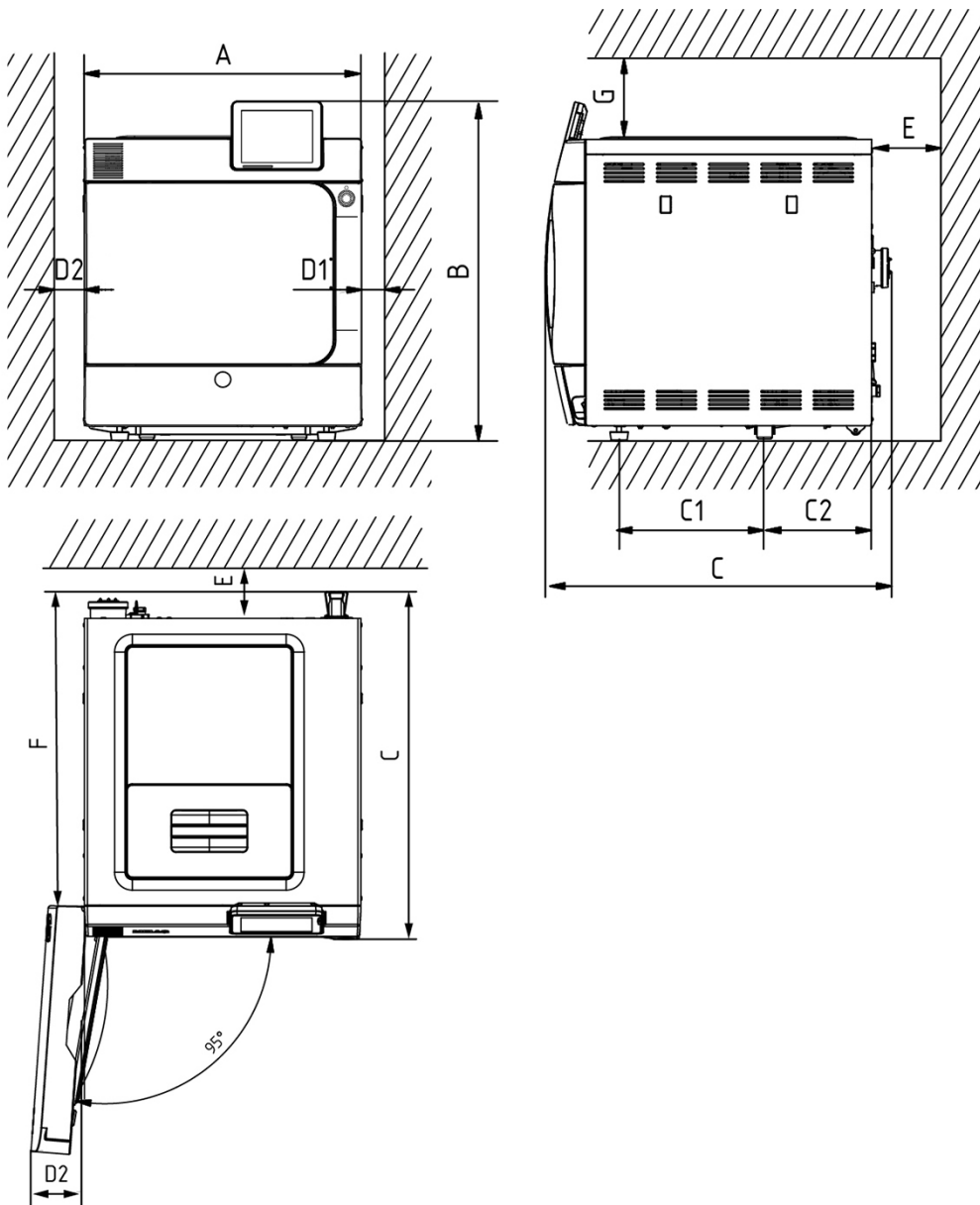
Property	Vacuklav 41 B+	Vacuklav 43 B+
Installation surface	level and horizontal	
Installation location	interior of a building (dry and protected from dust)	
Floor loading (normal operation)	3.70 kN/m ²	3.37 kN/m ²
Floor loading (pressure resistance test)	3.77 kN/m ²	3.64 kN/m ²
Heat emission (with max. load)	1.7 kWh	
Ambient temperature	5-40 °C (ideal range 16-26 °C)	
Relative humidity	max. 80 % at temperatures of up to 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)	

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



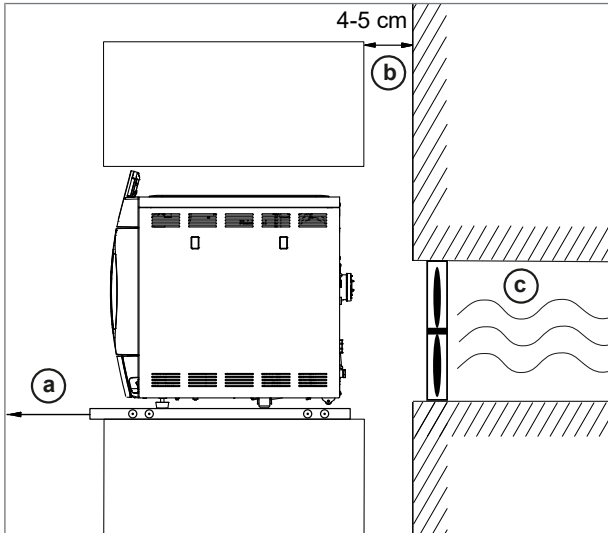
Dimensions		Vacuklav 41 B+	Vacuklav 43 B+
Width	A	46 cm	
Height	B	56.5 cm	
Depth	C	58 cm	69 cm
Clearance between the device feet	C1	24 cm	35 cm
Clearance from rear device foot up to the rear panel	C2	17.6 cm	
Min. clearance to the side	D1	5 cm	
Min. clearance to the side of the door hinge	D2	14 cm	
Min. clearance to the rear	E	10 cm	
Free space when door open fully	F	52 cm	63 cm
Min. clearance to the top (can be pulled out / with exhaust shaft)	G	5 / 20 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, MELAG advise against incorporating the steam sterilizer and is only possible if sufficient air circulation is ensured.

Requirements for installing the device

If it is absolutely necessary to install the device, implement one of the following measures:

1. It must be possible to pull out the device for operation (pos. a).
2. In the installation space, there must be an exhaust shaft in the rear area that discharges the warm air upwards (pos. b).
3. There must be an exhaust shaft in the rear area of the installation space that actively discharges the warm air to the rear (pos. c).
4. Switching off the DRYtelligence (menu **Settings > Intelligent drying**).



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

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 device can be disconnected from the electrical mains at any time if necessary by pulling the mains plug.

On-site requirements of the mains connection

Property	On-site requirements
Power supply	Socket with 220-240 V, 50/60 Hz
Electrical power	3400 W or 2800 W ^{*)}
Max. voltage range	207-253 V
Building fuse	with 3400 W ^{*)} : separate electrical circuit with 16 A, RCD 30 mA with 2800 W ^{*)} : separate electrical circuit with min. 13 A, RCD 30 mA (to guarantee continued practice operation during steam sterilizer malfunction)
Other	additional socket 230 V, 50 Hz for MELAprint 60 label printer, MELAprint 42/44 log printer etc.
Length of the power cable	2 m
*) see type plate	

Water connection

Observe the following requirements for the water connection if there is no manual filling or emptying.

