MELAG
competence in hygiene

User Manual

Vacuclave® 550

Steam sterilizer

from software version 4.0.1

EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument reprocessing and hygiene field.

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE 0197

Contents

1 General guidelines

Please read this user manual carefully before commissioning the device. The manual includes important safety instructions. Make sure that you always have access to digital or printed version of the user manual.

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.
	Indicates the section in the document that contains content relevant for the service technician.

Formatting rules

Example	Explanation
`Universal-Program`	Words or phrases appearing on the display of the device are marked as display text.
	Prerequisites for the following handling instruction.
	Refer to the glossary or another text section.
	Information for safe handling.

Disposal

MELAG devices are synonymous with high quality and a long life-span. When you eventually need to decommission your MELAG device, the required disposal of the device can take place with MELAG in Berlin. Simply contact your stockist.

Dispose of accessories and consumption media which you no longer require in the appropriate manner. Comply with all relevant disposal specification in terms of possibly contaminated waste.

The packaging protects the device against transport damage. The packaging materials have been selected for their environmentally-friendly disposability and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials.

Dispose of spare parts that are no longer used, e.g. seals, properly.

MELAG draws the operator’s attention to the fact that they are responsible for deleting personal data on the device to be disposed of.

MELAG draws the operator’s attention to the fact that they may be legally obliged (e.g. in Germany according to ElektroG) to remove used batteries and accumulators non-destructively before handing over the device, provided they are not enclosed in the device.

2 Safety

When operating the device, comply with the following safety instructions as well as those contained in subsequent chapters. Use the device only for the purpose specified in these instructions. Failure to comply with the safety instructions can result in injury and/or damage to the device.

Qualified personnel

- As with the preceding instrument reprocessing, only ▸competent personnel should undertake sterilization using this steam sterilizer.
- The operator must ensure that the users are regularly trained in the operation and safe handling of the device.

Power cable and power plug

- Only the power cable included in the scope of delivery may be connected to the device.
- The power cable may not be replaced by a cable determined to be insufficient.
- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- The power cable or plug should only be replaced by ▸authorised technicians.
- Never damage or alter the power plug or cable.
- Never bend or twist the power cable.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Ensure that the power cable does not become jammed in.
- Never lead the cable along a source of heat.
- Never fix the power cable with sharp objects.
- 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.

Normal operation

- The door area as well as the cooler and safety valves at the rear of the device may become hot during operation and remain hot for an extended period after switching off.
- The sterile filter is no longer effective if it has become wet. Stop using the sterile filter and replace it.
- Do not replace the sterile filter during a program run.

Opening the housing

- Never open the device housing. Incorrect opening and repair can compromise electrical safety and pose a danger to the user. The device may only be opened by an ▸authorised technician who must be a ▸qualified electrician.

Notification requirement in the event of serious accidents in the European Economic Area

- Please note that all serious accidents which occur in connection with the medical device (e.g. death or serious deterioration in the state of health of a patient) which were presumably caused by the device, must be reported to the manufacturer (MELAG) and the relevant authority of the member state, in which the user and/or patient resides.

3 Performance specifications

Intended use

The Vacuclave 550 steam sterilizer is mainly intended for use in the medical sector, e.g. in medical and dental practices.

The small steam sterilizer is designed according to ▸EN 13060. It uses the fractionated vacuum process to ensure effective steam penetration of the load with saturated steam. It is suitable for ▸reprocessing instruments and materials that may come into contact with blood or body fluids during treatment. The steam sterilizer is not intended for use on patients or in patient care and is not intended for the sterilization of liquids. Typical groups of users are doctors, skilled medical personnel and service technicians.

WARNING

Any attempt to sterilize liquids can result in a ▸delay in boiling. This can result in burns and damage to the device.

- Never use this device to sterilize fluids. It is not licensed for the sterilization of fluids.

Sterilization procedure

The steam sterilizer sterilizes on the basis of the ▸fractionated vacuum procedure. This guarantees the complete and effective wetting or penetration of the load with saturated steam.

The steam sterilizer uses double jacket technology to generate the sterilization steam, i.e. the steam sterilizer is fitted with a separate steam generator combined with a double-walled sterilization chamber. After heating, steam is held constantly available in the double jacket. This gives the walls of the sterilization chamber a defined temperature and protects the chamber itself from overheating.

This especially effective procedure supports the quick ▸evacuation of the air from the sterilization chamber, the sterilization packages and instrument cavities. This allows you to sterilize large quantities of instruments or textiles in a very short time and achieve very good drying results.

Type of the feed water supply

The steam sterilzer works with a feed water one-way system. This means that it uses fresh ▸feed water (▸demineralised or ▸distilled water) for every sterilization procedure. The quality of the feed water is subject to permanent monitoring via integrated ▸conductivity measurement. If combined with a proper preparation of the instruments, this serves largely to prevent stain accretion on the instruments and soiling of the steam sterilizer.

Program runs

A reprocessing program runs in three main phases: the air removal and heating up phase, the sterilization phase and the drying phase. After program start, you can follow the program run on the display. It shows the chamber temperature and pressure as well as the time until the end of drying.

Program phases of a standard reprocessing program

Program phase	Description
1. Air removal and heating up phase	**Air removal** The air removal phase comprises the conditioning and the fractionating phase. During conditioning, steam is repeatedly injected into and removed from the ▸sterilization chamber. This generates over-pressure and the residual air is removed. Then, during fractionation, the mixture of air and steam is evacuated from the sterilization chamber and steam is injected. This method is also called the fractionated vacuum method.
	Heating The continued steam injection into the sterilization chamber leads to an increase in pressure and temperature which continues until the program-specific sterilization parameters have been reached.
2. Sterilization phase	**Sterilizing** If the pressure and temperature correspond to the program-dependent nominal values, the sterilization phase begins. The corresponding process parameters (pressure and temperature) are held at sterilization level.
3. Drying phase	**Pressure release** The sterilization phase is followed by pressure release from the sterilization chamber.
	Drying The sterile material is dried using a vacuum (vacuum drying).
	Ventilation Upon program end, the sterilization chamber is filled with sterile air via the sterile filter and adjusted to the ambient pressure.

Program phases of the vacuum test

Program phase	Description
1. Evacuation phase	The sterilization chamber is evacuated until the pressure for the vacuum test has been reached.
2. Equilibration time	An equilibration time of five minutes will follow.
3. Measurement time	The measurement time amounts to ten minutes. The pressure increase within the sterilization chamber is measured during the measurement time. The evacuation pressure and the equilibration time or measurement time are shown on the display.
4. Ventilation	The chamber is ventilated after the end of the measuring time.
5. Test end	The display shows the test result, the batch number, the total number of batches and the leakage rate.

Safety equipment

Internal process monitoring

A ▸process evaluation system is integrated in the electronics of the steam sterilizer. It compares the process parameters (such as temperature, time and pressure) during a program run. It monitors the parameters in terms of their threshold values during control and regulation and guarantees safe and successful sterilization. A monitoring system checks the device components of the steam sterilizer for their functionality and their plausible interaction. If one or more parameters exceeds pre-determined threshold values, the steam sterilizer issues warnings or malfunction messages and if necessary, aborts the program. In the case of a program abort, follow the instructions on the display.

The steam sterilizer uses an electronic parameter control. This enables the steam sterilizer to optimise the total operating time of a program in dependence on the load.

Internal logic monitoring

The electronics of the steam sterilizer monitor the successful program run by means of two separate test processes. When a program has been successfully completed, it is shown on the display as a successful program. In addition, the status LED below the display illuminates green.

Door mechanism

The device checks the pressure in the sterilizer chamber at any time and prevents the door from being opened if an over-pressure exists. The motor-driven automatic door locking mechanism opens the door slowly by turning the locking spindle. This also holds the door whilst it opens. Even if pressure differences exist, the pressure equalisation takes place until the door is completely open.

Automatic monitoring of the feed water

The quantity and quality of the ▸feed water is automatically checked before every program start.

Performance characteristics of reprocessing programs

The results in this table show which inspections were performed on the steam sterilizer. The marked fields demonstrate compliance with all the applicable sections of the standard ▸EN 13060.

Type tests	Universal-B	Quick-S	Gentle-B	Prion-B
Program type in accordance with ▸EN 13060	Type B	Type S	Type B	Type B
▸Dynamic pressure test of the sterilization chamber	X	X	X	X
▸Air leakage	X	X	X	X
▸Empty chamber test	X	X	X	X
▸Solid load	X	X	X	X
▸Porous partial load	X	--	X	X
▸Porous full load	X	--	X	X
▸Simple hollow bodies	X	X	X	X
▸Product with narrow lumen	X	--	X	X
▸Single wrapping	X	--	X	X
▸Multiple wrapping	X	--	X	X
Drying ▸solid load	X	X	X	X
Drying ▸porous load	X	--	X	X
Sterilization temperature	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	5:30 min	3:30 min	20:30 min	20:30 min
X = Complies with all applicable sections of the standard ▸EN 13060				

4 Description of the device

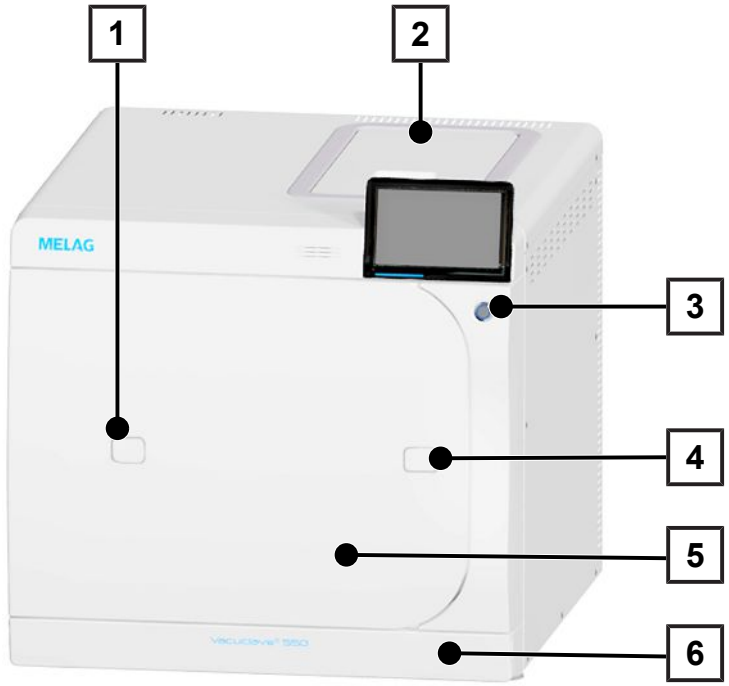
Scope of delivery

Please check the scope of delivery before setting up and connecting the device.

