MELAG
competence in hygiene

Technical Manual

Vacuklav® 41 B+ *Evolution*
Vacuklav® 43 B+ *Evolution*

Steam sterilizer

from software version 3.218

CE 0197

Contents

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 or a direct waste water connection.

The following additional material can be ordered as required:

Qty.	Article	Art. no.
1	Water connection set for Premium-Class (41 B+ / 43 B+)	09034
1	Water outlet hose for steam sterilizers, 2 m	36585
1	Outlet hose for pressure release 41B+ Evo/43 B+ Evo	39181
1	Surface-mounted siphon	37410
1	Double hose grommet for siphon (with non-return valve 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 an existing angle valve)	58130
1	Water stop	01056

During initial commissioning, the steam sterilizer consumes three litres water (one-off) in accordance with EN 13060, Appendix C, to fill the double jacket. We recommend refilling the right-hand chamber of the internal storage tank immediately.

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.

Properties	Vacuklav 41 B+	Vacuklav 43 B+
Set-up surface	level and horizontal	
Max. floor loading (normal operation)	3.70 kN/m²	3.37 kN/m²
Heat emission (with max. load)	1.7 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	

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
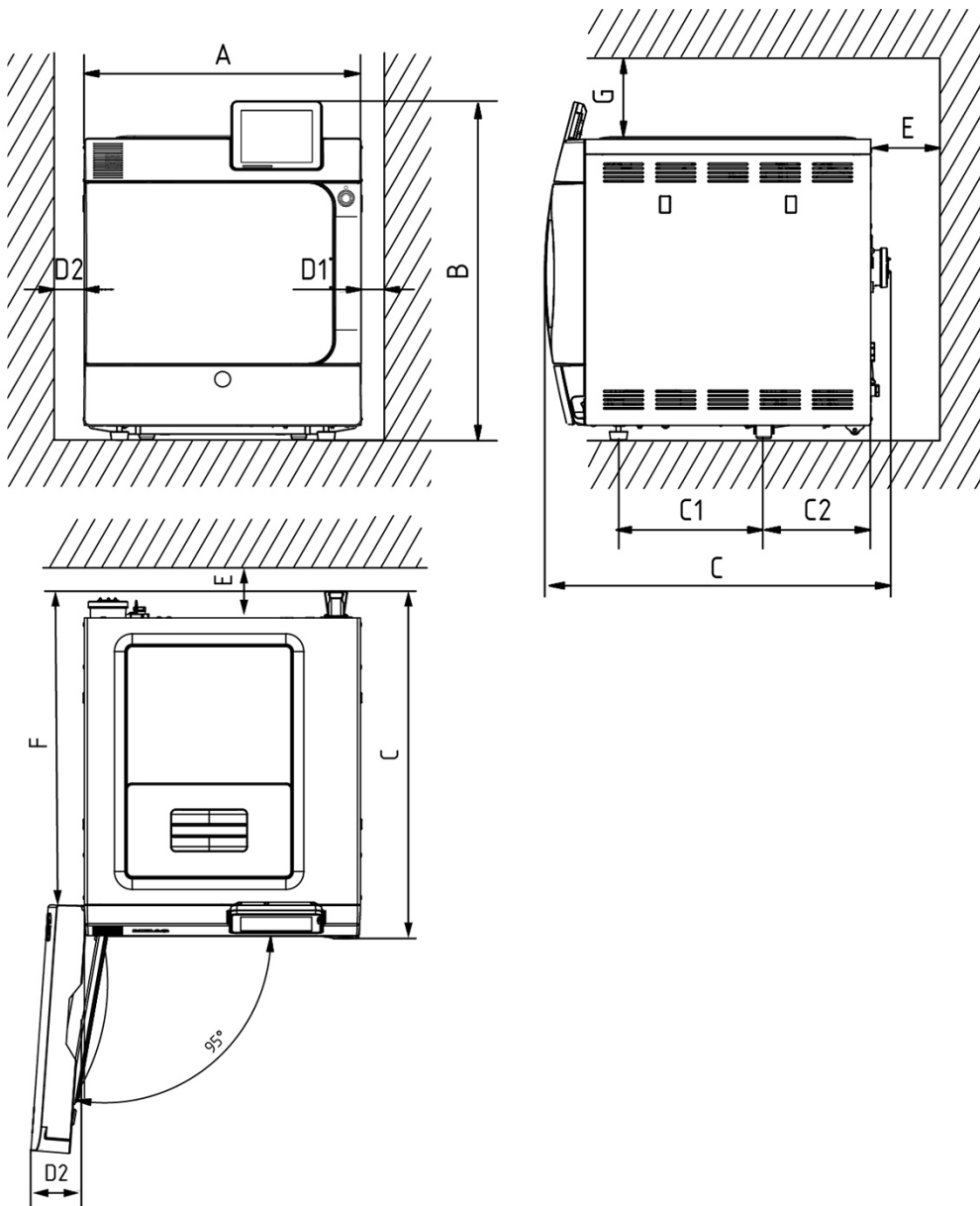
Dimensions			Vacuklav 41 B+	Vacuklav 43 B+
Width	A		46 cm	46 cm
Height	B		56.5 cm	56.5 cm
Depth	C		58 cm	69 cm
Clearance between the device feet	C1		24 cm	35 cm
Clearance from rear device foot up to the rear panel	C2		17.6 cm	17.6 cm
Min. clearance to the side	D1		5 cm	5 cm
Min. clearance to the side of the door hinge	D2		14 cm	14 cm
Min. clearance to the rear	E		10 cm	10 cm
Free area with a fully-opened door	F		52 cm	63 cm
Min. clearance above (pull-out / with exhaust shaft)	G		5 / 20 cm	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 the incorporation of a device