	Feed water	Wastewater
Connection in the practice	via a water treatment unit, e.g. MELAdem	via the one-way drain, e.g. with the water connection set Wall outlet, nominal width 40 or to a U-trap (flush outflow)
Installation height	--	min. 30 cm under the steam sterilizer
Min. flow pressure	1.5 bar at 3 l/min	--
Recommended flow pressure	1.5-4 bar at 1.4 l/min	--
Min. static water pressure	2 bar	--
Max. static water pressure	10 bar	--
Max. water temperature	35 °C	98 °C
Water quality	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)	

Leakage water detector

MELAG recommends the installation of a leakage water detector with a cut-off valve (e.g. MELAG water stop).

At first commissioning, the Vacuklav 41 B+ consumes 2.5 l and the Vacuklav 43 B+ consumes 3.5 l of feed water (in accordance with EN 13060, Appendix C) once to fill the double jacket.

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
CF card slot	CF type I	CF card up to 4 GB with an FAT16 or FAT32 file system	Writing log data on a CF card
		CF card up to 4 GB with a FAT16 file system	Device software update
Ethernet	Ethernet IEEE 802.3	Switch port (via CAT-5 patch cable)	MELAviView Service saving log data, querying device data
			MELAtTrace saving log data
			FTP server saving log data
			MELAConnect (mobile app) querying device data
		Connection to the local network (LAN)	
		MELAPrint 60 (via CAT-5 patch cable)	Label printing
		MELAPrint 42/44 (via CAT-5 patch cable with network adapter)	Log printing



NOTICE

When performing a device software update, use only the update data authorised 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 (without malware, etc.)
- writeable
- formatted with a correct file system

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

Only use 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 device is configured to obtain the IP address automatically from a DHCP server operated in a LAN.



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:

Log	Source port	Destination port	Direction	Purpose
TCP	≥ 1025	21	Outgoing	FTP control
TCP	any	≥ 1025	Listening / incoming	FTP (active) data transfer (device set to FTP logging)
UDP	68	67	Outgoing	Communication to DHCP server - requests to the DHCP server
UDP	67	68	Listening / incoming	Answers from DHCP server(s)
TCP	any	80	Listening	Data transfer to the web browser
TCP	any	65001	Listening / incoming	Data transfer log data (device set to TCP logging)
UDP	17784	17784	Outgoing	Broadcast search log printer
TCP	50001	50000	Outgoing	Data transfer to the log printer
UDP	42380	3000	Outgoing	Broadcast search label printer
TCP	52382 - 53382	9100	Outgoing	Data transfer to the label printer

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, legend, program, malfunction log	10 kB	2-6 kB
System log	64 kB	--
Graphic log	800 kB	580 kB
Data transfer MELAconnect	240 bit/s per device	approx. 200 bit/s per device
Data transfer, web interface (browser)	12 kbits/s per connection	--

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 authorised 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.

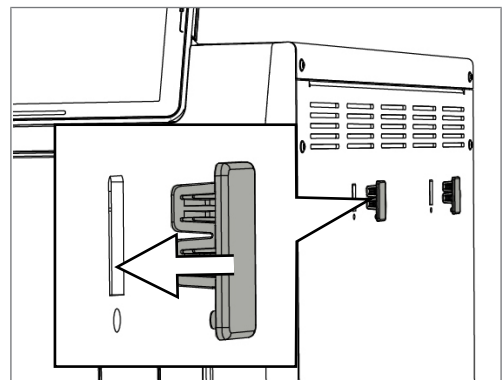
- The device should always be carried by two people.
- Use the correct carrying straps to carry the device.
- Comply with the safety regulations that apply to you.

1. Lift the device out of the box by the carrying straps.
2. Unscrew the four screws from each side of the unit cover to remove the straps.
3. Screw the screws back in tightly without washers.
4. Store the carrying straps and washers in a safe place.
5. After switching on the device, immediately open the door and remove the tablets and the accessories.

Applying the cover caps at the side wall

There are rectangular recesses on both side walls of the steam sterilizer for attaching the mounts of the water treatment unit MELAdem 40. Close the recesses with the cover caps (included in the scope of delivery) if you are not using a water treatment unit.

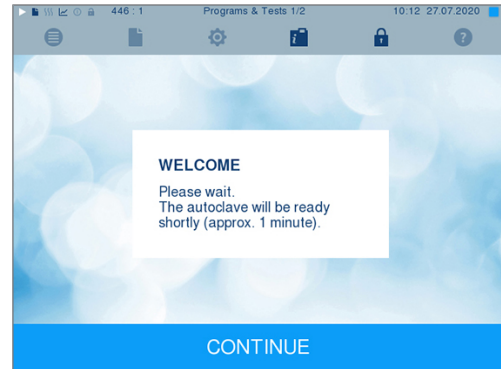
- ▶ Press the cover caps into the recesses as shown in the figure.



For further information see user manual MELAdem 40.

Connecting the power cable / removing accessory parts

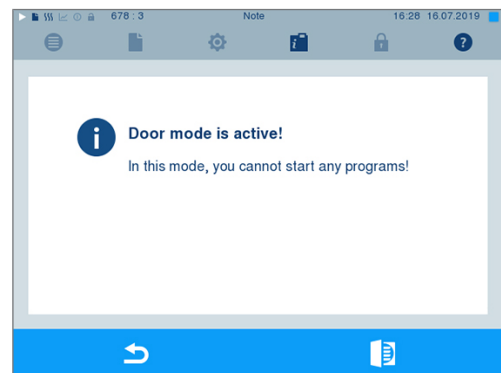
1. Connect the device power plug to the mains socket.
2. Switch on the device at the power switch. The display shows the WELCOME screen.




PLEASE NOTE

The display automatically switches to the **Programs & Tests** menu after five seconds. Then the steam sterilizer will attempt to pump water; this will trigger a malfunction message if no feed water is available.

3. As soon as the WELCOME screen has appeared, press the place of the second symbol from right in the action bar and hold it depressed until the display shows the the adjacent screen.



4. Open the door by pressing the door symbol .
5. Remove all accessory parts from the device.

Connecting the feed water supply (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 with the same water quality is possible after consultation with MELAG.

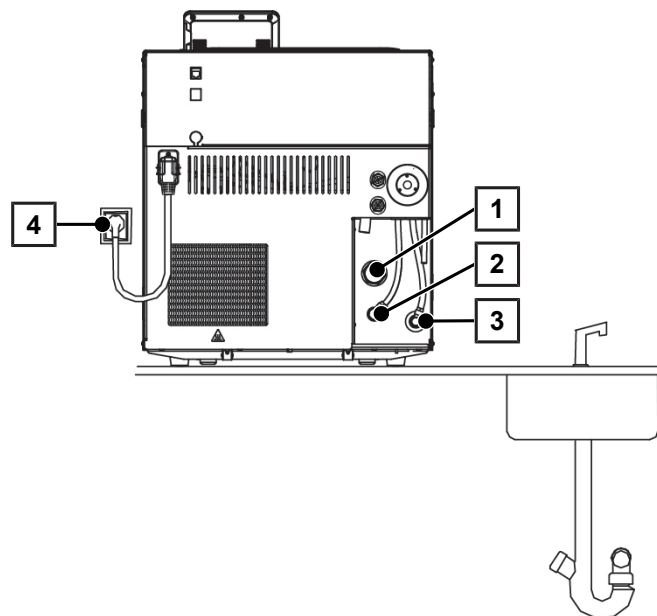


PLEASE NOTE

For detailed information on the cold water connection of the water treatment unit, see the user manual of the unit.