- Vacuclave 550
- User manual
- User manual Accessories for small steam sterilizers
- Manufacturer's inspection report including declaration of conformity
- Warranty certificate
- Record of installation and setup
- 2x Tray lifter
- MELAG USB flash drive
- Drain hose
- Power cable
- Carrying system
- Allen key for opening the door in an emergency
- Test gauge TR20 for door lock nut
- MELAG oil for door lock nut
- Level increase, tank overflow
- Installation material

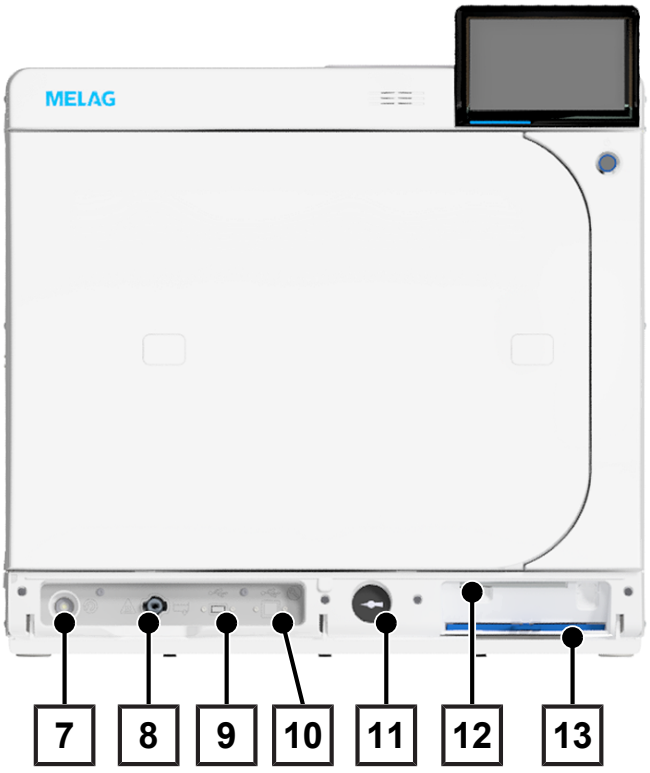
Views of the device

View from the front



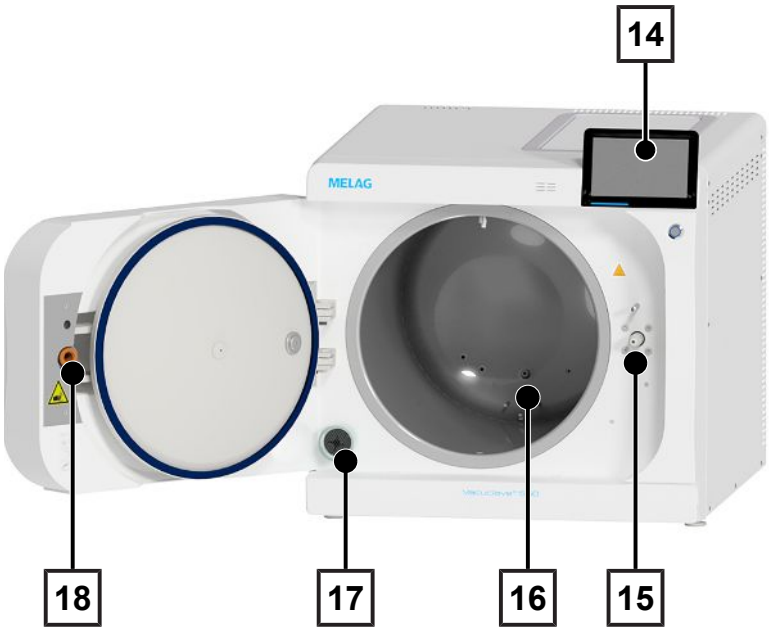
1 Access to the validation fitting
2 Feed water tank cover
3 Power switch
4 Opening for door opening in an emergency
5 Door
6 Service hatch

View from front, with open service hatch



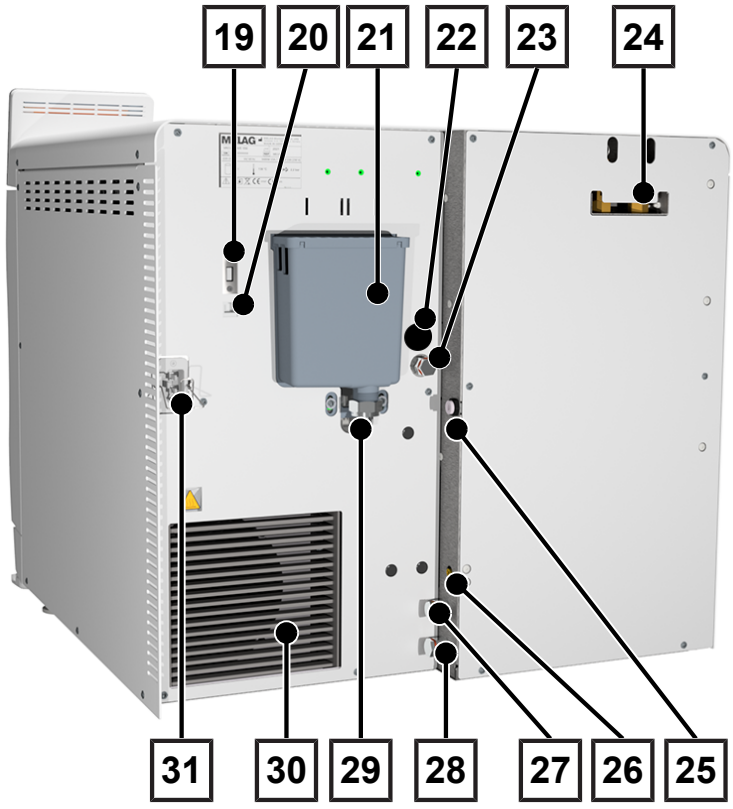
7 Overheat protection reset button
8 Feed water tank drain valve
9 USB connection
10 Service connection
11 Manometer (double jacket steam generator)
12 Allen key with which to open the door in an emergency
13 Dust filter

View from the front, with open door



14 Colour touch display
15 Door lock nut
16 Pressure release filter
17 Sterile filter
18 Locking spindle

View from rear



19 USB connection
20 Ethernet connection
21 Overflow funnel
22 Electrical connection, filling pump (optional)
23 Feed water connection of the filling pump
24 Spring-loaded safety valves
25 Direct drain (optional)
26 Connection for level sensor for external wastewater container
27 Feed water connection, water treatment unit
28 Wastewater connection, water treatment unit
29 Wastewater connection
30 Cooler
31 Power cable connection

Symbols on the device

Type plate


Manufacturer of the product


Date of manufacture of the product

Label as medical device

Article number of the product

Serial number of the product


Observe user manual or electronic user manual


Do not dispose of product in household waste


CE marking

Identification number of the notified body responsible for conformity assessment according to Pressure Equipment Directive 2014/68/EU

Identification number of the notified body responsible for conformity assessment according to Regulation (EU) 2017/745 on medical devices

Volume of the sterilization chamber


Working overpressure in sterilization chamber


Operating temperature in sterilization chamber

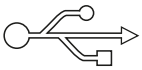
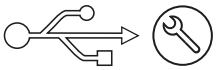

Electrical connection of the product: Alternating current (AC)

Warning symbols


This symbol indicates that the marked area becomes hot during operation. Contact with it during or shortly after operation can pose the danger of burns.


This symbol draws attention to an increased danger of crushing resulting from the improper closure of the steam sterilizer door. Please comply with the instructions outlined in the corresponding chapter.

Device symbols - front

Symbol	Description	Symbol	Description
	Feed water drain connection		Overheat protection reset button
	USB connection		Service connection

Device symbols - rear

Symbol	Description	Symbol	Description
Aqua dem 	Feed water connection, water treatment unit	**Osmosis drain** 	Wastewater connection, water treatment unit
Pump aqua dem 	Feed water connection of the filling pump	**Drain** 	Wastewater connection
Pump power 	Electrical connection, filling pump (optional)	**Sensor drain** 	Sensor of the wastewater container

Service hatch

The service hatch is magnetic and is opened by pulling on any side.

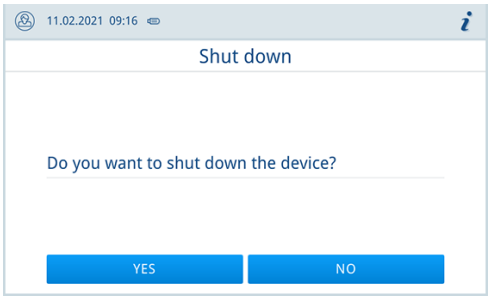
Power switch

PLEASE NOTE

The device cannot be shut down during a running program.

Press the power switch to open the shutdown dialog.

Press the power switch again to restart the device.



The illumination of the power switch indicates the status of the device.

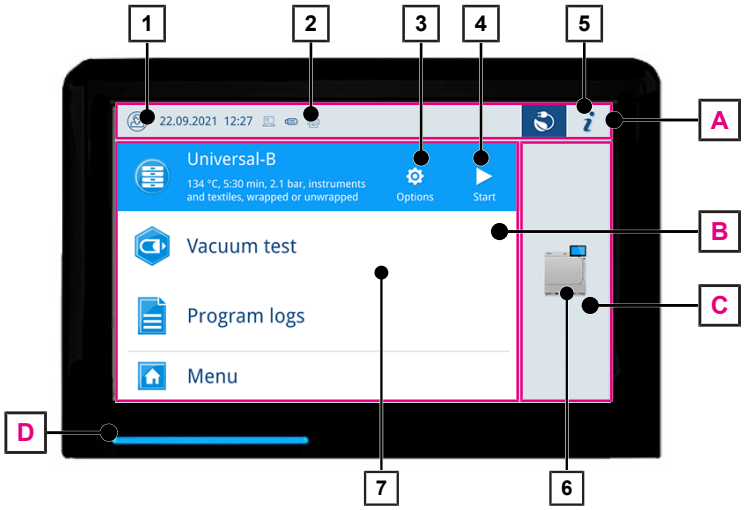
State	Description
illuminated	The device is shut down.
not illuminated	The device is in standby or a program is running.
pulsing	The device is powering up.

Colour touch display

The user interface consists of a colour 7-inch touch display.

The selected menu item is highlighted in colour.

The display of the areas (A, B, C) is dynamic and can change depending on the device status. Due to the dynamic display, the display and position of the buttons on the device may differ from the illustrations shown.



1 Login/logout user role
2 Activated/connected output media
3 Program options
4 Starting the program
5 Device status
6 Opening the door
7 Favourites menu*)
A Information area (minimised display)
B Menu area (maximised display)
C Device function area (minimised display)
D LED status bar

*) recommended programs and functions for quick access

User role symbols

Symbol	User role	Description
	Practice employee	Operating the device, making general settings
	Administrator	Operating the device, making administrative settings
	Service technician	Operating the device, making administrative settings and service settings

Symbols of the output media

Symbol	Output media	Description
	MELAtrace	Output to MELAtrace
	FTP	Output to an FTP server
	USB flash drive	Output to a USB stick connected to the USB port
	Label printer	Output to a connected label printer

Buttons in the information area

Button	Description
	Show or hide **Device status**
	Open or close **Device status**
	Malfunction message present Show or hide malfunction message
	Warning message present Show or hide warning message
	Energy-saving activated Show or hide energy-saving dialog

Buttons in the program selection

Button	Description
	Starting the program
	Select program options and start program
	Aborting/ending the program

LED status bar

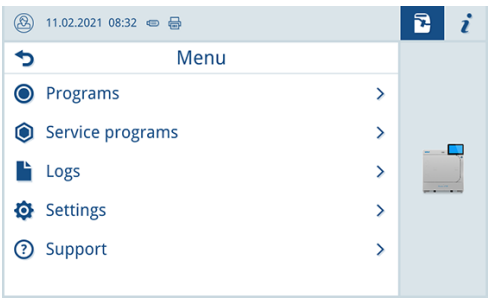
The LED status bar on the lowest edge of the display indicates different situations with various colours.

Colour	Description
Blue	Device is in operation, no program active Program in progress
Green	Program successfully completed Drying in progress
Red	Malfunction message Program abort in progress Program not successfully completed
Yellow	Warning message

Menu

The **Menu** gives you access to the programs available in the device mode, to various settings and to the log output.

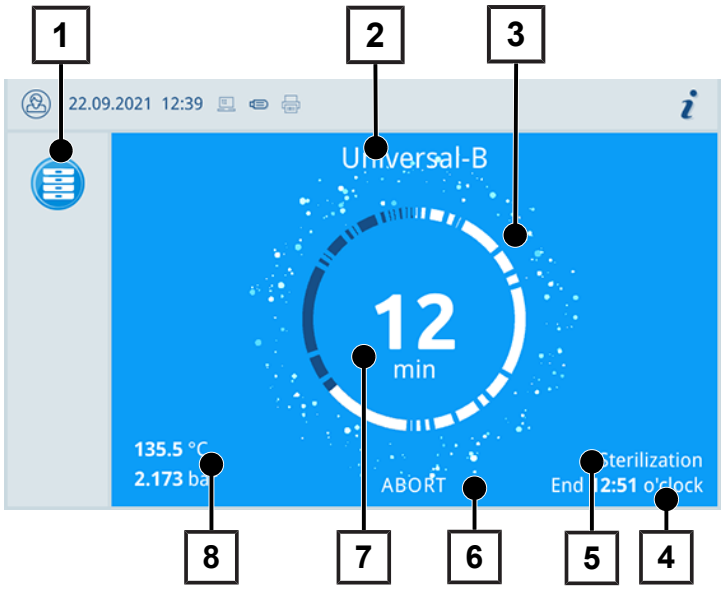
The **Support** menu item contains service contact details and the **License information**.