If the incorporation of the device is absolutely necessary, one of the following measures must be implemented:

1. The device must be able to be pulled out for operation (pos. a).

2. In the installation space, there must be an exhaust air duct in the rear area which diverts the warm air upwards (pos. b).

3. In the installation space, there must be an exhaust air duct in the rear area which diverts the warm air actively to the rear (pos. c).

4. Switching off the DRYtelligence (menu `Settings` > `Intelligent drying`).
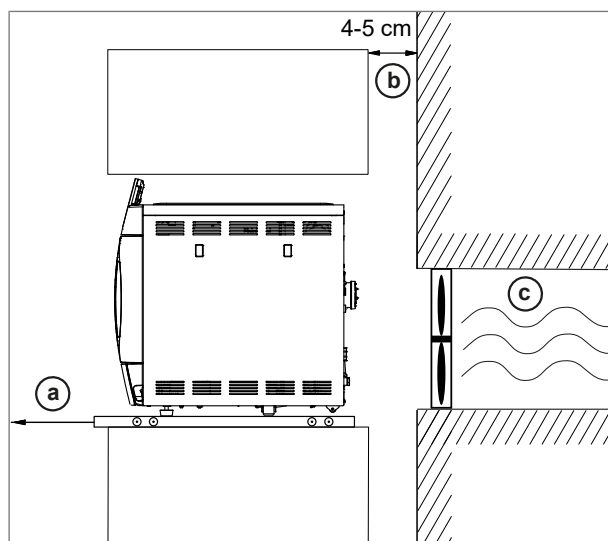
Additional space requirement for the feed water supply

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

On-site requirements of the mains supply

Properties	On-site requirements
Electricity supply	socket with 220-240 V, 50/60 Hz, 3400 W*)
Building fuses	a separate circuit with 16 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 or MELAprint 42/44 log printer etc.
Length of power cable	2 m
*) max. voltage range 207-253 V	

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

Water connection

Comply with the following specifications for the water connection if no manual filling or emptying is carried out.

	Feed water	Wastewater
Connection in the practice	via a water treatment unit e.g. MELAdem	via the one-way outlet e.g. with the water connection set

wall outlet, nominal width DN 40 or to a siphon (flush outflow) |
Installation height	--	min. 30 cm under the steam sterilizer
Min. flow pressure	1.5 bar at 3 l/min	--
Recommended flow pressure	1.5-10 bar at 1.4 l/min	--
Min. water pressure (static)	2 bar	--
Max. water pressure (static)	10 bar	--
Max. water temperature	--	98 °C
Water quality	distilled or demineralized 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; fused in accordance with EN 1717)	

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

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	MELAflash CF card up to 4 GB with an FAT16 or FAT32 file system	Writing log data on a MELAflash CF card
		MELAflash CF card up to 4 GB with a FAT16 file system	Update of the device software
Ethernet	Ethernet IEEE 802.3	Switch port (via CAT-5 patch cable)	MELAview saving log data, querying device data
			MELAtrace 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

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! **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 (CF card)

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 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	Port source	Port destination	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 MELAconnect app or 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 log printer
UDP	42380	3000	Outgoing	Broadcast search label printer
TCP	52382 - 53382	9100	Outgoing	Data transfer to 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	c. 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 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.

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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.

Cover caps or brackets for the MELAdem 40

Rectangular recesses are located on both side walls of the steam sterilizer for the application of brackets for the MELAdem 40 water treatment unit. Should you decide not to use them, seal them with the cover caps included in the scope of delivery.
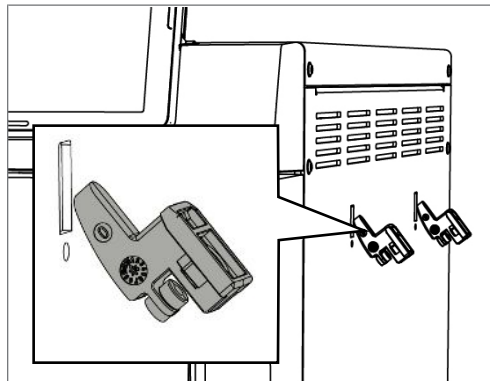
Applying the cover caps