Example 1: Using the internal water storage container

The steam sterilizer is supplied with feed water directly from the internal storage tank via a hose. Thus, apart from the mains connection, no additional water connection is necessary. 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 in the wastewater chamber notifies a full wastewater chamber.



Pos.	Description	Art. no.	Note
1	One-way drain with Yellow plastic cap 3/4" and Rubber seal 3/4" for external water supply	-- ME58140 ME56950	present on device-side
2	Feed water connection, Vacuklav	ME21175	present on device-side
3	Threaded connection 1/4", angle, for hose 8/6 mm (pressure release connection)	ME53471	present on device-side
4	Mains connection	--	on-site

Example 2: Using the MELAdem 40 ion exchanger

The most simple installation is the direct connection of the ion exchanger to the steam sterilizer feed water inflow; this generates demineralised water from normal tap water. The MELAjet spray gun can be installed as an option.



NOTICE

When connecting an external feed water supply it is necessary to connect an external wastewater outflow as well.

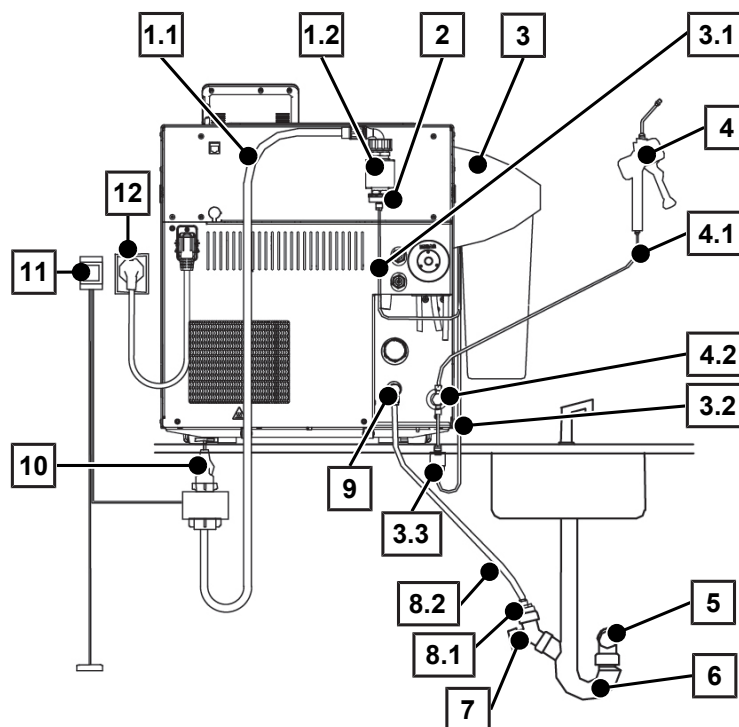
There is a risk that hot wastewater might run through the emergency overflow.

To convert to the feed water supply from a water treatment unit, make the following preparations:

1. Empty both chambers of the internal storage tank.
2. Replace the feed water inflow fitting (5) located on the steam sterilizer with the hollow screw with feed water inflow fitting for hose Ø 6x1 (art. no. ME25655) because of the different hose diameter. Both parts are included in the water connection set (art. no. ME09034). When using a MELAjet spray pistol use the swivel screw connection (art. no. ME53465).
3. Replace both Cu seals (art. no. ME42360, included in the scope of delivery) for the hollow screw.

In this example, the used feed water (wastewater) is fed directly via the pressure drain into the siphon of the domestic water network. Use the outlet hose (PTFE hose, Ø 8/6 mm, art. no. ME39180). Alternatively, the wastewater can also be directed into the siphon via the one-way drain, see [Example 3: Using the MELAdem 47 reverse osmosis unit](#) [▶ Page 15].

When connecting the water treatment unit directly to the domestic water network, MELAG recommends the additional installation of the leakage water detector (water stop) with shut-off valve and probe.



Pos.	Description	Art. no.	Note
1	Mounting set EN 1717 for MELAdem	ME49600	optionally available to order
1.1	Water inlet hose (2.5 m, complies with EN 1717)	ME24930	included in ME49600
1.2	Safety combination EN 1717 incl. holder	ME82375	included in ME49600
2	Cold water adapter 3/4" to 1/4" (direct connection water hose)	ME09037	optionally available to order
3	MELAdem 40 ion exchanger	ME01049	optionally available to order
3.1	PUR hose (6/4 mm, inlet hose MELAdem 40)	ME28820	included in ME01049
3.2	PUR hose (6/4 mm, feed water inlet hose)	ME28820	included in ME01049

Pos.	Description	Art. no.	Note
3.3	Filter for MELAdem	ME48240	included in ME01049
4	MELAJet spray pistol	ME27300	optionally available to order
4.1	PUR hose (6/4 mm, MELAJet hose)	ME28820	included in ME27300
4.2	Feed water inlet connection (swivel screw connection) MELAJet	ME53465	included in ME27300
5	Wall outlet NW 40	--	on-site
6	Double-chamber siphon	ME26635	optionally available to order
7	Double support sleeve for an existing trap (optional)	ME37400	optionally available to order
8	Wastewater hose for pressure release 41 B+ (Evo)/43 B+ (Evo)	ME39181	optionally available to order
8.1	Hose PTFE (8/6 mm, 5 m, wastewater hose)	ME39180	included in ME39181
8.2	Wastewater adapter (G1/4" internal thread)	ME56930	included in ME39181
9	Threaded connection 1/4", angle, for hose 8/6 mm (pressure release connection)	ME53471	present on device-side
10	Water tap with safety combination	--	on-site
11	Water stop (leakage water detector with shut-off valve and probe)	ME01056	optionally available to order
12	Mains connection	--	on-site

Example 3: Using the MELAdem 47 reverse osmosis unit

The reverse osmosis unit is connected directly to the feed water inflow of the steam sterilizer and uses normal tap water to generate demineralised water.



NOTICE

When connecting an external feed water supply it is necessary to connect an external wastewater outflow as well.

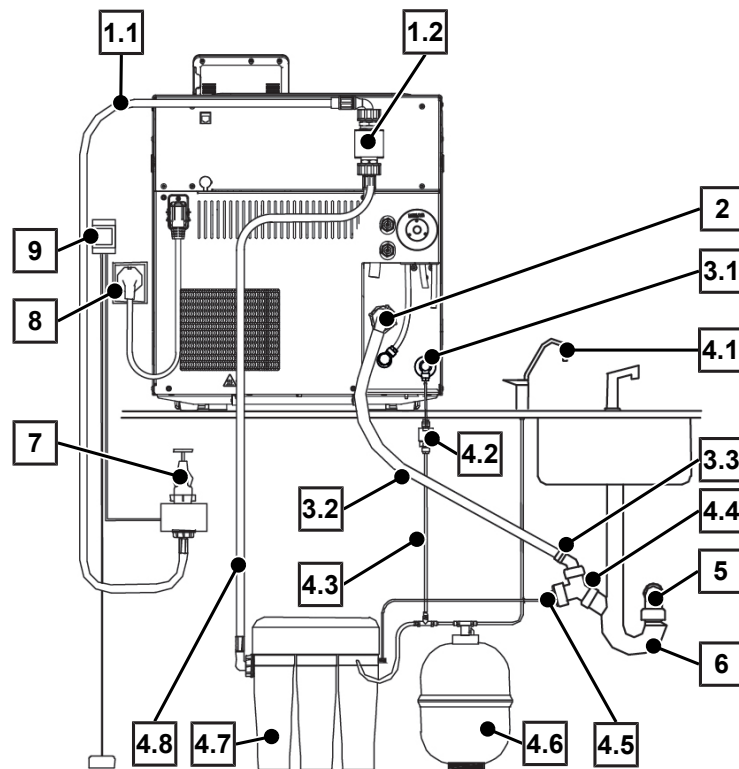
There is a risk that hot wastewater might run through the emergency overflow.