Program run

During a program run, all important information is shown on the display.

If no input is made on the display, the program display maximises and overlays the menu. Touch the display to show the menu.



1 Running program
2 Program name
3 Busy indicator
4 Estimated end of the program
5 Program phase
6 Abort/end button
7 Remaining run time (remaining program duration)
8 Program parameters (temperature/pressure)

The display indicates whether the sterilization phase has been completed successfully. The busy indicator and the LED status bar both change from blue to green as soon as the drying phase is initiated.

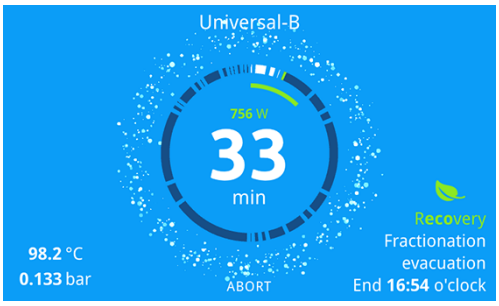
Heat recovery

The **Recovery** symbol indicates active heat recovery.

The heat of the wastewater is used to heat the feed water. This means that the feed water has to be heated less. By recovering this heat, electricity consumption is reduced.

The power recovered through heat recovery is shown in green.

The energy saved over time is displayed in the **`Status log`**.



Load mounts

The device is delivered without a mount for holding trays or cassettes. No mount is necessary for the sterilization of sterilization containers or MELAstore Box, but MELAG recommends use of the loading slide.

Depending on the typical load, different accessories can be combined with the device.

For detailed instructions on use of the accessories and their combinability with different load carriers, refer to the Mounts and loading slide [▸ Page 49] section and the "User manual Accessories for small steam sterilizers" document.

5 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.

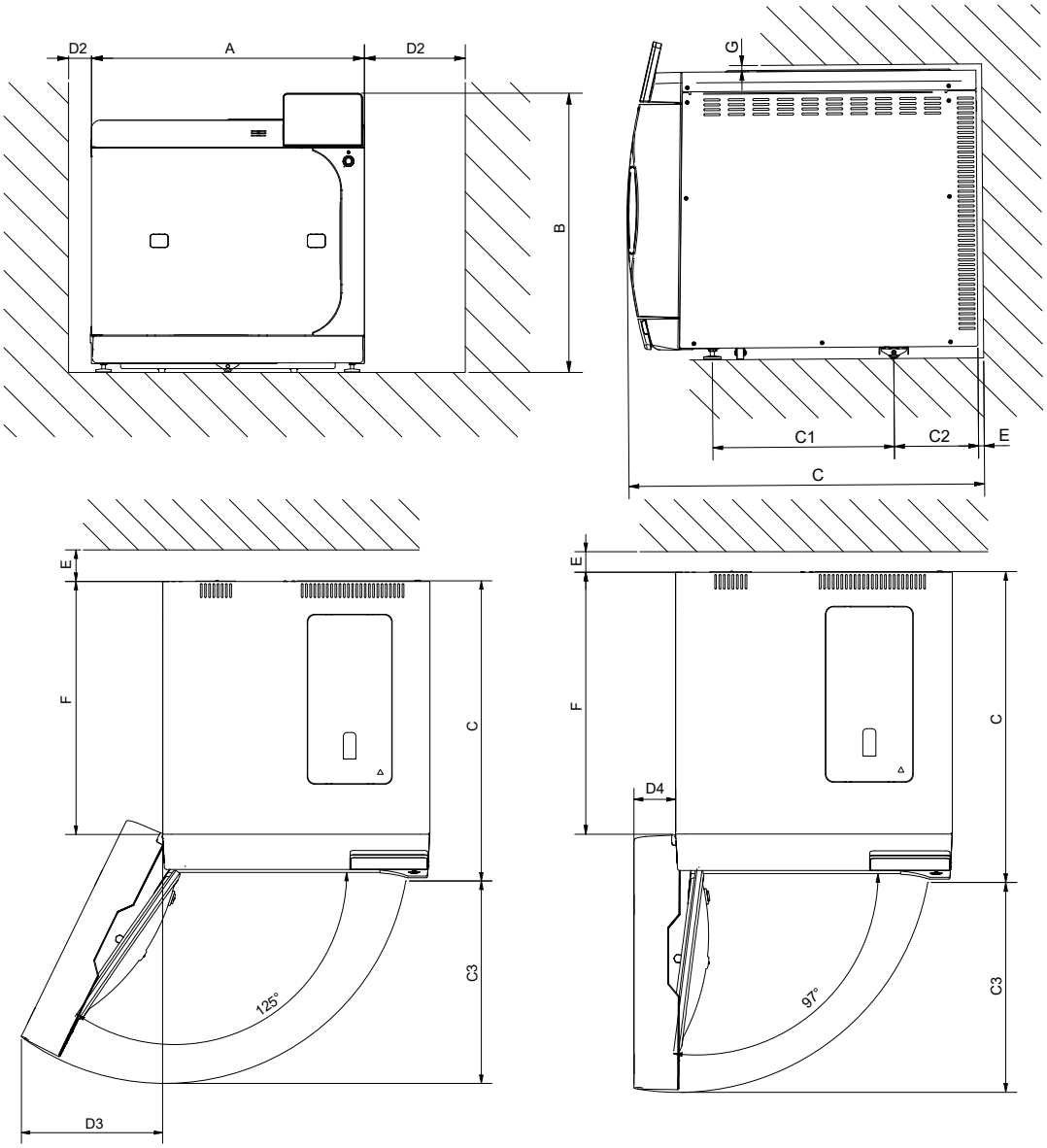
Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.

Make sure that the ambient conditions meet the requirements, see Technical data [▸ Page 93]

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		Vacuclave 550
Width	A	63.6 cm
Height	B	65 cm
Chamber depth	C	45 cm
Clearance between the device feet	C1	37.1 cm
Clearance from rear device foot up to the rear panel	C2	17.3 cm
Max. swivel distance with open door	C3	48.2 cm
Min. clearance to right side (heat emission)	D1	20 cm
Min. clearance to left side (heat emission)	D2	5 cm
Clearance to the door hinge side 125°	D3	34.1 cm
Clearance to the door hinge side 97°	D4	9.6 cm
Min. clearance to the rear	E	1 cm
Free space when door open fully	F	57 cm
Min. clearance to the top	G	1 cm (wall cupboard 60 cm above worktop)

Additional space requirement for the feed water supply

If the device is operated with a water treatment unit or filling pump with storage tank, additional space is required. It is necessary to ensure free access to the hoses and cables of the device leading to the water treatment unit.

Dimensions	MELAdem 47	
	Osmosis module	Storage tank
Width	42 cm	Ø 24 cm
Height	47 cm	51 cm
Depth	15 cm	--

Space is required above the MELAdem 53 / MELAdem 53 C for free access to the hose connections.

Dimensions	MELAdem 53	MELAdem 53 C
Diameter	24 cm	24 cm
Height of the unit incl. connecting parts	57 cm	45 cm

Requirements for installing the device

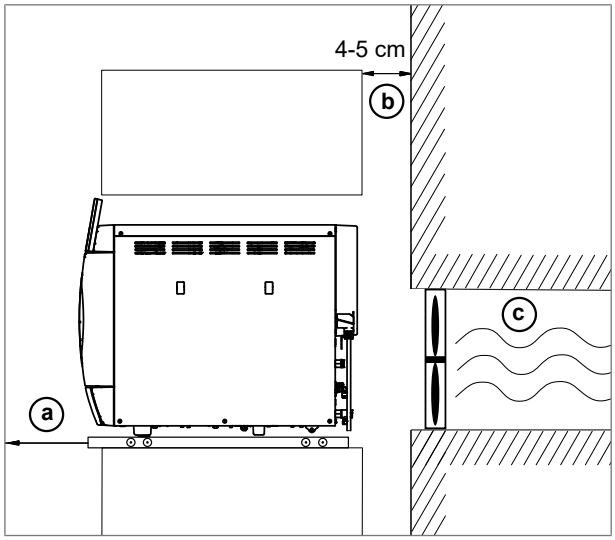
NOTICE

The steam sterilizer may only be installed if sufficient air circulation can be guaranteed.

The function and life of the steam sterilizer can be compromised if heat dissipation via the cooler is restricted.

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 maintenance and operation (pos. a), among other things, to ensure free access to the feed water and wastewater tank.
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).



Mains connection

Make sure that the electrical connection meets the requirements on site, see Technical data [▸ Page 93].

Water connection

	Feed water	Wastewater
Connection in the practice	• water treatment unit, e.g. MELAdem 47 • optional: external storage container • emergency operation: manual filling via the feed water tank	• automatic disposal, wall outlet (nominal size DN 40) or U-trap (sink drain) • optional: manual disposal via the external wastewater container
Installation height	--	min. 30 cm below the device
Measures for protecting the drinking water	The steam sterilizer has an internal air gap (type AB) to protect the drinking water. To protect the MELAdem 47, MELAdem 53 and MELAdem 53 C water treatment units, MELAG recommends the installation of a safety combination according to EN 1717. Further country specific measures may be required for protecting the drinking water.	

Connection of a water treatment unit

	MELAdem 47	MELAdem 53/53 C
Permissible hydraulic pressure	2-6 bar	1.5-10 bar
Water stop	It is necessary to install a water stop with shut-off valve for the connection of a water treatment unit.	

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	Software/purpose
USB	Type-B	USB type-A socket (via USB type-B to type-A cable)	MELAview Service Saving log data, querying device data using diagnostics mode
USB	Type-A	MELAG USB flash drive with FAT32 file system	Saving log data
		MELAG USB flash drive with FAT32 file system and software-update container	Device software update
		MELAprint 60/80	Label print
Ethernet	Ethernet IEEE 802.3	Switch port (Practical network)	MELAtrace saving log data, querying device data
			FTP server saving log data
			Label printing via MELAprint 60/80

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 MELAG USB flash drives.

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	63000 - 64000	21	Outgoing	FTP control
TCP	any	63000 - 64000	Listening/Incoming	FTP (passive) 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	3333	Listening/Incoming	Data transfer log data (device set to TCP logging)
UDP	62000	3000	Outgoing	Broadcast search printer
UDP	3000	62000	Listening/Incoming	Search answers printer
TCP	≥ 1025	9100	Outgoing	Data transfer to the 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
Program log	1 MB	200 kB
Malfunction log	64 kB	10 kB
Status log	64 kB	20 kB
System log	40 MB	--

6 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.

Comply with the following for safe handling:

- The connections for electrical provision and water supply and discharge must be setup by trained personnel.
- Using the optional electronic leak detector (water stop) minimises the risk of water damage.
- Install and operate the device in a frost-free environment.
- For the initial commissioning, observe all instructions described in this manual.
- The spring safety valve must be able to move freely and not become stuck or blocked. Position the device in such a way that the faultless functioning of the spring safety valve is guaranteed.

Removing from the packaging

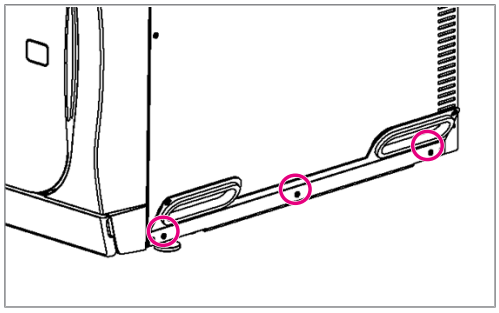
CAUTION

Danger of injury from incorrect carrying.