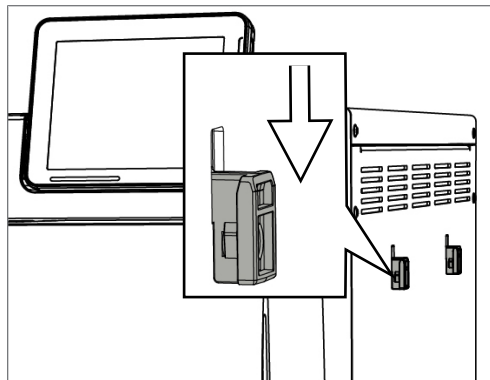▶ Press the cover caps into the recesses as shown in the figure.
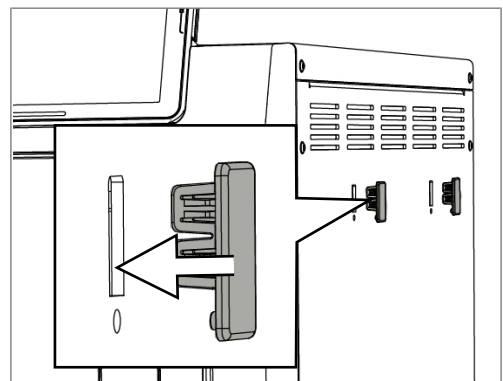
Applying the brackets for the MELAdem 40 water treatment unit

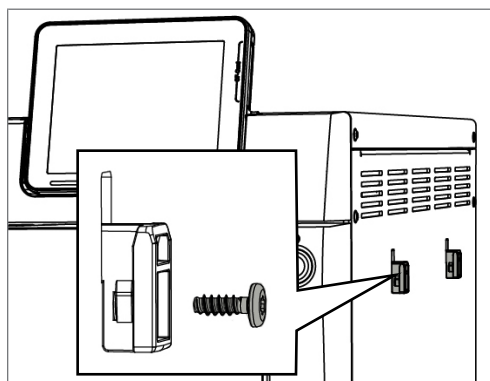1. Guide the brackets into the recesses at an angle, with the hooks pointing upwards.

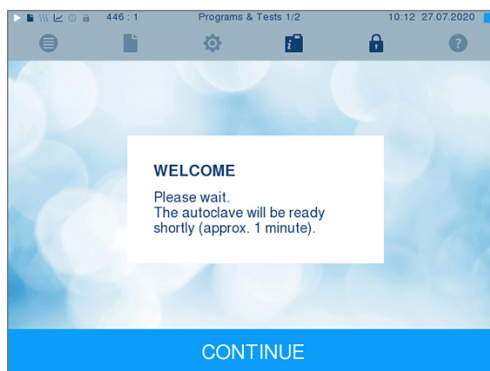2. Pull the brackets vertically downwards until they engage.

3. Fix both brackets with the screws included with the delivery.

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.

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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.
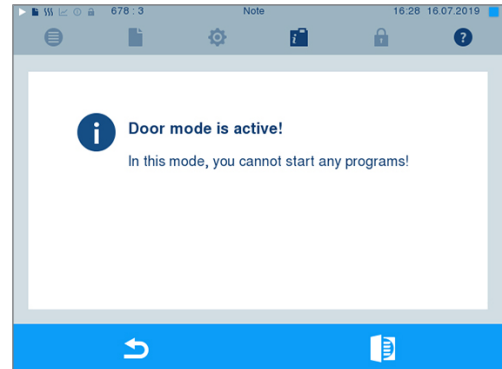
4. Open the door by pressing the door symbol

 .

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.

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. This means that no additional water connection apart from the mains connection is required. 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.
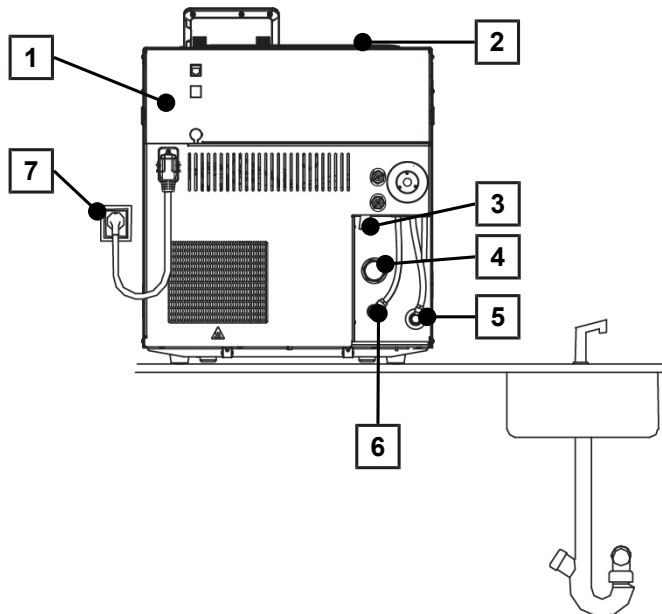
1	Rear view of the steam sterilizer
2	Tank lid
3	Emergency overflow
4	One-way discharge
5	Feed water inflow
6	Pressure release connection
7	Mains socket

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 demineralized water from normal tap water. The MELAjet spray pistol can be installed as an option; this can be used to perform the final rinse of the instruments with demineralized water before sterilization.


! **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.

The following steps are required to upgrade from feed water supply via a water treatment unit:

1. Empty both chambers of the internal storage tank.

2. Due to the difference in hose diameter, replace the existing feed water inflow fitting (5) in the steam sterilizer with a hollow screw with feed water inflow fitting for the Ø 6x1 hose. Both parts are included in the water connection set (art. no. 25655).