To convert to the feed water supply from a water treatment unit, make the following preparations:

1. Empty both chambers of the internal storage tank.
2. Replace the feed water inflow fitting located on the steam sterilizer with the banjo bolt with feed water inflow fitting for hose Ø 6x1 (art. no. ME25655) because of the different hose diameter. Both parts are included in the water connection set (art. no. ME09034). When using a MELAJet spray pistol use the swivel screw connection (art. no. ME53465).
3. Replace both Cu seals (art. no. ME42360, included in the scope of delivery) for the hollow screw.

In this example, the used feed water (wastewater) is fed via the one-way outlet drain into the siphon of the domestic water network. To do this, connect the outlet hose and mount it to the double-chamber siphon via the double hose nozzle.

When connecting the water treatment unit directly to the domestic water network, MELAG recommends the additional installation of the leakage water detector (water stop) with shut-off valve and probe.



Pos.	Description	Art. no.	Note
1	Mounting set EN 1717 for MELAdem	ME49600	optionally available to order
1.1	Water inlet hose (2.5 m, complies with EN 1717)	ME24930	included in ME49600
1.2	Safety combination EN 1717 incl. holder	ME82375	included in ME49600
2	One way drain	--	present on device-side
3	Water connection set for Premium-Class (41 B+/43 B+)	ME09034	optionally available to order
3.1	Feed water connection of Euroklav/Vacuklav	ME25655	included in ME09034
3.2	Hose for water drain of steam sterilizers, 2 m	ME36585	included in ME09034
3.3	Cold water adapter 3/4" to 1/4" (direct connection water hose)	ME09037	included in ME09034
4	MELAdem 47 reverse osmosis unit	ME01047	optionally available to order
4.1	External tap for demineralised water	ME91900	included in ME01047
4.2	Filter for MELAdem	ME48240	included in ME01047
4.3	PUR hose (6/4 mm, feed water inlet hose)	ME28820	included in ME01047
4.4	Double support sleeve for an existing trap	ME37400	included in ME01047
4.5	Wastewater adapter (G1/4" internal thread)	ME56930	included in ME01047
4.6	Pressure tank MELAdem 47 (with shut-off valve and hose)	ME57065	included in ME01047
4.7	MELAdem 47 reverse osmosis unit (without accessories)	ME56740	included in ME01047
4.8	Water inflow hose (2.5 m) (inlet hose MELAdem 47)	ME37220	included in ME01047
5	Wall outlet NW 40	--	on-site
6	Double-chamber siphon	ME26635	optionally available to order
7	Water tap with safety combination	--	on-site
8	Mains connection	--	on-site
9	Water stop (leakage water detector with shut-off valve and probe)	ME01056	optionally available to order

Connection to the wastewater

Method 1: Via the one-way drain

If you connect the one-way overflow hose of the device to the siphon of the domestic water supply, you need a drain hose with a length of 2 m (art. no. ME36585, not included in the scope of delivery).

Method 2: Via the pressure release

To connect the device directly to the wastewater, i.e. from the pressure outlet directly into the siphon of the domestic water supply, you need a drain hose with a length of 1 m (art. no. ME39180, not included in the scope of delivery).

Setting up the steam sterilizer

For malfunction-free operation, set up the device horizontally using a spirit level resting against the chamber flange. Depending on the type of the steam sterilizer the front feet of the device must be unscrewed by about three (Vacuklav 40 B+/41 B+) or five (Vacuklav 43 B+/44 B+) rotations in order to give the steam sterilizer a slight backwards tilt.

Test runs

Vacuum test with cold sterilization chamber

Perform a **Vacuum test** with an empty cold sterilization chamber and record the result.

Universal-Program

If the vacuum test was successful, run a **Universal-Program** with 1.5 kg load (instruments) and record the result.

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 of the Pressure Equipment Directive and the Medical Device Directive are included in the manufacturer's inspection report.

4 Settings and adjustment

Settings on the device

Date and time

Check the date and time and set if necessary, see User manual.

Display settings

If required, working in the Settings menu, adjust the brightness, key tone and the touch-sensitivity, see User manual.

Contact data of the service partner

Working in the **Settings** > **Service** menu, enter the name and address of the responsible service partner.

Resetting the maintenance counter

Reset the maintenance counter in accordance with the instructions "Resetting the maintenance counter upon initial commissioning and maintenance" (doc. PW_common).

User administration and logging

Instruct the user in the user administration and possible logging: consult user manual. If you require an admin PIN, enter this and any further settings in the record of installation and setup.

IP addresses



NOTICE

The setting up in the (practice) network will require in-depth understanding of the network technology.

Handling errors of IP addresses can result in malfunctions and data loss in your user network.

- IP addresses may only be set by the (practice) network system administrator.

The device is equipped as standard with IP addresses which all belong to a common network with the subnet mask stated in the following table. These pre-set IP addresses listed in may not yet been assigned in the (practice) network.

Works pre-setting of the device IP addresses

Device	IP address	Remarks
Steam sterilizer	192.168.40.40	Pre-set ex works
computer	192.168.40.140	Pre-set ex works
Log printer	192.168.40.240	Pre-set ex works
Label printer	192.168.40.160	Pre-set ex works
Gateway	192.168.40.244	Not relevant within a network
Subnet mask	255.255.255.0	Possibly to be adopted by customer network

Additional drying and further program modifications

The stages of the steam sterilizer programs (fractionating, heating, sterilizing, pressure release, drying and aeration) and its parameters (pressure, temperature and time) are conform with the usual requirements placed by a practice environment. The **Additional drying** function in the **Settings** menu provides a standard possibility of influencing the course of the program run. Further alterations to the program run are possible in each individual case and will still ensure the effectiveness of the sterilization, but may only be performed by authorized technicians. Please consult your stockist or MELAG.

System and status log

Output a system and status log and document this on the record of installation and setup.

Counter stands

Working in menu **Info & Status**, you can access counter stands and other up-to-date technical data.

5 Frequently Asked Questions (FAQ)

What does the log name mean?

Complete encoding of both the serial number and the total batch number is performed in the 8 digit log name. Manually re-named files are always easy to identify but not to be recommended. A log name is never assigned twice. The log name achieves good log sortability.

Knowledge of the encoding within the name of the log file is not necessary, as a double-click on the file reveals the content and thus serial number and total batch number immediately. This requires assignment of a log file to a text editor.

Example	H	2	0 S E	0 0 F	.	P R O
Meaning	Serial number			Total batches		File ending
	Year of construct.	Type	Production no.			
Explanation	H...2017 I...2018 J...2019 K...2020	0...40 B+ 1...41 B+ 2...43 B+ 4...44 B+				Example: .PRO = successfully ended program

Date and time of the log files

The date and time of the log files in Windows explorer are identical with the time of the program start, provided of course that the files were saved on the corresponding medium via immediate output. The information is lost upon subsequent collected issue on a medium or e-mail dispatch.