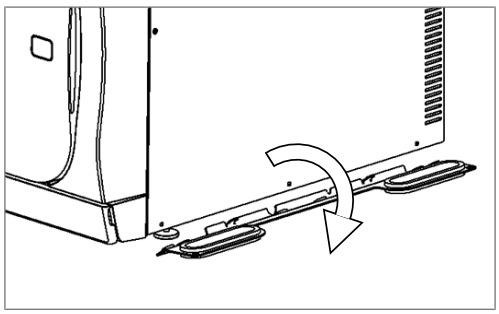
Lifting and carrying too heavy a load can result in spinal injury. Failure to comply with these provisions can result in crushing.

- The device should always be carried by two people.
- Use the carrying system to carry the device.

1. Use the carrying system to lift the device out of the box.
2. Check the device after unpacking for any damage suffered during transport.
3. To remove the carrying system, undo the three bottom housing screws.



4. Unhook the carrying system from the baseplate from below.



5. Tighten the housing screws again.
6. Keep the carrying system.

Connecting the power cable and removing accessories

NOTICE

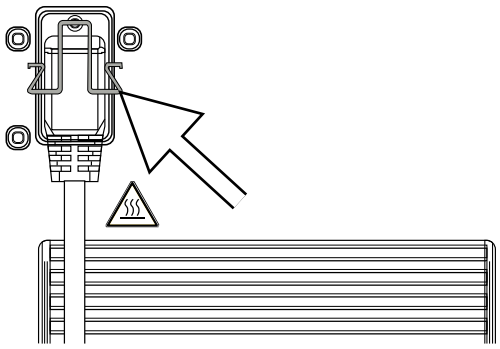
Before switching on for the first time, the device must have acclimatised to the required ambient temperature (5-40 °C).

PLEASE NOTE

In the case of automatic feed water supply, the device attempts to supply feed water after start-up.

If no feed water is available yet, a malfunction message is displayed, see Malfunctions [▶ Page 83].

1. Connect the power cable to the rear of the device and fold down the safety latch.



2. Connect the device power plug to the mains socket.
3. Switch on the device at the power switch. The start screen appears on the display.

   ↪ After a short waiting time, the Favourites menu is displayed.
4. Press the OPEN DOOR button to open the door.
5. Remove all accessories from the sterilization chamber.
6. Close the door.
7. Press the power switch to shut down the device.
8. Remove the mains plug to disconnect the device from the power supply.

Installation examples

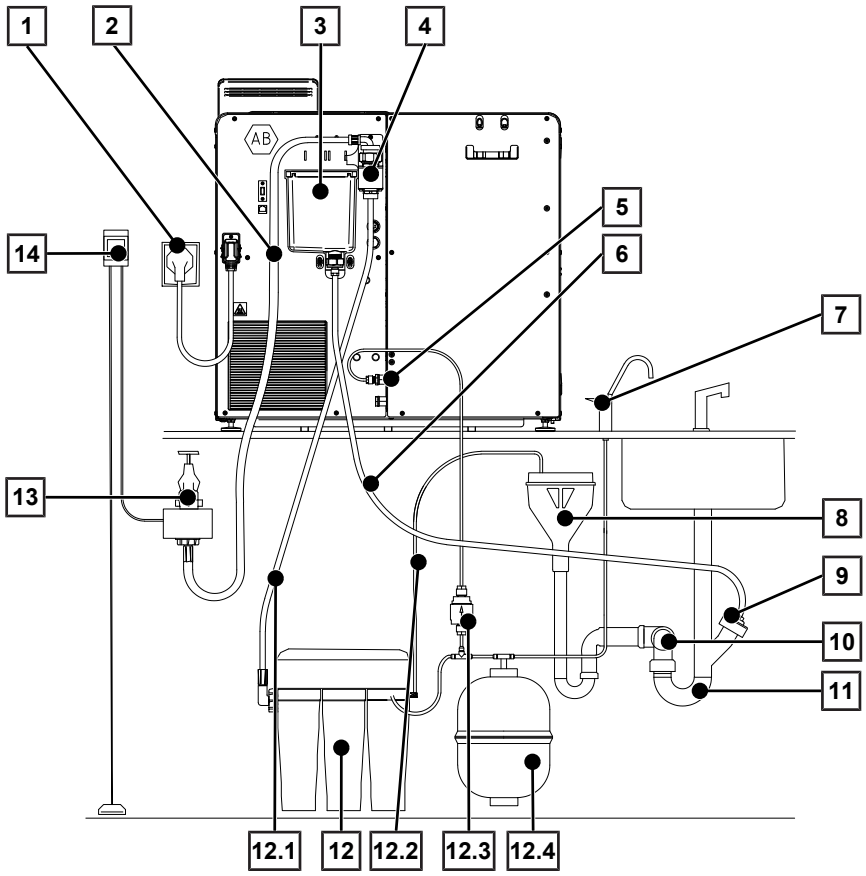
On the following pages you will find examples for the recommended types of installation for the supply of feed water and the disposal of wastewater.

PLEASE NOTE

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

Example 1 - Automatic water supply and disposal with reverse osmosis unit MELAdem 47 (HD)

Automatic water disposal should always be installed in case of automatic water supply. In addition, it is necessary to install a water stop.



Item	Description	Art. no.	Contained in
1	Mains connection*)	--	--
2	Water inlet hose (2.5 m, complies with EN 1717)	ME24930	--
3	Overflow funnel	--	Steam sterilizer
4	Safety combination HD according to EN 1717 for wall mouting	ME70685	--
5	**Feed water connection, water treatment unit**	--	Steam sterilizer
5.1	Cu seal 13.5x20	ME32050	Scope of delivery
5.2	QSS-E straight	ME31240	Scope of delivery
6	PTFE hose, 8/6 mm (2.5 m)	--	Scope of delivery
7	External tap for demineralised water	ME91900	ME01047

Item	Description	Art. no.	Contained in
8	on-site protection (air gap to EN 1717)*)	--	--
9	**Double hose nozzle connection**	--	--
9.1	Cu seal 13.5x20	ME32050	Scope of delivery
9.2	QSS-E straight	ME38710	Scope of delivery
9.3	Wastewater adapter (G1/4” internal thread)	ME56930	Scope of delivery
10	Wall outlet NW40*)	--	--
11	Wastewater connection vented upwards (washing machine connection)*)	--	--
12	**MELAdem 47 reverse osmosis unit**	ME01047	--
12.1	Water inlet hose	ME37220	ME01047
12.2	Outlet hose for concentrate	ME37458	ME01047
12.3	Filter for MELAdem	ME48240	ME01047
12.4	Pressure tank MELAdem 47 (with shut-off valve and hose)	ME57065	ME01047
13	Water tap 3/4” with safety combination	ME37310	--
14	Water stop (leakage water detector with shut-off valve and probe) (leak water detector with cut-off valve and sensor)	ME01056	--
Optionally available:			
--	Hose PUR (black) 6/4 mm (10 m)	ME28820	--
*) present on the building side			

NOTICE

Improper installation

There is a risk of water damage if the water connection is installed improperly.

- Check all water connections and joints.

1. Connect the outlet hose to the existing U-trap of the building’s wastewater system, see Connection to the wastewater [▸ Page 35].
2. Fasten the safety combination HD to the wall. When doing so, pay attention to the flow direction indicated on the safety combination. Observe the minimum distance of the fall section (25 cm) above the following maximum liquid level.

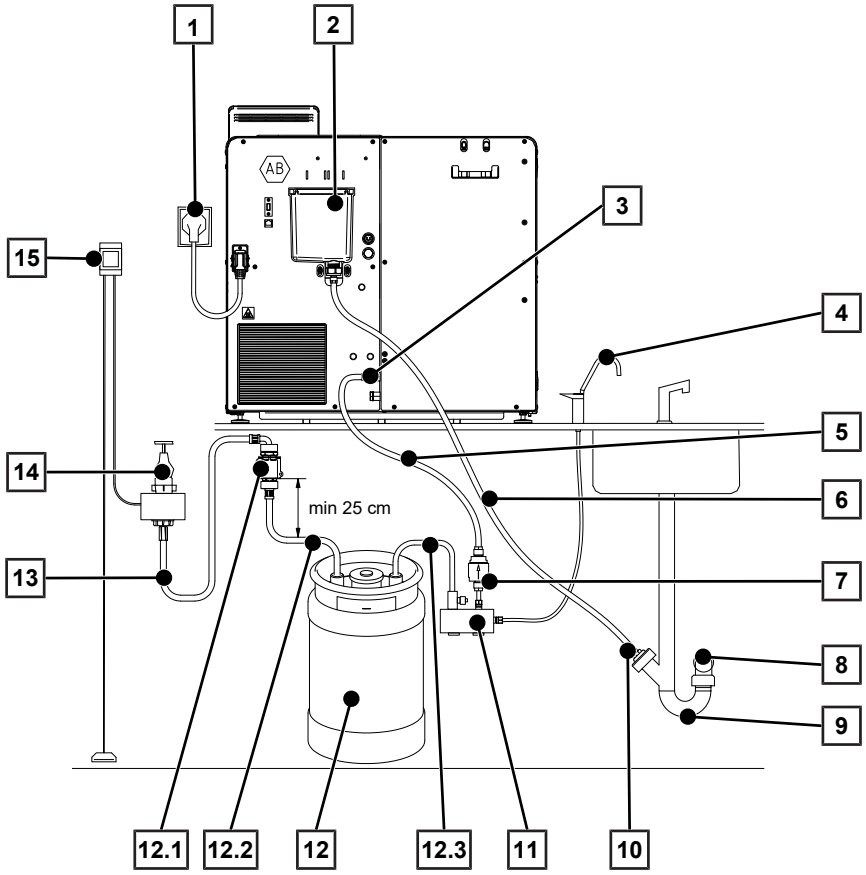
   PLEASE NOTE: An EN 1717 compliant installation to the drinking water system requires a water tap with safety combination.
3. Install the MELAdem 47 as described in the relevant installation instructions.

   PLEASE NOTE: Discharge the concentrate of the reverse osmosis unit into a building drain with air gap. The continuous discharge of the concentrate must be ensured by means of a type AA device for separation from the wastewater disposal in accordance with EN 1717.
4. Check whether the water supply and disposal is set to `Automatic`, see Checking the water supply and disposal [▸ Page 39].

Example 2 - Automatic water supply and disposal with ion exchanger MELAdem 53/53 C (HD)

Automatic water disposal should always be installed in case of automatic water supply. In addition, it is necessary to install a water stop.

The MELAdem 53/53 C water treatment unit is either connected to the device's feed water connection either via a water branch or by means of a water distributor.



Item	Description	Art. no.	Contained in
1	Mains connection*)	--	--
2	Overflow funnel	--	Steam sterilizer
3	**Feed water connection, water treatment unit**	--	--
3.1	Cu seal 13.5x20	ME32050	Scope of delivery
3.2	QSS-E swivel	ME31240	Scope of delivery
4	External tap for demineralised water	ME91900	--
5	PUR hose (black) 6/4 mm	--	Scope of delivery
6	PTFE hose, 8/6 mm (2.5 m)	--	Scope of delivery
7	Filter for MELAdem	ME48240	--
8	Wall outlet NW40*)	--	--
9	Wastewater connection vented upwards (washing machine connection)*)	--	--
10	**Connection to U-trap**	--	--
10.1	Cu seal 13.5x20	ME32050	Scope of delivery
10.2	QSS-E straight	ME38710	Scope of delivery

Item	Description	Art. no.	Contained in
10.3	Wastewater adapter (G1/4” internal thread)	ME56930	Scope of delivery
11	Water distributor for MELAdem 53 for connecting several devices	ME69005	--
12	**MELAdem 53/53 C**	ME01038/ ME01036	--
12.1	Safety combination HD according to EN 1717 for wall mouting	ME70685	ME01038/ ME01036
12.2	Tap water supply hose EN 1717, 0.8 m	ME24932	ME01038/ ME01036
12.3	Pipe elbow with drain valve	ME70405	ME01038/ ME01036
13	Water inlet hose (2.5 m, complies with EN 1717)	ME24930	ME01038/ ME01036
14	Water tap 3/4” with safety combination	ME37310	--
15	Water stop (leakage water detector with shut-off valve and probe)	ME01056	--
*) present on the building side			

NOTICE

Improper installation

There is a risk of water damage if the water connection is installed improperly.