3. Replace the two copper seals (art. no. 42360) against the hollow screw - also in the water connection set.

In this example, the used feed water (wastewater) is led directly into the siphon of the domestic water supply via the pressure release. This is performed using the Ø 8/6 mm PTFE hose (art. no. 39180). Alternatively, the wastewater can be led into the siphon via the one way discharge, see Example 3: Using the MELAdem 47 reverse osmosis unit [▶ page 18].
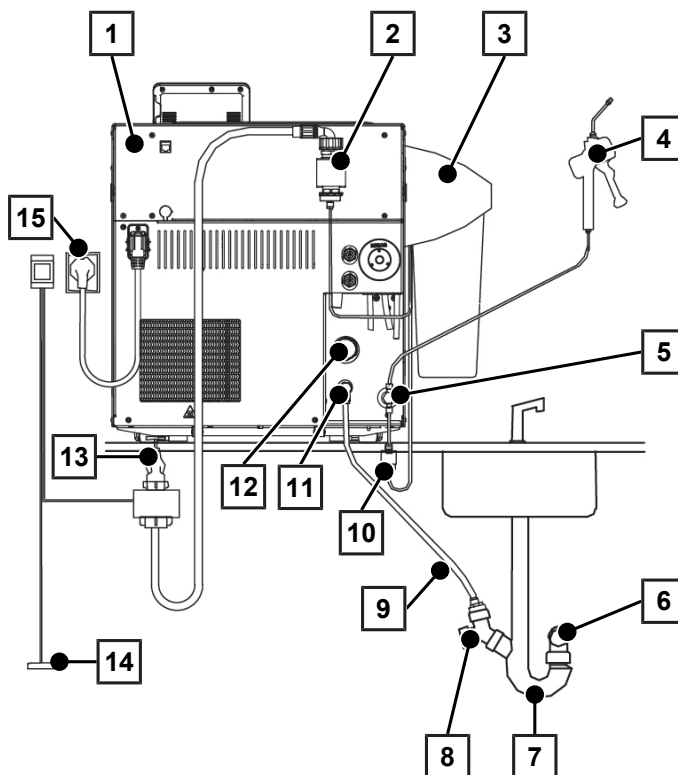
1	Rear view of the steam sterilizer	9	PTFE hose, 8/6 mm, per metre
2	Safety combination in accordance with EN 1717	10	Filter for MELAdem
3	MELAdem 40 ion exchanger	11	Pressure release connection
4	MELAjet spray pistol for MELAdem 40	12	One-way discharge
5	Hollow screw with feed water inflow fitting for Ø 6x1 hose (replaces the fitting for the Ø 8x1 hose, alternative straight)	13	Water tap, available on the building side

6	Wall outlet, available on the building side (DN 40)	14	Water stop
7	Double chamber siphon[1]	15	Mains socket
8	Double hose grommet for siphon (optional)[2]		

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[1] a surface-mounted siphon (separately-available) can be used as an alternative
[2] not included in the scope of delivery of the steam sterilizer

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 demineralized 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.**

The following steps are required to upgrade from feed water supply via a water treatment unit:

1. Empty both chambers of the internal storage tank.
2. Due to the difference in hose diameter, replace the feed water inflow fitting (4) in the steam sterilizer with a hollow screw with feed water inflow fitting for the Ø 6x1 hose. Both parts are included in the water connection set (art. no. 25655).
3. Replace the two copper seals for the hollow screw (art. no. 42360) against the hollow screw - also in the water connection set).

In this example, the used feed water (waste water) is led into the siphon of the domestic water supply via the one-way drain. To this end, connect one end of the water outlet hose (15) to the device and the other end to the double chamber siphon (9) via the double hose grommet (7). With a direct connection of the water treatment unit to the domestic water supply, we recommend the additional installation of the leakage water detector (water stop) with the cut-off valve and sensor (19).
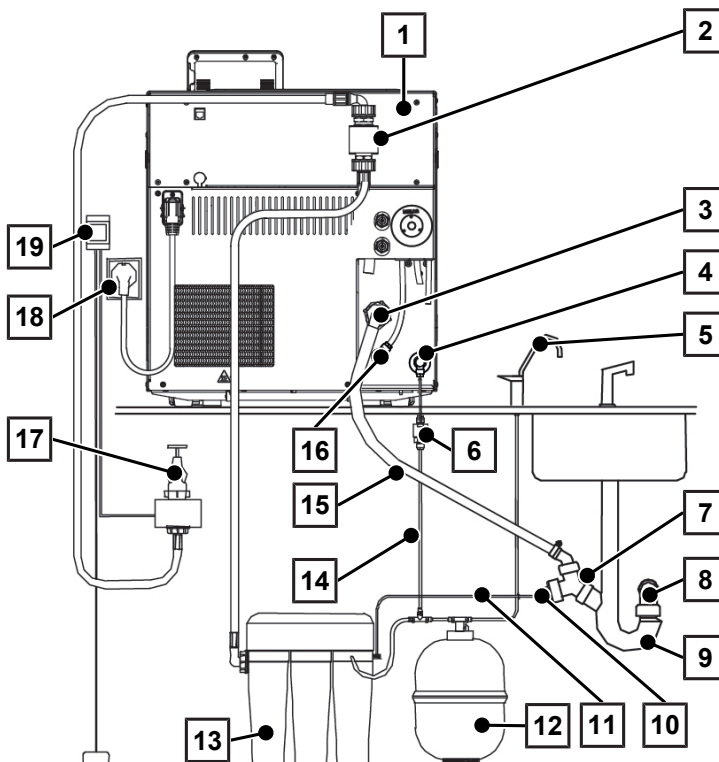
1	Rear view of the steam sterilizer	11	Concentrate line of the reverse osmosis unit
2	Safety combination in accordance with EN 1717	12	Pressure tank of the reverse osmosis unit
3	One-way discharge	13	MELAdem 47 reverse osmosis unit
4	Feed water inflow fitting (swivel screw connection for hose Ø 6x1, alternative straight)	14	Permeate line (feed water) to the steam sterilizer
5	MELAdem spigot	15	Water outlet hose for steam sterilizers, 2 m (DN 16)
6	Filter for MELAdem	16	Pressure release connection