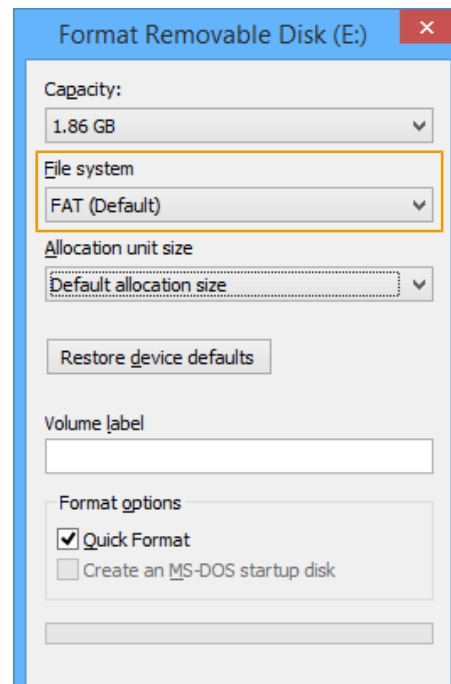
How to format a CF card on the computer correctly?

The CF card should only be formatted on the device. In exceptional circumstances, this can be performed on the computer. The CF card used may have a max. memory space of 4 GB and must be formatted with the file system FAT16 or FAT32. CF cards from which a software update is to be performed may only be formatted in a FAT16 file system.

The device can only file or read data on CF cards formatted in this way. CF cards supplied by MELAG fulfil these requirements and have already been formatted.

Formatting on a computer is described in Windows 7:

1. Insert the CF card in the MELAflash card reader installed and connected to the computer.
2. Working in Windows Explorer "Computer" > "Devices with Removable Storage" select the corresponding drive and open the menu window by right-click.
3. Working in the menu window, select the "Format..." option. The adjacent dialogue window opens.
4. Working under file system, select the format "FAT (Default)".
5. Working under "Allocation unit size" Windows automatically selects the appropriate allocation unit for the respective size of the CF card. The allocation unit is dependent of the size of the CF card.
6. Click on "Start".



How to incorporate the device in a (practice) network?

Arrange for the IT company that services your network to incorporate your device in the network.

Note the following:

- The computer is equipped with a network card with a RJ45 bushing (LAN).
- Log archive via FTP: An FTP server^{*)} or an FTP service is installed on the computer that permits the creation of users with write permission independent of the operating system.
- Log output via TCP: A suitable program, e.g. MELAtrace, is installed.

^{*)} We recommend using the MELAG FTP server to incorporate network-compatible MELAG devices in a (practice) network.

1. Setting up the FTP server (only with log output via FTP)

A computer must be determined in the (practice) network on which the FTP server should run. This program receives the logs via data transfer. The steam sterilizer searches for the FTP server using the IP address set in the steam sterilizer and logs on. The logs of the completed program are saved on this computer later. When choosing the computer, be aware that it would be advantageous to integrate the logs thus saved in the practice automatic data saving system.

MELAG provides its own FTP program free of charge. Using the MELAG FTP server enables the registration of multiple devices as users simultaneously and the receipt of data from the steam sterilizer and other devices such as a washer-disinfector. The FTP server supports the so-called multithread capability. You can determine the folder in which the device directory and log files are to be stored in the FTP server program.

1. Working in the (practice) network, determine which computer should run on the FTP server.
2. If an FTP server has not yet been installed, install the MELAG FTP server for preference and set the steam sterilizer as user with a user name and password.
3. Working on the steam sterilizer, set the computer as the log output medium (log output via FTP). Further information regarding log output is set out in the user manual (chapter Settings, Logging).

2. Connecting the network cable

- ▶ Connect the network cable (crossover) to any network data connection of the device and connect it to the (practice) network. If "smart switches" are used in the network, the cable type (1:1 or crossover cable) does not matter.



PLEASE NOTE

Should you wish to connect the steam sterilizer to a computer directly without a network connection, use a 1:1 cable.

3. Adjusting IP addresses in the steam sterilizer



NOTICE

The setting up in the (practice) network will require in-depth understanding of the network technology. Handling errors of IP addresses can result in malfunctions and data loss in your user network.

- IP addresses may only be set by the (practice) network system administrator.



NOTICE

If you use a subnet mask other than that set in the steam sterilizer, an IT specialist should adapt all the IP addresses in the device.

As a matter of course: The selected computer must always have a fixed IP address, regardless of whether it is in an automatically or manually configured network. In an automatically configured network, it is necessary to inform the DHCP server of the area with the number or the number itself as a static IP address(es). The computer can also be assigned multiple IP addresses if those already present in the computer are not to be used.

1. Ask the IT administrator for the IP address of the computer first or find out yourself.
2. Check whether the computer has a dynamic or a fixed IP address.
 - ↳ The computer must be issued with a fixed IP address. Change this if necessary.

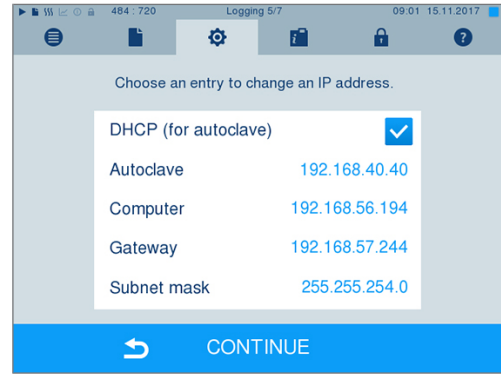
With a manually-configured (practice) network:

1. Check whether the steam sterilizer and the computer belong to a subnetwork. In the majority of cases, this usually means that the first three numbers of the IP address of the sub network should correspond (e.g. **192.168.40.xx**). The IP addresses of the steam sterilizer and the computer must be different in the fourth number block (e.g. IP steam sterilizer: 192.168.40.**20** and IP computer: 192.168.40.**140**).
 - ↳ If the IP addresses of both devices do not belong to a subnetwork, change the steam sterilizer IP address directly in the steam sterilizer.
2. Check whether the IP address of the computer set in the steam sterilizer is correct.
 - ↳ If the IP address of the practice computer deviates from the IP address set in the steam sterilizer, adapt the IP address of the computer in the steam sterilizer.

With a dynamic (practice) network (DHCP):

The steam sterilizer can also be administered automatically in a dynamic network. If log output is made via FTP, the computer should be issued with a fixed IP address which is entered on the steam sterilizer.

- Working in the **Settings** menu > **Logging**, set the IP address of the steam sterilizer to DHCP.



- Check whether the IP address of the computer set in the steam sterilizer is correct.
 - If the IP address of the practice computer deviates from the IP address set in the steam sterilizer, adapt the IP address of the computer in the steam sterilizer.



PLEASE NOTE

If a DHCP server cannot be located in the (practice) network, the steam sterilizer will automatically receive the pre-set static IP address.

How do I determine the IP address or network setting of a computer (Windows 7/10)?

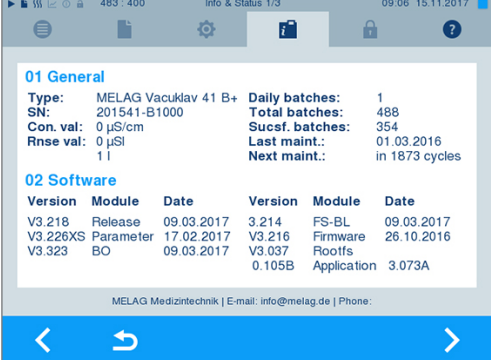
- Open "Network and Sharing Center" or the network and internet settings.
- Open the Properties window under "Local Area Connection" > right-click on "Properties".
- Working in the Properties window, select "Internet Protocol Version 4 (TCP/IPv4)" and click on push-button "Properties".
 - If "Obtain the IP address automatically" is selected in the opening dialogue window, the computer is addressed dynamically in the (practice) network i.e. via DHCP.