- Check all water connections and joints.

1. Connect the outlet hose to the existing U-trap of the building’s wastewater system, see Connection to the wastewater [▸ Page 35].
2. Fasten the safety combination HD to the wall. When doing so, pay attention to the flow direction indicated on the safety combination. Observe the minimum distance of the fall section (25 cm) above the following maximum liquid level.

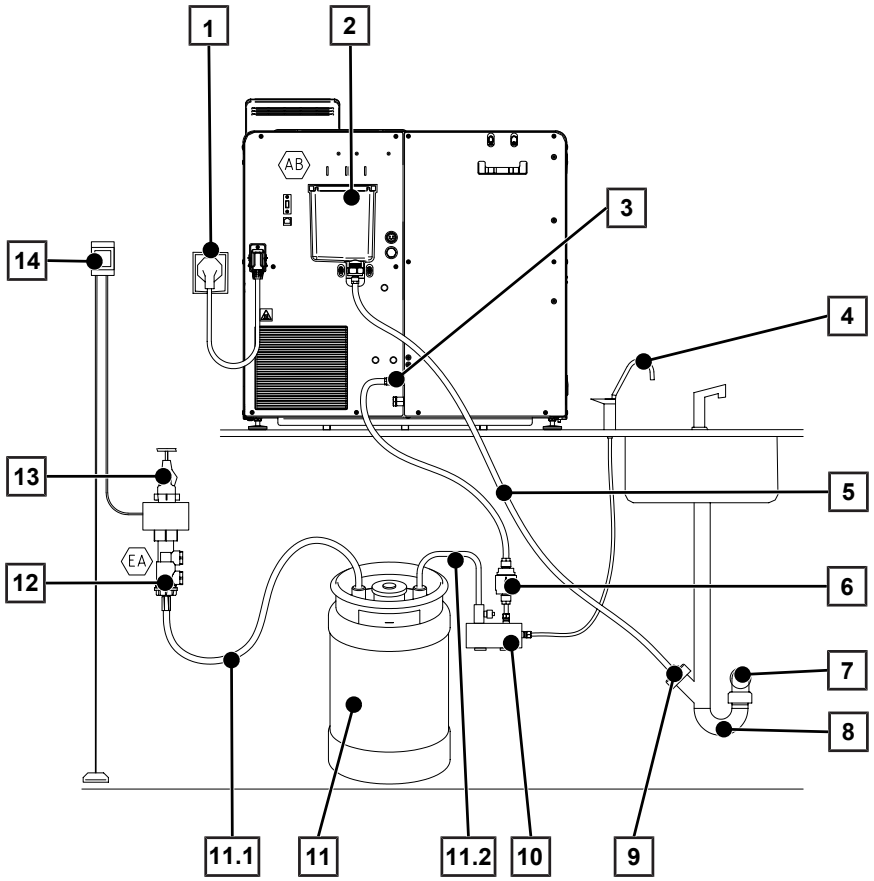
   PLEASE NOTE: An EN 1717 compliant installation to the drinking water system requires a water tap with safety combination.
3. Install the MELAdem 53/53 C as described in the relevant installation instructions.

   PLEASE NOTE: Discharge the concentrate of the reverse osmosis unit into a building drain with air gap. The continuous discharge of the concentrate must be ensured by means of a type AA device for separation from the wastewater disposal in accordance with EN 1717.
4. Check whether the water supply and disposal is set to `Automatic`, see Checking the water supply and disposal [▸ Page 39].

Example 3 - Automatic water supply and disposal with ion exchanger MELAdem 53/ 53 C (EA)

Automatic water disposal should always be installed in case of automatic water supply. In addition, it is necessary to install a water stop.

The MELAdem 53/ 53 C water treatment unit is either connected to the device's feed water connection either via a water branch or by means of a water distributor.



Item	Description	Art. no.	Contained in
1	Mains connection*)	--	--
2	Overflow funnel	--	Steam sterilizer
3	**Feed water connection, water treatment unit**	--	--
3.1	Cu seal 13.5x20	ME32050	Scope of delivery
3.2	QSS-E swivel	ME31240	Scope of delivery
4	External tap for demineralised water	ME91900	--
5	PTFE hose (8/6 mm), 2.5 m	--	Scope of delivery
6	Filter for MELAdem	ME48240	--
7	Wall outlet NW40*)	--	--
8	Wastewater connection vented upwards (washing machine connection)*)	--	--
9	**Connection to U-trap**	--	--
9.1	Cu seal 13.5x20	ME32050	Scope of delivery
9.2	QSS-E straight	ME38710	Scope of delivery
9.3	Wastewater adapter G1/4" internal thread	ME56930	Scope of delivery

Item	Description	Art. no.	Contained in
10	Water distributor for MELAdem 53 for connecting several devices	ME69005	--
11	**MELAdem 53/53 C**	ME01038/ ME01036	--
11.1	Water inlet hose (2.5 m, complies with EN 1717)	ME24930	ME01038/ ME01036
11.2	Pipe elbow with drain valve	ME70405	ME01038/ ME01036
12	Return flow inhibitor type EA	ME75300	--
13	Water tap*)	--	--
14	Water stop (leakage water detector with shut-off valve and probe)	ME01056	--
*) present on the building side			

NOTICE

Improper installation

There is a risk of water damage if the water connection is installed improperly.

- Check all water connections and joints.

1. Connect the outlet hose to the existing U-trap of the building's wastewater system, see Connection to the wastewater [▸ Page 35].
2. Fasten the safety combination HD to the wall. When doing so, pay attention to the flow direction indicated on the safety combination. Observe the minimum distance of the fall section (25 cm) above the following maximum liquid level.

   PLEASE NOTE: An EN 1717 compliant installation to the drinking water system requires a water tap with safety combination.
3. Install the MELAdem 53/53 C as described in the relevant installation instructions.

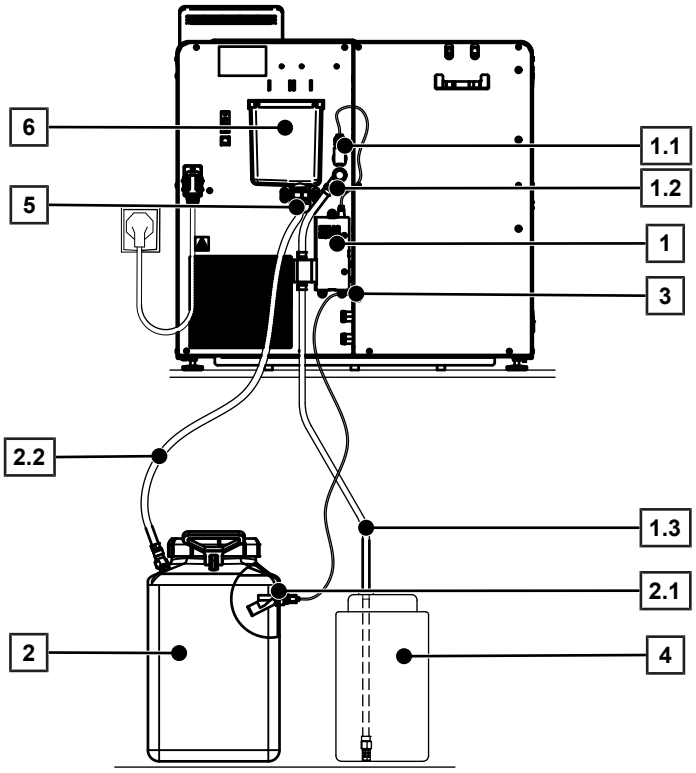
   PLEASE NOTE: Discharge the concentrate of the reverse osmosis unit into a building drain with air gap. The continuous discharge of the concentrate must be ensured by means of a type AA device for separation from the wastewater disposal in accordance with EN 1717.
4. Check whether the water supply and disposal is set to `Automatic`, see Checking the water supply and disposal [▸ Page 39].

Example 4 - Use of the filling pump with external storage and wastewater container

The device is supplied with feed water from the storage container via the filling pump. The maximum suction lift is 1.2 m. The wastewater is fed into the wastewater container via the drain hose. The filling level of the wastewater container is monitored by the device with a level sensor.

PLEASE NOTE

Note the separate instructions for installation of the filling pump (doc. ZBA_P10).



Item	Description	Art. no.	Contained in
1	Filling pump	ME65010	--
1.1	Electrical connection of the filling pump	--	Steam sterilizer
1.2	Inlet hose	--	ME65010
1.3	Suction hose with suction hose storage container	--	ME65010
2	**Wastewater container**	ME65020	--
2.1	Sensor for external wastewater container	--	ME65020
2.2	Wastewater container outlet hose	--	ME65020
3	Connection for sensor for external wastewater container	--	Steam sterilizer
4	Storage container for feed water	--	--
5	Wastewater connection	--	Steam sterilizer
6	Overflow funnel	--	Steam sterilizer

NOTICE

Improper installation

There is a risk of water damage if the water connection is installed improperly.

- Check all water connections and joints.

1. Connect the outlet hose to the external wastewater container (doc. ZBA_ABW).
2. Install the filling pump as described in the separate installation instructions (doc. ZBA_P10).
3. In the **`Settings`** > **`Water management`** menu, set the wastewater disposal to **`Manual`**, see Water management [▸ Page 67].

Connection to the wastewater

To ensure safe operation of the device, the wastewater must be able to flow freely and unobstructed to the wall outlet. Comply with the following:

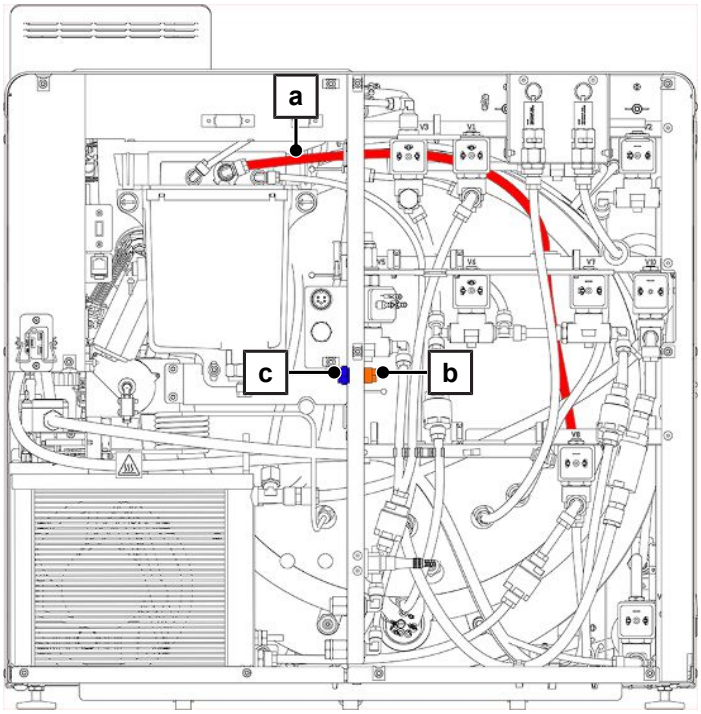
- The outlet hose must not be longer than 2.5 m.
- The outlet hose must be laid with a continuous fall and kink-free.
- The wall outlet should be located directly under the device.
- The U-trap used must be ventilated (not a double-chamber U-trap)

1. Cut the outlet hose supplied (PTFE hose) to the required length.
2. Depending on the installation variant, connect the overflow funnel to the existing U-trap or to the external wastewater container.
3. Pour 500 ml into the overflow funnel and perform a drain test.