7	Double hose grommet for siphon	17	Water tap, available on the building side
8	Wall outlet, available on the building side (DN 40)	18	Mains socket
9	Double chamber siphon[3]	19	Water stop[4]
10	Wastewater adapter		

Connection to sewage system

Version 1: Via the one-way drain

If you connect the one-way overflow hose from the steam sterilizer to the siphon of the domestic water supply, you will require a 2 m water outlet hose (art. no. 36585), which you can order from MELAG.

Method 2: Via the pressure release

To connect the steam sterilizer to the wastewater directly, i.e. from the pressure release directly in the siphon of the domestic water supply, you can order a 1 m water outlet hose from MELAG (art. no. 39180).

Setting up the steam sterilizer

For a fault-free operation, the steam sterilizer must be set up horizontally by using a water level located close to the sterilization-chamber flange. Then depending on the type of steam sterilizer, the front feet of the unit 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 chamber

Perform a vacuum test with a cold empty chamber and record the outcome.

Universal-Program

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

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.

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[3] a surface-mounted siphon (separately-available) can be used as an alternative
[4] included in the scope of delivery of the steam sterilizer

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.

Display settings

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

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 works side
Computer	192.168.40.140	Pre-set works side
Log printer	192.168.40.240	Pre-set works side
Label printer	192.168.40.160	Pre-set works side
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	1	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.
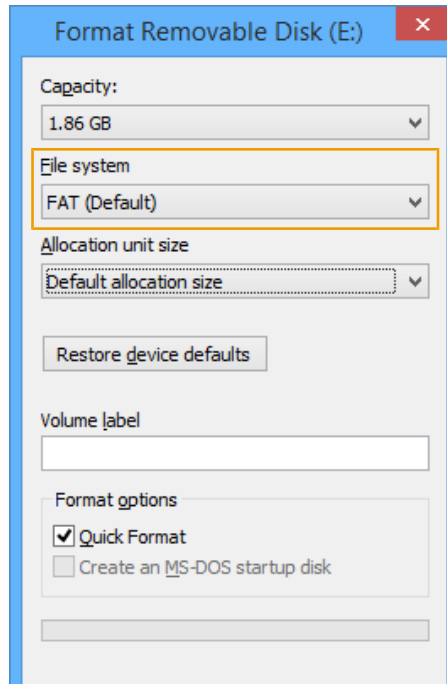
How to format a CF card on the computer correctly?

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".

Format Removable Disk (E:)

Capacity:
1.86 GB

File system
FAT (Default)

Allocation unit size
Default allocation size

Restore device defaults

Volume label

Format options
☑ Quick Format
☐ Create an MS-DOS startup disk

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

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

The following requirements must be fulfilled:

▶ The computer is fitted with a network card with 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. MELAview/MELAtrace, is installed.

[*] We recommend using the MELAG FTP server to integrate 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.

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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.

1. Working in the `Settings` menu > `Logging`, set the IP address of the steam sterilizer to DHCP.
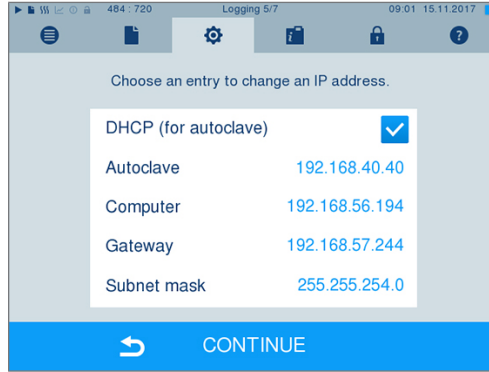
2. Check whether the IP address of the computer set in the steam sterilizer is correct.

   ➥ 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.