What do the terms IP address, subnetwork and DHCP mean?

Term	Meaning
IP address	The IP address is a identifier of the computer or device expressed in numbers in a network. It serves to identify the computer or device with four number blocks (e.g. 192.168.88.8).
Subnetwork	Every IP address is divided into a network and a device (host) section. The division is performed via the subnetwork mask (also: subnet/sub-net mask). The network section of the IP addresses must be identical so that the devices can communicate with each other. With a network entry mask = 255.255.255.0 (the most often) the first three numbers (e.g. 192.168.88.x) must be the same. The device part of the IP address is assigned individually and only once. The first (network itself) and the highest (broadcast) device address may not be issued.
DHCP	The IP addresses are automatically issued in a computer network via DHCP (= Dynamic Host Configuration Protocol) i.e. the IP addresses need not be entered manually in every device in the network. The precondition is the presence of a DHCP server in a network.

How can I check the software version of the steam sterilizer?

- ▶ You can read off the software version of the activated steam sterilizer from the **Info & Status** menu.



The screenshot shows the 'Info & Status' menu of a MELAG steam sterilizer. The top status bar displays 'Info & Status 1/3' and the date '09.06.15.11.2017'. The main content is divided into two sections: '01 General' and '02 Software'.

01 General

Type:	MELAG Vacuklav 41 B+	Daily batches:	1
SN:	201541-B1000	Total batches:	488
Con. val:	0 µS/cm	Sucsf. batches:	354
Rnse val:	0 µS/l	Last maint.:	01.03.2016
	1 l	Next maint.:	in 1873 cycles

02 Software

Version	Module	Date	Version	Module	Date
V3.218	Release	09.03.2017	3.214	FS-BL	09.03.2017
V3.226XS	Parameter	17.02.2017	V3.216	Firmware	26.10.2016
V3.323	BO	09.03.2017	V3.037	Rooffs	
			0.105B	Application	3.073A

MELAG Medizintechnik | E-mail: info@melag.de | Phone:

6 Technical tables

Feed water quality

Minimum requirements to the feed water following 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
Traces of heavy metal apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 2 mg/l
Phosphate	≤ 0.5 mg/l
pH value	5 - 7.5
Appearance	≤ colourless, clear, without sediments
Hardness	≤ 0.02 mmol/l

Precision and drift behaviour

Sensors

Temperature sensors

Sensor type	PT 1000 Class A according to DIN EN 60751
Precision (at 135 °C)	± 0.42 K
Drift per year	± 0.05 K
Drift in 5 years	± 0.25 K

Pressure sensor

Sensor type	Piezoresistant absolute pressure sensor 0 to 4000 mbar
Precision	± 0.3 % corresponds to ± 12 mbar corresponds to approx. ± 0.13 K steam
Drift per year	± 0.2 % corresponds to ± 8 mbar corresponds to approx. ± 0.09 K steam
Drift in 5 years	± 1.0 % corresponds to ± 40 mbar corresponds to approx. ± 0.44 K steam

Measuring chains

Measuring chain for the temperature measurement on the electronics (without sensor)

Precision (at 135 °C)	± 0.2 K
Drift per year	± 0.005 K
Drift in 5 years	± 0.025 K

Measuring chain for the pressure measurement on the electronics (without sensor)

Precision	± 0.2 % corresponds to ± 8.0 mbar corresponds to approx. ± 0.09 K steam
Drift per year	± 0.004 % corresponds to ± 0.16 mbar corresponds to approx. ± 0.017 K steam
Drift in 5 years	± 0.02 % corresponds to ± 0.8 mbar corresponds to approx. ± 0.09 K steam

After 1 year**Entire measuring chain of the temperature measurement**

Precision (at 135 °C)	at pure addition of individual errors approx. ± 0.70 K
Precision (at 135 °C)	according to Gauss' law of propagation approx. ± 0.47 K

Entire measuring chain of the pressure measurement

Precision	at pure addition of indiv. errors	± 0.70 % corresponds to ± 28.0 mbar corresponds to approx. ± 0.30 K steam temperature
Precision	per Gauss' law of propagation	± 0.41 % corresponds to ± 16.5 mbar corresponds to approx. ± 0.18 K steam temperature

After 5 years**Entire measuring chain of the temperature measurement**

Precision (at 135 °C)	at pure addition of individual errors approx. ± 0.70 K
Precision (at 135 °C)	according to Gauss' law of propagation approx. ± 0.47 K

Entire measuring chain of the pressure measurement

Precision	at pure addition of individual errors	± 0.70 % corresponds to ± 28.0 mbar corresponds to approx. ± 0.30 K steam temperature
Precision	per Gauss' law of propagation	± 0.41 % corresponds to ± 16.5 mbar corresponds to approx. ± 0.18 K steam temperature

Nominal value tolerances

Step	Universal-Program		Quick-Program B		Prion-Program		Gentle-Program		Quick-Program S		All values in mbar	
	Press. P	Tolerance	P	Tol.	P	Tol.	P	Tol.	P	Tol.		
SK11	1600	+100/- 20	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake	1
SK12	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	◀	◀	Press. release	
SK11	1600	+100/- 20	◀	◀	◀	◀	◀	◀	---	---	Steam intake	
SK12	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	---	---	Press. release	
SK21	1600	+100/- 20	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake	
SK22	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	◀	◀	Press. release	
SK21	1600	+100/- 20	◀	◀	◀	◀	◀	◀	---	---	Steam intake	
SK22	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	---	---	Press. release	
SK21	1600	+100/- 20	---	---	◀	◀	◀	◀	---	---	Steam intake	
SK22	1300	+ 20/- 50	---	---	◀	◀	◀	◀	---	---	Press. release	
SF12	500	+ 30/- 30	◀	◀	◀	◀	◀	◀	300	◀	Evacuation	2
SF13	1600	+100/- 20	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake	
SF21	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	◀	◀	Press. release	
SF22	180	+ 30/- 30	◀	◀	◀	◀	◀	◀	200	◀	Evacuation	
SF23	1800	+100/- 20	◀	◀	◀	◀	◀	◀	◀	◀	Steam intake	
SF31	1300	+ 20/- 50	◀	◀	◀	◀	◀	◀	---	---	Press. release	
SF32	200	+ 30/- 30	◀	◀	◀	◀	◀	◀	---	---	Evacuation	
SF33	1900	+100/- 20	◀	◀	◀	◀	◀	◀	---	---	Steam intake	
SF41	1300	+ 20/- 50	---	---	◀	◀	◀	◀	---	---	Press. release	
SF42	400	+ 30/- 30	---	---	◀	◀	◀	◀	---	---	Evacuation	
SF43	1700	+100/- 20	---	---	◀	◀	1500	◀	---	---	Steam intake	
SH01	2750	+ 60/- 60	◀	◀	◀	◀	1850	◀	◀	◀	Hold steam intake	
SH02	2850	+ 60/- 60	◀	◀	◀	◀	1950	◀	◀	◀	Hold control	
SS01	3080	+ 60/- 60	◀	◀	◀	◀	2080	◀	◀	◀	Steriliz. entry	
SS02	3170	+ 60/- 60	◀	◀	◀	◀	2150	◀	◀	◀	Sterilization	
SA00	1300	+ 20/- 50	◀	◀	◀	◀	1300	◀	◀	◀	Press. release	