   ↪ The overflow funnel must empty within 30 s.

Direct connection to the wastewater

If one of the requirements for the wastewater connection cannot be met or a display message indicates poorly discharging wastewater (e.g. event 10101, 10102, see Malfunctions [▸ Page 83]), you can connect the steam sterilizer directly to the wastewater.



1. Undo the screws (TX20) in the rear device cover and remove the cover.
2. Connect the overflow funnel to the wastewater, see Connection to the wastewater [▸ Page 35].
3. Dismantle the wastewater hose (pos. a) from the overflow funnel.
4. Shorten the wastewater hose and connect it to the internal connection socket of the direct outlet (pos. b).
5. Remove the external screw plug of the direct outlet (pos. c) to the opposite side.
6. Connect the direct outlet to the buildings' wastewater connection. To do so, use the material from the table.

Description	Art. no.	Contained in
SVS-E straight 1/8"	ME53520	--
Copper seal for 1/8" external thread	ME42360	--
PTFE hose (8/6 mm, 5 m, wastewater hose)	ME39180	--
Cu seal 13.5x20	ME32050	--
QSS-E straight	ME38710	--
Wastewater adapter G1/4" internal thread	ME56930	--
Double chamber U-trap	ME26635	--
Double support sleeve for an existing trap	ME37400	--

Aligning the device

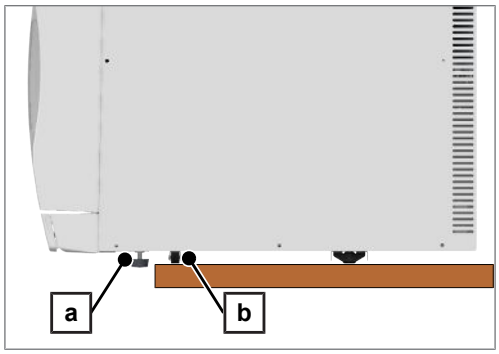
For fault-free operation, the device must be aligned, so that the residual water / condensate from the sterilization chamber can drain.

1. Position a spirit level on the top cover plate and align the device horizontally.
2. Fix the feet of the device with the lock nut (AF13).

Turning the device

To make it easier to reach the components installed on the device sides when working (e.g. maintenance), the device can be turned as follows.

1. Close the door so that it does not swing open unintentionally.
2. Switch off the device.
3. Disconnect the power cable.
4. Disconnect the drain hose on the drain side.
5. Disconnect any other connections if necessary.
6. Lift the device slightly and carefully pull it forward on the worktop until the two front device feet (pos. a) are no longer on the worktop.

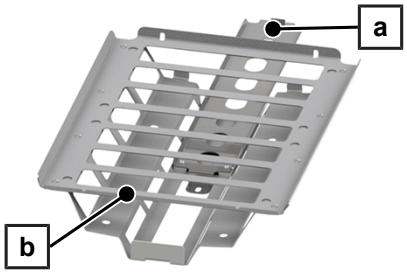


   ➥ The middle caster (pos. b) remains on the worktop.
7. Loosen the hexagon nuts (AF13) on the device feet.
8. Unscrew the hexagon nuts until they touch the device feet.

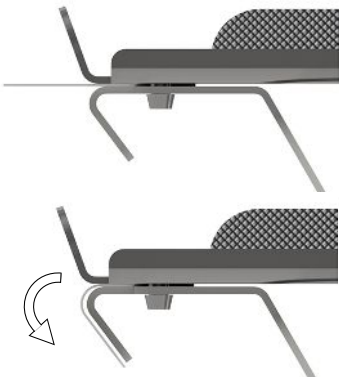
9. Screw in the device feet completely.
10. Turn the device on the worktop in the desired direction.
    ➥ The device does not need to be lifted.
11. Carry out the necessary work on the device.
12. Turn back the device.
13. Unscrew the two device feet (approx. 1 cm).
14. Lift the device slightly and push it back onto the worktop until the two device feet are resting on the worktop.
15. Use a spirit level to align the device horizontally.
16. Lock the hexagon nuts on the device feet to fix the adjustment.

Mounting the loading slide

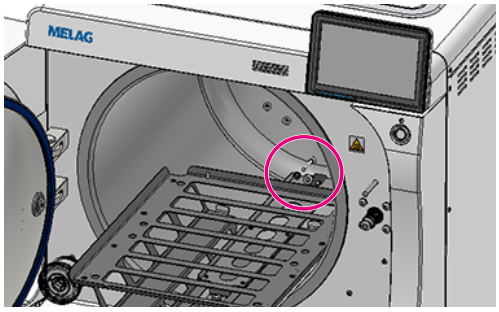
1. Place the fixing plate (pos. a) from behind into the loading slide (pos. b).



2. Fold the sliding film down.

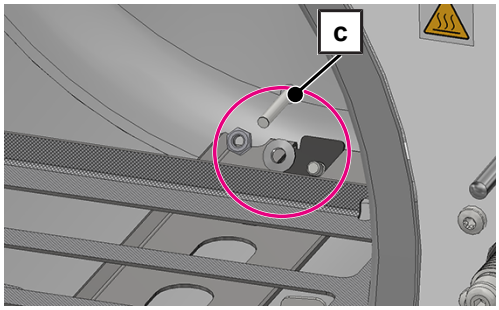


    ➥ The sliding film prevents the sterilization chamber from being scratched.
3. **NOTICE! Make sure that the sliding film remains folded downwards.** Place the loading slide in the sterilization chamber together with the fixing plate.
4. Align the fixing plate so that the thread of the pressure release filter protrudes through the rear lug of the fixing plate.

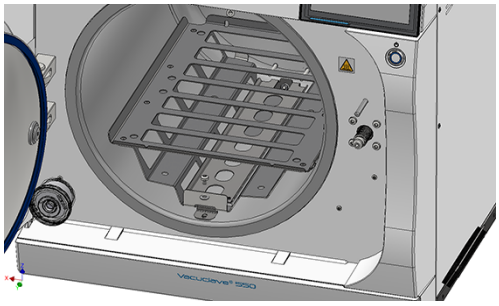


5. Pull the loading slide out slightly to better access the pressure release filter (pos. c).

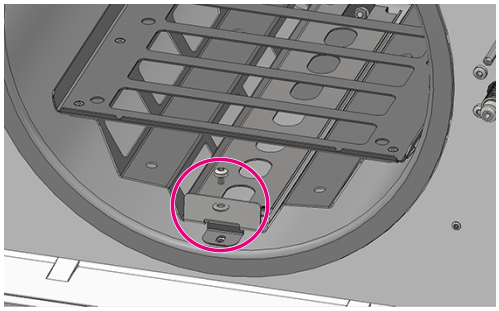
6. Mount the loading slide to the rear of the pressure release filter using a locking edge washer and the hex nut.



7. Slide the loading slide fully into the device.



8. Mount the loading slide at the front with a locking edge washer and the flat-head screw.



9. If the loading slide is difficult to move after assembly, check the sliding ability again after the test run in the **`Universal-B`** program.

PLEASE NOTE

If the loading slide is still difficult to move even after the trial run, the contact for of the fixing plate on the loading slide is too high.

- Dismantle the loading slide and unscrew the pressure release filter by half a turn or one turn.

Checking the software version

1. Open the status of the device with ℹ in the header of the display.
2. Check the software version.
3. Update the software if necessary, see Software update [▸ Page 74].

Checking water supply and disposal

1. Check the water supply and disposal in the **`Settings`** > **`Water management`** menu.
2. If necessary, set the water supply and disposal according to the installation variant, see Installation examples [▸ Page 28].

Checking date and time

Date and time of the device must be correctly set for proper batch documentation. Ensure that you take into account any clock change, as this is not adjusted automatically.

1. Check the date and time in the header of the display.
2. If necessary, set the date and time in the **`Settings`** menu, see Date and time [▸ Page 65].

Display brightness and volume

1. If necessary, adjust the brightness of the display in the **`Settings`** > **`Brightness`** menu, see Display brightness [▸ Page 66].
2. If necessary, adjust the volume in the **`Settings`** > **`Volume`** menu, see Volume [▸ Page 66].

Test runs

Vacuum test with cold sterilization chamber

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

Universal-B Program

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

Check for leaks

After the **`Universal B`** program, check the installed hose connections for leaks.

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 Devices Regulation are included in the manufacturer's inspection report.

Record of installation and setup

The record of installation is to be completed by the responsible stockist and a copy sent to MELAG as proof of the correct setup, installation and initial commissioning. This is a constituent part of any guarantee claim.

Service connection

PLEASE NOTE

While using the service connection with MELAtrace, no other activities may be carried out at the device.

The service connection enables the diagnosis of the device and the control of valves via the MELAtrace software.

Service settings

To make service settings, such as a **`Software reinstallation`**, you must log in as a service technician, see Logging on user role [▸ Page 71]. Only ▸authorised technicians have access to the further service documents required for this purpose.

7 First steps

Switching on the device

The following must be fulfilled or present:

- ✓ The device is connected to the power supply.
- ✓ The feed water supply is secure.
- ✓ The wastewater disposal is connected.

1. Switch on the device at the power switch, see Device views [▸ Page 13].
   - ➥ The start screen appears on the display.
   - ➥ The double jacket steam generator is ventilated, whereby the air flow can cause a hissing noise.
   - ➥ The feed water level is checked immediately after activation.

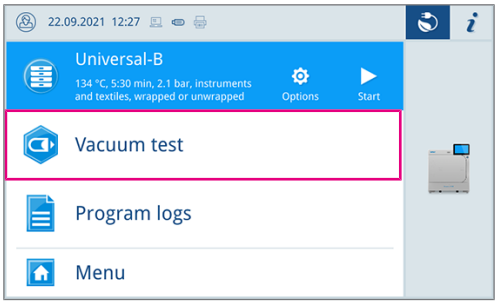
PLEASE NOTE

In the case of automatic feed water supply, the device attempts to supply feed water after start-up. If no feed water is available yet, a malfunction message is displayed, see Malfunctions [▸ Page 83].

2. Wait until the favourites menu is displayed.

   PLEASE NOTE: You can start a program immediately without waiting for the ▸preheating time.

   Within the first 30 s after the device is started, switch to the `Vacuum test` to prevent automatic preheating.



Opening and closing the door

The device has a motor-driven, automatic door locking mechanism with threaded spindle.

Opening the door

PLEASE NOTE

The door is to be left open only whilst loading and unloading the device. Keeping the door closed saves energy.

Please observe the following when opening the door:

- Never use force to open the door.
- Do not pull vigorously at the door to open it. The door unlocks automatically.

The following must be fulfilled or present:

✓ The device is switched on and booted up.

▶ Open the door by pressing **OPEN DOOR**.
The button is displayed when the menu area is minimised.

➥ The door unlocks automatically.

Closing the door

When closing the door, comply with the following instructions to guarantee faultless operation of the door locking mechanism:

- Do not slam the door.
- Keep pressing the door closed until the door lock engages.

▶ Press the door firmly for at least 3 s.

➥ After the door has been closed, the display returns to the default view.

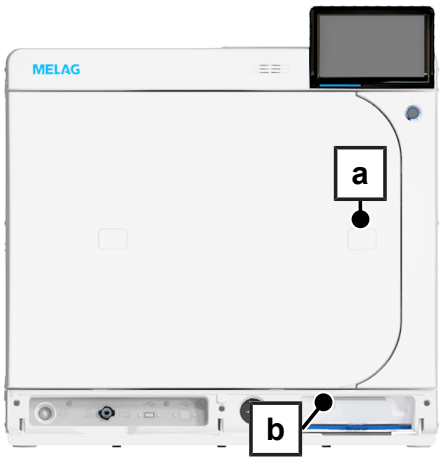
➥ The door is locked pressure-tight upon program start.

Manual door emergency-opening

The door can be opened manually via the emergency opening following a power failure or malfunction.

1. Switch off the device and remove the power plug from the socket.

2. Remove the cover cap (pos. a) in order to enable the emergency door opening by pressing the cover cap in on one side.



3. Insert the Allen key (5 mm) included in the scope of delivery into the opening. The Allen key can be stored in the specially designed bracket behind the service hatch (pos. b).