☞ **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)?
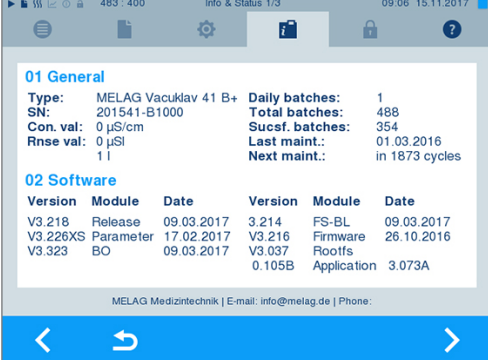
1. Open "Network and Sharing Center" or the network and internet settings.
2. Open the Properties window under "Local Area Connection" > right-click on "Properties".
3. Working in the Properties window, select "Internet Protocol Version 4 (TCP/IPv4)" and click on push-button "Properties".

   ➥ 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.

6 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

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 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 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).
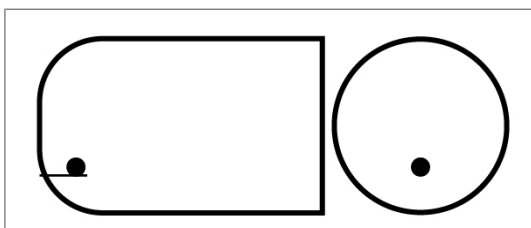

Fig. 1: Schematic side and fore view of the sterilization chamber
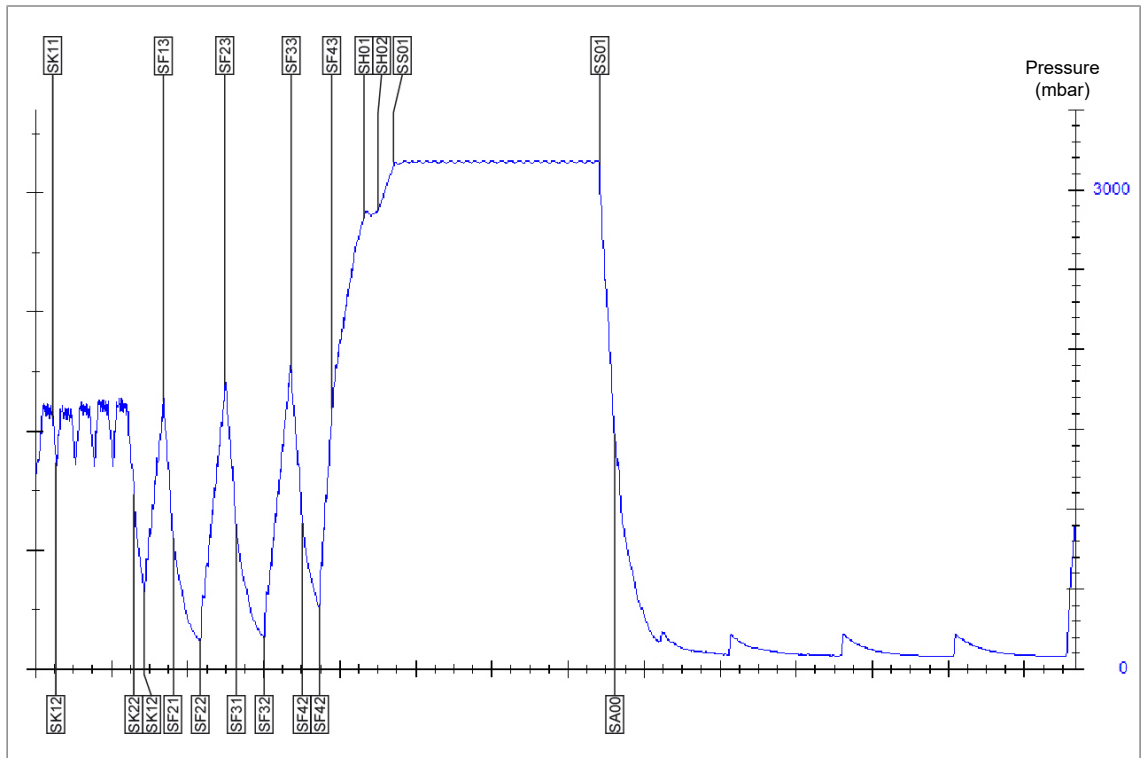
Pressure-time charts