Key:

◀ As in Universal-Program

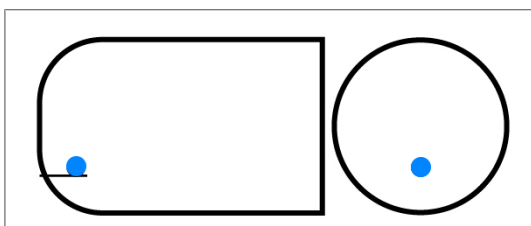
1 - Conditioning

2 - Fractionation

Empty chamber test

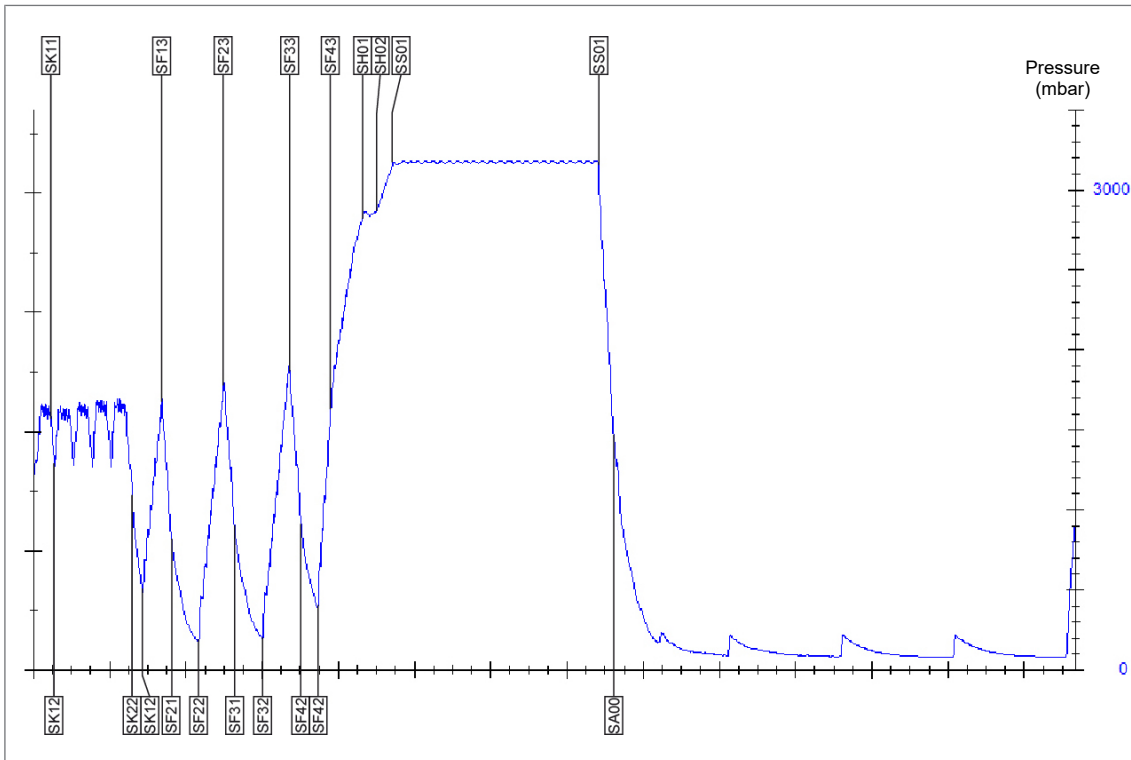
The coldest point in the sterilization chamber during the empty chamber test lies directly on the temperature sensor (see circular marking in the following figure). The temperature in the rest of the sterilization chamber is almost the same all over (0.6 K range).