CAUTION

When opening the door in an emergency, hot steam may escape and there may still be hot water in the sterilization chamber.

This could result in scalding.

- Never touch the mount, loading slide, loading, sterilization chamber or door with unprotected hands. The components are hot.

4. Tighten the Allen key clockwise.

   ➥ The door opens a crack.

5. Remove the Allen key.

6. Open the door and return the cover cap.

Feed water supply

Steam sterilization requires the use of ▸distilled or ▸demineralised water, known as ▸feed water. Annex C of ▸EN 13060 specifies the guideline values to be observed.

The feed water is either supplied via a separate water treatment unit (e.g. MELAdem 47) an external storage container or, in emergency mode, via the internal storage tank.

The steam sterilizer requires approx. 5 l of feed water for the first filling of the steam generating system.

Using of a water treatment unit

To protect the drinking water system, a water treatment unit is connected via a safety device in accordance with the national ordinance. The respective system is selected in accordance with the number of sterilization runs per day and the type of the load.

PLEASE NOTE

Should you wish to use a water treatment unit from another manufacturer, please consult MELAG.

Using an external storage container

For the feed water supply via an external storage container, the feed water is pumped into the device via a filling pump. For a storage container with a capacity of 25 l, the quantity of feed water is sufficient for at least 12 sterilizations.

1. Fill the storage container with a sufficient quantity of demineralised water.
2. Before each program start, check the condition and level of the feed water in the storage container.

NOTICE

Danger of algae development

- To prevent algae from forming, do not expose the storage storage container to sunlight.

Using the feed water tank (emergency operation)

The manual filling of the internal feed water tank is only used for emergency operation (e.g. failure of the water treatment unit). The feed water tank holds a maximum of 4.2 l. This volume of feed water is sufficient for one sterilization.

1. Open the cover of the feed water tank.
2. Place the level increase tank overflow (included in the scope of delivery) in the feed water tank.
3. Fill the tank up to the MAX mark of the level increase with fresh ▸feed water.
4. Switch the water supply to **`Manual`**, see Water management [▸ Page 67].

Disposal of the wastewater

The Vacuclave 550 has no internal wastewater tank.

The wastewater is either drained automatically via the overflow funnel or it is collected in an external wastewater container and is drained manually.

NOTICE

Water damage due to overflowing wastewater container

- When draining manually, check the level in the wastewater occasionally.

8 Important information for routine operation

Comply with the recommendations issued by the Robert Koch Institute (▸RKI) and the information contained in ▸DIN 58946-7.

Manufacturer's recommendation for the routine operation of type B steam sterilizers [1)]

When is it necessary to make checks?	How should the checks be made?
Once per working day	• Visual check of the door seal and the door lock for damage • Check the operating media (electricity, ▸feed water and water connection if necessary) • Check the documentation media (printer paper, computer, network) MELAG recommends performing the steam penetration test with MELAcontrol Helix/MELAcontrol Pro in the Universal-Program (test system in accordance with ▸EN 867-5).
Once a week	• Vacuum test • **Tip:** In the mornings before starting work – the steam sterilizer must be cold and dry
Batch-related tests	With "Critical B" instruments: • MELAcontrol Helix/MELAcontrol Pro must be used as ▸batch control with every sterilization cycle. With "Critical A" instruments: • The process indicator (type 5 in accordance with ▸EN ISO 11140) must be used as batch control with every sterilization cycle. With "Critical A + B" instruments: • MELAcontrol Helix/MELAcontrol Pro must be used as batch control with every sterilization cycle. This simplifies the working procedure and increases security. You can omit the daily steam penetration test with MELAcontrol Helix/MELAcontrol Pro (see above). The use of another test system in accordance with ▸EN 867-5 is possible. The number of the available test systems means that MELAG is not able to provide technical support when using a different system.

PLEASE NOTE

Document the results of the tests.

- The indicator test strips used need not be stored.

[1)] in accordance with the current recommendations from the Robert Koch Institute

9 Sterilization

Preparing the load

Always clean and disinfect properly before sterilization. Only in this way is it possible to guarantee the subsequent sterilization of the ▸load. The materials used, cleaning agents and reprocessing procedure are of decisive significance.

Comply with the following for safe handling:

- Only ever use packaging material and systems which have been cleared by their manufacturer for steam sterilization.
- Use only original MELAG accessories or those from other suppliers authorised for use by MELAG.

Reprocessing instruments

Unwrapped sterile material loses its sterility on contact with ambient air. If you intend to store your instruments sterilely, wrap them in suitable packaging before sterilization.

When ▸reprocessing used and brand-new instruments, comply with the following:

- Always observe both the instrument manufacturer's reprocessing instructions and the relevant standards, guidelines and directives (in Germany, for example, from ▸RKI, ▸DGSV and ▸DGUV Regulation 1).
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with de-mineralised or distilled water and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- Use only those care agents suitable for steam sterilization. Consult the manufacturer of the care agents. Do not use any water repellent agents or oils impermeable to steam.
- When using ultrasound devices, care equipment for handpieces and washer-disinfectors, comply with the manufacturer's reprocessing instructions.

NOTICE

The presence of residual disinfection and cleaning fluids results in corrosion.

This could result in increased maintenance requirements and a restriction of the steam sterilizer function.

Reprocessing textiles

Comply with the following points when ▸reprocessing textiles and placing the textiles in sterile containers:

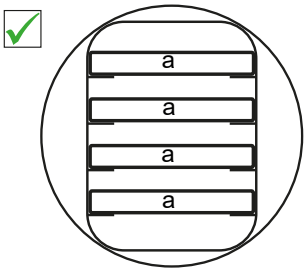
- Comply with both the reprocessing instructions of the textile manufacturer the relevant standards, guidelines and directives (in Germany e.g. of the ▸RKI and ▸DGSV).
- Arrange the folds in the textiles parallel to each other.
- Stack textiles vertically wherever possible and not too closely together in the sterile container. This enables the development of flow channels.
- If textile packages do not remain together, wrap the textiles in sterilization paper.
- Only ever sterilize dry textiles.
- The textiles may not be permitted to come into direct contact with the sterilization chamber; otherwise they will become saturated with ▸condensate.

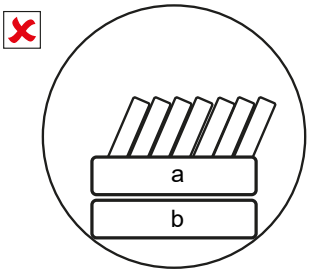
Loading the steam sterilizer

Effective sterilization and good drying is only possible if the steam sterilizer has been loaded correctly.

Ensure the following during loading:

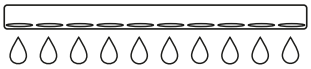
- Insert trays in the chamber only with their appropriate mount.





a Tray
b Sterilization container

- Wherever possible, ensure the separate sterilization of textiles and instruments in separate sterile containers or sterilization packages. This leads to better drying results.
- The use of paper tray inserts can result in poor drying results.
- Use perforated trays such as those from MELAG. Only in this way can ▸condensate drain off. Non-perforated bases or half-shells for holding the ▸load lead to poor drying results.



Packaging

Only ever use packaging materials and systems (▸sterile barrier systems) which fulfil the standard ▸EN ISO 11607-1. The correct use of suitable packaging is important in achieving successful sterilization results. You can use re-usable rigid packaging systems or soft packaging such as transparent sterilization package, paper pouches, sterilization paper, textiles or fleece.

Closed sterile containers

WARNING

Risk of contamination due to insufficient steam penetration or poor drying.

- Use only suitable sterile containers.
- Do not cover the perforations when stacking the sterile containers so that the condensate can drain off.

Please comply with the following when using closed sterile containers:

- Use aluminium sterile containers. Aluminium retains and conducts heat and thus accelerates drying.
- Closed sterile containers must be either perforated or have a valve on at least one side. MELAG sterile containers, e.g. MELAstore Box, fulfil the requirements for successful sterilization and drying.
- Wherever possible, ensure that sterile containers are only stacked on top of those of identical size, so that the condensate can run down their sides.
- Ensure that the perforations are not covered when stacking the sterile containers.

Soft sterilization packaging

WARNING

Risk of contamination due to insufficient drying

To improve the drying results for full loads of soft sterilization packages, the setting **`Drying`**: **`Intelligent`** must be activated.

Soft sterilization packages can be used in both sterile containers and on trays. Please comply with the following when using soft sterilization packages e.g. MELAfol:

- Arrange transparent sterilization packages on edge and close together. If this is not possible, place them with the paper side facing downwards.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- When loading the steam sterilizer, make sure that either the film or paper sides of different pouches are facing each other.
- If the seal seam tears during sterilization, this could be caused by the choice of undersized packaging. Pack the instruments with larger packaging and perform sterilization again.
- Should the seal seam tear during sterilization despite sufficient bag size, adjust the sealing temperature on the sealing device or make a double seam.

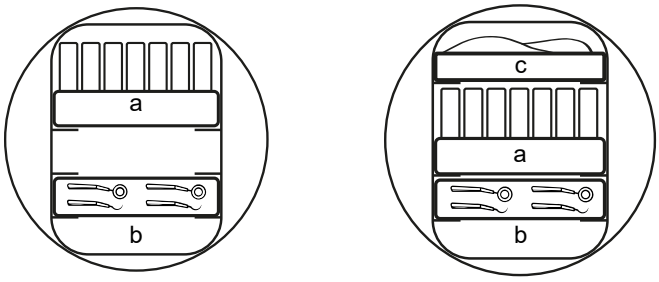
Multiple wrapping

The device uses a fractionated vacuum procedure. This permits the use of multiple wrapping.

Mixed loads

Please observe the following when sterilizing mixed loads:

- Always place textiles at the top
- Sterile containers at the bottom
- Place unwrapped instruments at the bottom
- Place the heaviest loads at the bottom
- Transparent sterilization packages and paper packages on the top. Exception: At the bottom in combination with textiles



a Wrappings
b Heavy loads/instruments
c Textiles

Load quantities and versions

Maximum weight per component

Load*)	
Max. weight per component	2 kg
*) For MELAG mounts, trays, sterile containers, see Accessories and spare parts.	

Maximum load quantities for instruments and textiles

The total weight is the sum of the mass of the load to be sterilized, the packaging materials, the containers and the mount.

Load type		Instruments		Textiles	
		13 A operation	15 A operation	13 A operation	15 A operation
Full load	wrapped	MELAstore Box 100 8 x 1.75 kg	MELAstore Box 100 10 x 1.75 kg	2 kg	3.5 kg
		MELAfol 9 kg	MELAfol 11 kg		
	unwrapped	17.5 kg	25 kg*)		
Mixed load	wrapped	9 kg	11 kg	0.9 kg	0.9 kg
	unwrapped				
*) 20 kg in the program Quick-S					

The maximum current draw of the device can be set to 13 A or 15 A. Depending on the current draw set, different load quantities can be sterilized. The setting is made by an ▸authorised technician depending on the local electrical installation when the device is set up. The setting can be viewed under **`Device status` > `Device` > `Power limitation`**.

Mounts and loading slide

Note the following depending on the use of the accessories:

Loading without mount or loading slide

For loading with containers or MELAstore Box without using the Basic mount or the loading slide, you can position two inverted trays in the sterilization chamber as shown to ensure a better hold.

Basic mount

The Basic mount can be used for sterilization of soft-packaged products (e.g. in MELAfol) on trays. A combination of trays (short, long or large) can be arranged on up to nine levels. The mount is fixed in the device and remains in the sterilization chamber during loading and unloading. The mount has no sliding clips and should not be removed from the sterilization chamber regularly.

Loading slide

The loading slide allows convenient loading and unloading. The slide can be pulled out of the chamber with a tray lifter or heat protection gloves.

Start loading containers or MELAstore Box at the rear end of the slide. You can stack the MELAstore Box 100 cross-wise on top of each other up to four times.