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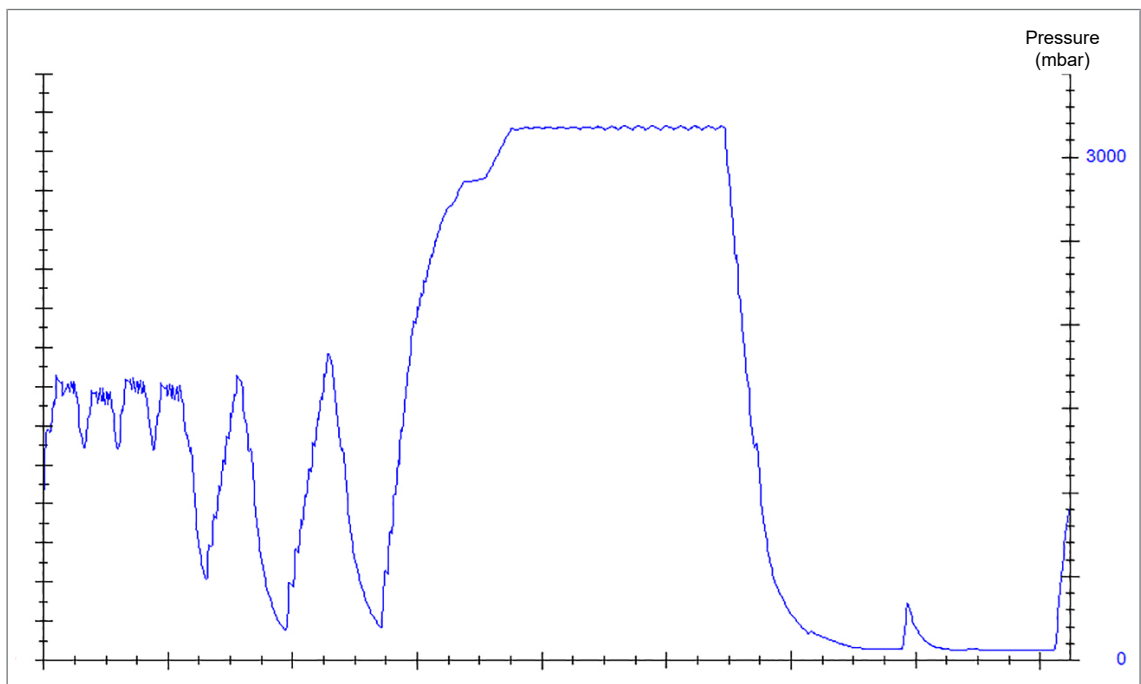

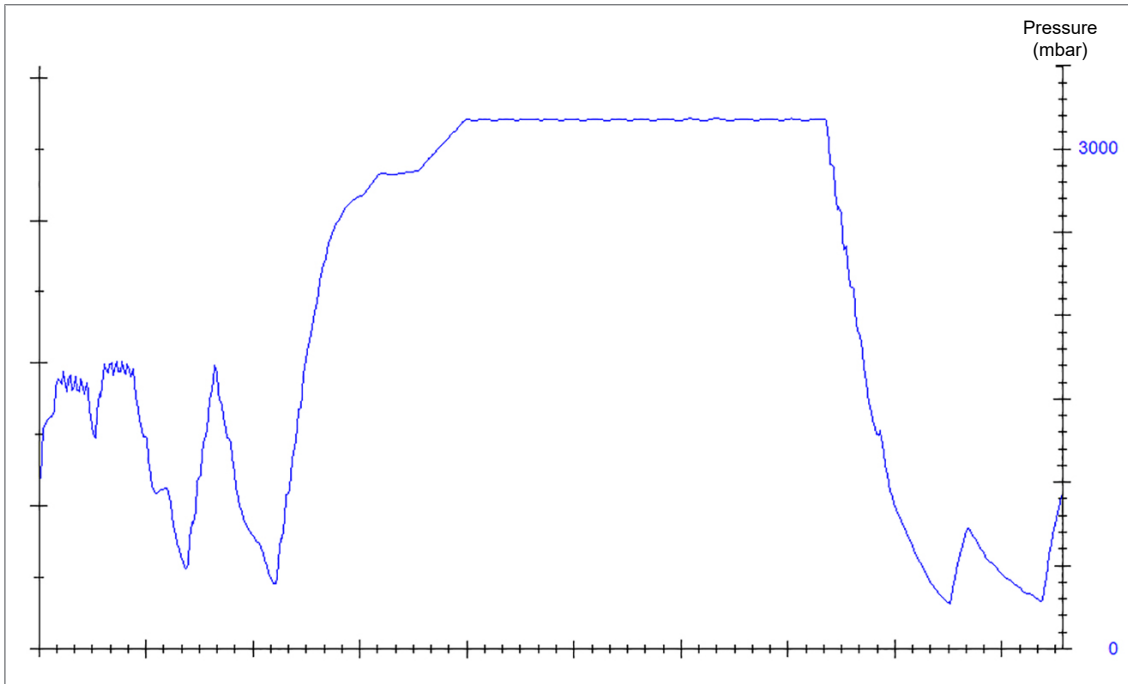Fig. 3: Pressure-time chart for the Quick-Program B, 134 °C and 2.1 bar