Schematic side and fore view of the sterilization chamber

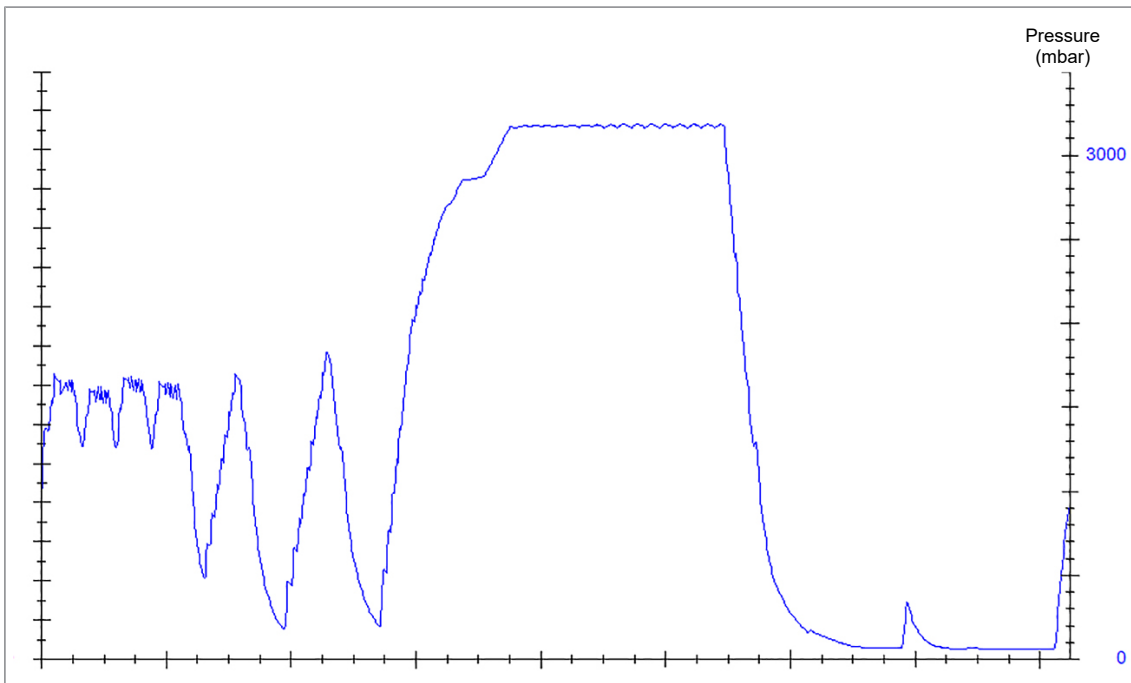


Pressure-time charts

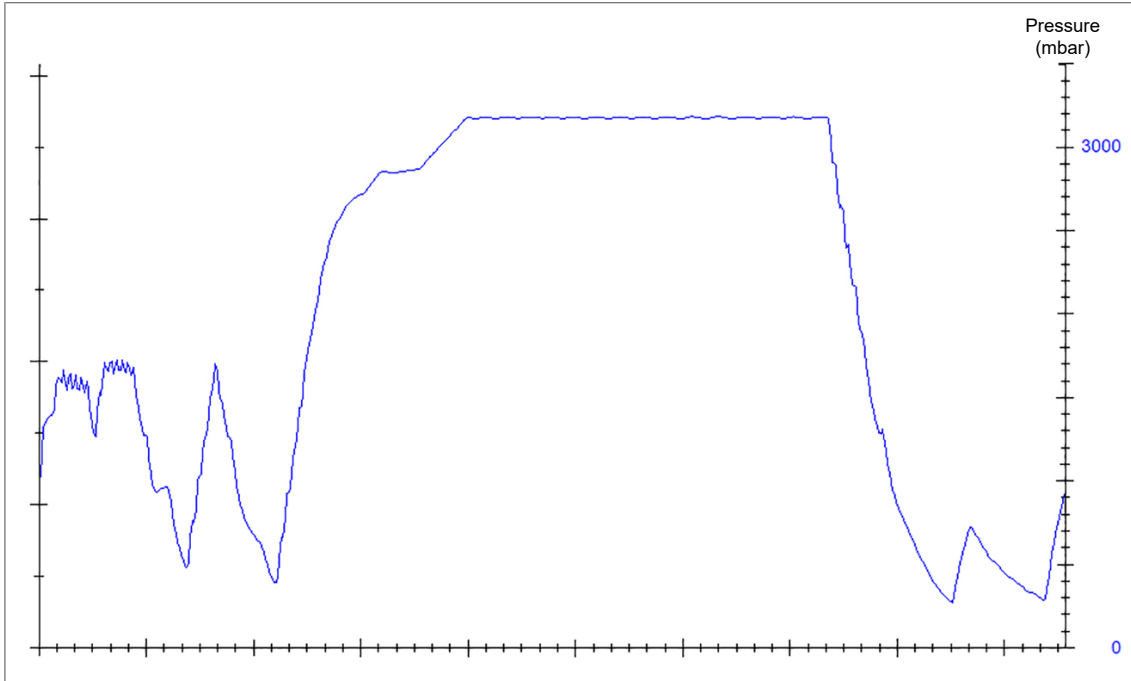
Universal-Program, 134 °C and 2.1 bar



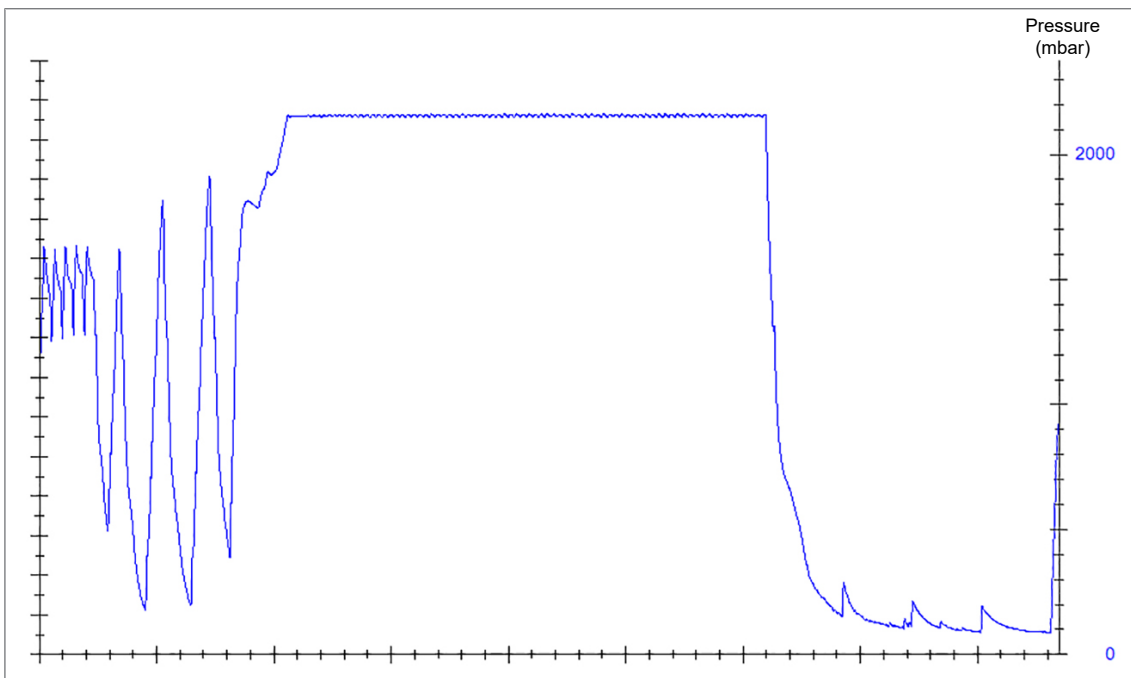
Quick-Program B, 134 °C and 2.1 bar



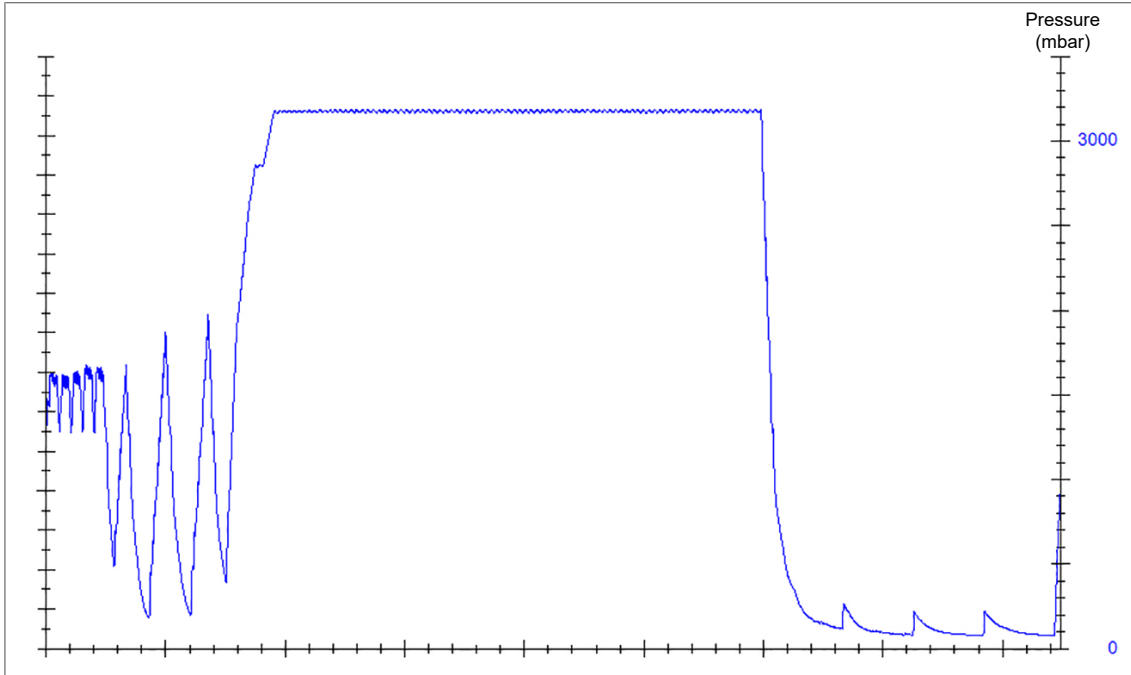
Quick-Program S, 134 °C and 2.1 bar



Gentle-Program, 121 °C and 1.1 bar



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® 41 B+/Vacuklav® 43 B+
Type of device:	Steam sterilizer
Classification:	Class IIb
Device type acc. to EN 13060:	Type B

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

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

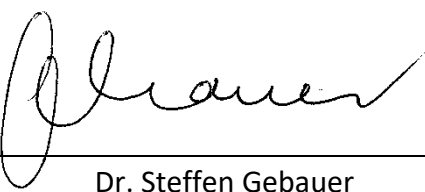
Instructions on load quantities and loading variants are specified in the user manual and must be observed.

Be sure to observe the manufacturer's instructions for medical devices intended for sterilization according to EN ISO 17664-1.

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

- **MELAcontrol® Helix and MELAcontrol® Pro**

Berlin, 01.08.2023



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