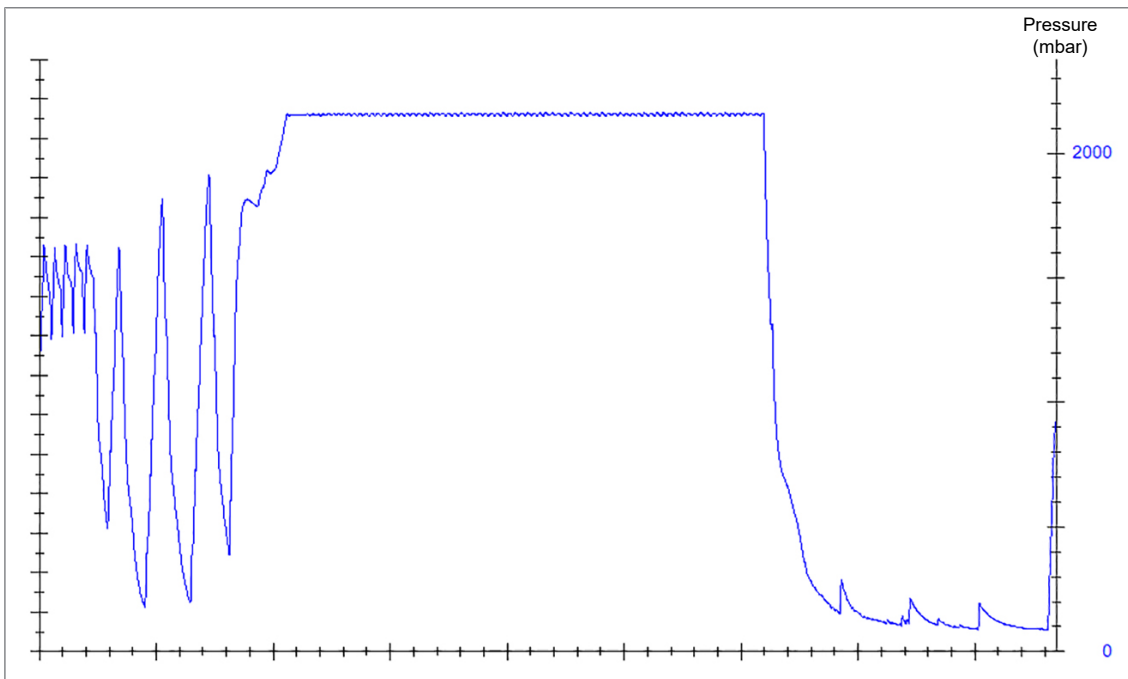Fig. 4: Pressure-time chart for the Quick-Program S, 134 °C 2.1 bar

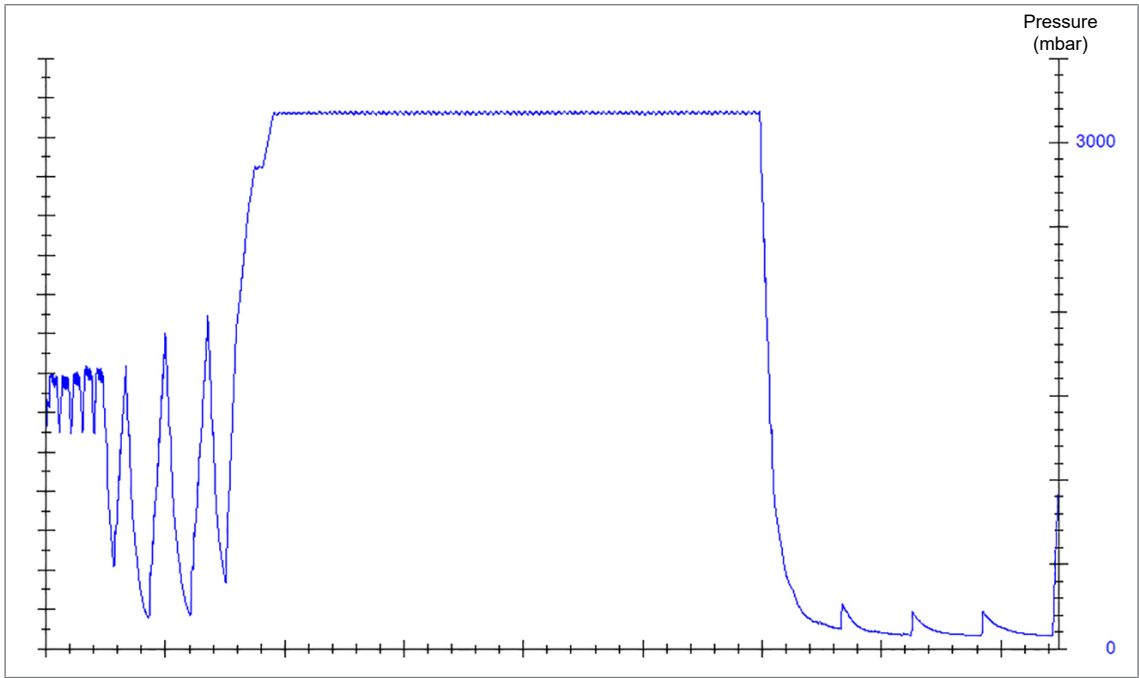Fig. 5: Pressure-time chart for the Gentle-Program, 121 °C 1.1 bar

MELAG

Fig. 6: Pressure-time chart for the Prion-Program, 134 °C 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)**
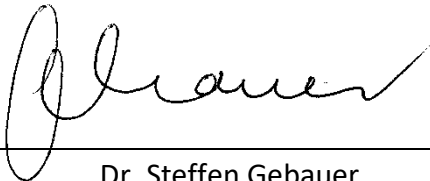- **Simple hollow items (wrapped and unwrapped)**

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.

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

- **Helix-Test body according to DIN EN 867-5: MELAcontrol® and MELAcontrol® PRO**

Berlin, 24.08.2020

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Dr. Steffen Gebauer

(Management)

Quality - made in Germany

Your stockist