Loading slide with Comfort mount

The loading slide can be extended with the Comfort mount when the user switches between tray and container loading. A combination of trays (short, long or large) can be arranged on up to nine levels.

Selecting the program

All sterilization programs are displayed in the **`Programs`** menu. The following tables list the correct program for each ▸load.

When selecting the sterilization program, proceed as follows:

- Select the sterilization program based on which products you want to sterilize.
- Select the sterilization program according to whether and how the load is wrapped.
- Observe the permissible max. load quantities.
- Note the temperature resistance of the load.

Program loading

Program	Packaging	Especially suitable for	
Universal-B		Single and multiple wrapped	• Mixed loads • Products with narrow lumen
Quick-S		Only unwrapped (no textiles)	• Simple solid instruments • Simple hollow bodies
Gentle-B		Single and multiple wrapped	• Textiles • Thermo-unstable equipment (e.g. plastic, rubber articles) • Products with narrow lumen
Prion-B		Single and multiple wrapped	• Instruments that can come into contact with prion risk tissue and which could not be cleaned in an explicit prion decontaminating method*) • Products with narrow lumen
*) RKI guidelines, Annex 7, chapter 1.3.1			

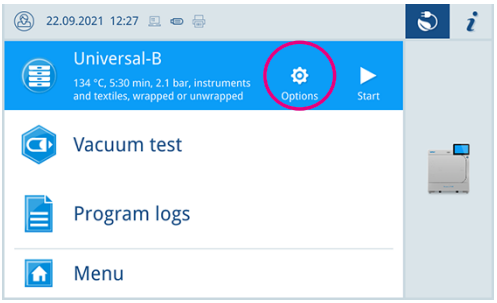
Program parameters

Program	Sterilization temperature	Sterilization pressure	Sterilization time	Operating time, without drying *), **)	Intelligent drying	Time-controlled drying
Universal-B	134 °C	2.1 bar	5:30 min	13-43 min	5-30 min	13 min
Quick-S	134 °C	2.1 bar	3:30 min	12-33 min	5-30 min	13 min
Gentle-B	121 °C	1.1 bar	20:30 min	25-62 min	5-30 min	13 min
Prion-B	134 °C	2.1 bar	20:30 min	28-58 min	5-30 min	13 min
*) depending on the load and installation conditions (such as the water temperature and supply voltage) **) in 13 A operation, the operating time can be extended by up to 10 min						

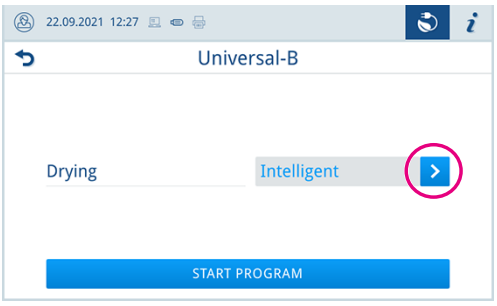
Program options

The `Options` button can be used to change settings one time for the selected program.

1. Press the `Options` button.



2. Select the desired option, see Program options [▶ Page 68].



3. Start the program with **START PROGRAM**.
4. If **Authentication at Reprocessing program start** is activated, enter the PIN, see Authentication [▸ Page 72].
5. Confirm the subsequent dialogue window with **START PROGRAM**.

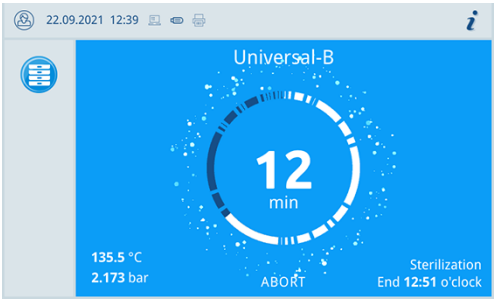
Starting the program

The following must be fulfilled or present:

- ✓ The sterile filter is screwed into the device.
- ✓ The load has been cleaned and disinfected, see Preparing the load [▸ Page 46].
- ✓ The device is loaded correctly, see Loading the steam sterilizer [▸ Page 47].
- ✓ The max. load quantity has not been exceeded, see Selecting the program [▸ Page 49].
- ✓ The date and time are set correctly, see Date and time [▸ Page 65].

1. Press **START PROGRAM**.
2. Confirm the subsequent dialogue window with **START PROGRAM**.

   ➥ The door locks pressure-tight upon program start. The device checks the quantity of feed water and its conductivity.
3. If **Authentication at Reprocessing program start** is activated, enter the PIN, see Authentication [▸ Page 72].



➥ During the program run, the display shows the current program duration, the current parameters and the expected end of the program.

Manual program abort

You can abort the program at any time. If you abort the program before the end of the sterilization phase, the load is **not** sterile.

WARNING

Danger of infection from early program abort

Aborting a program before the drying phase begins means that the load is unsterile. This endangers the health of your patients and practice team.

- Re-pack the load if necessary.
- Repeat the sterilization of the load.

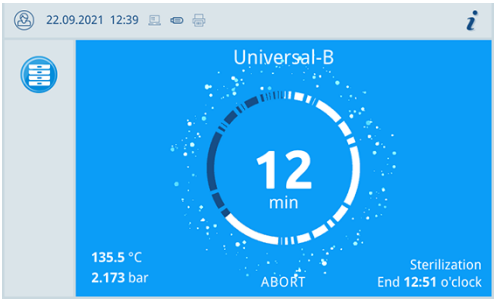
CAUTION

When the door is opened after a program abort, hot steam may escape and hot water may be present in the sterilization chamber.

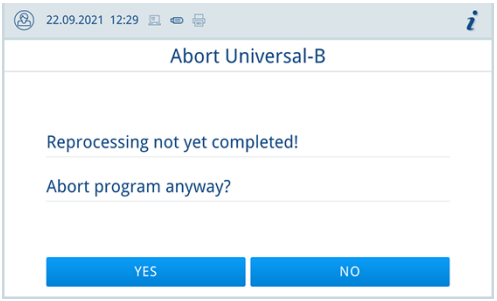
This could result in scalding.

- Never touch the load, the sterilization chamber or the door with unprotected hands. The components are hot.

1. Press **ABORT** to abort a program.



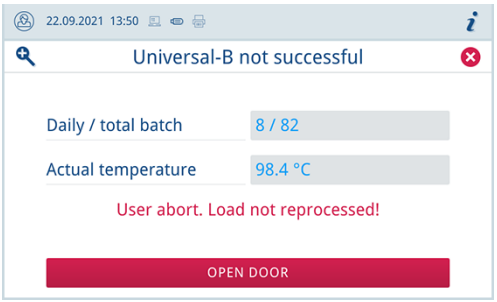
2. Confirm the security query with **YES**.



↪ The load is not sterile.

↪ Cancelling the program can take a few minutes as steam and condensate are removed from of the chamber.

3. Press **OPEN DOOR** to remove the load.



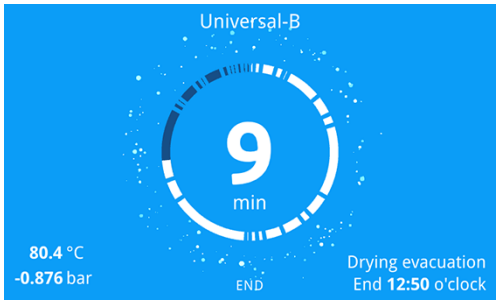
Ending the program prematurely

You can exit the program prematurely after the drying starts. If you exit the program before the drying has finished, the load is not completely dried and should be used immediately.

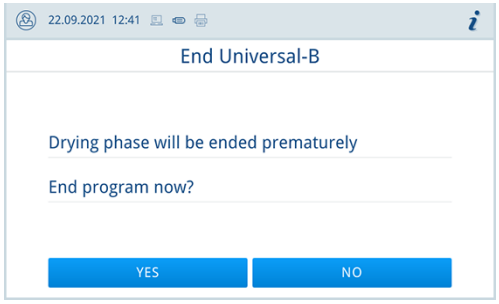
The following must be fulfilled or present:

✓ The sterilization program is in the drying phase.

1. To end the program prematurely, press **END**.



2. Confirm the end of drying with **YES**.



➥ The program will be aborted prematurely.

Program is ended

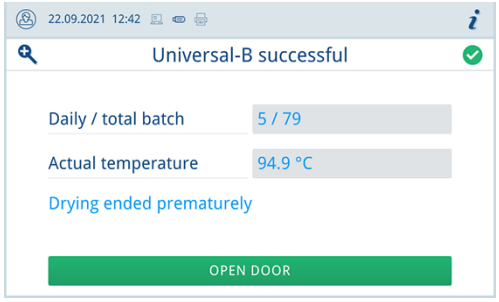
PLEASE NOTE

If the program has been carried out successfully, a corresponding message appears on the display and the status LED below the display illuminates green.

- If the display indicates that the program was not successful or the LED does not illuminate green, the program must be repeated.

1. Before opening the door, press the magnifying glass symbol to look up other values of the exited program (e.g. the plateau time or the conductivity).

2. Press **OPEN DOOR** to remove the load.



3. If **Authentication at Reprocessing program end** is activated, enter the PIN, see Authentication [▶ Page 72].

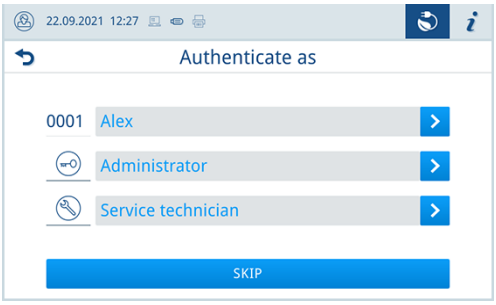
If automatic log output after the end of the program is activated in the **Settings** > **Log output** menu, the log of the run program is output to the activated output media after the door is opened.

Approval process

According to ▸RKI “Hygiene requirements for the reprocessing of medical devices”, instrument reprocessing ends with the documented approval of the ▸sterile material. The approval process consists of batch indication and batch approval. Both must be performed by an authorised expert.

Batch approval

The batch approval includes checking the process parameters using the sterilization results at the device and the sterilization log as well as checking the individual packaging for damage and residual moisture. The sterilization log records the release of the ▸batch and any indicators, see Logging [▸ Page 57]. Depending on the setting in the user administration, it is necessary to enter a user PIN for the batch approval, see Authentication [▸ Page 72].



Removing the sterile material

CAUTION

Danger of burns from hot loads.

- Use a tray lifter or heat protection gloves.

CAUTION

Unsterile instruments resulting from damaged or burst packaging. This endangers the health of your patients and practice team.

- Should the packaging be damaged or have burst after sterilization, wrap the load again and re-sterilize it.

If you remove the ▸sterile material from the device directly after the end of the program, it is possible that the instruments can be partially damp. According to the Arbeitskreis für Instrumentenaufbereitung (▸AKI), single drops of water (no puddles) that dry off within 15 min are considered tolerable residual moisture in practice.

Comply with the following specifications when removing the sterile material:

- Never use force to open the door. This could damage the device or result in the emission of hot steam.
- Hold the mount level when removing it from the device. Otherwise, the load could slide off.
- Keep the trays horizontal when removing them from the device. Otherwise, the load could slide off.
- When removing the load from the device separately, ensure that the mount does not slide out unintended.
- Use a tray lifter or suitable protective gloves to remove the tray.
- Use both hands and two tray lifters to remove large or long trays.
- Never touch the sterile material, the sterilization chamber, the mount or the inside of the door with bare hands. The components are hot.
- Check the packaging of the sterile material for damage when removing it from the device. Should the packaging be damaged, re-pack the load and re-sterilize it.

Storing sterile material

The maximum storage time is dependent on the packaging and the storage conditions. Please observe the regulatory requirements for the storage period of ▸sterile materials (in Germany e.g. ▸DIN 58953, Part 8 or the ▸DGSV guidelines) as well as the following listed criteria:

- Follow the manufacturer's instructions on the packaging, e.g. when setting the storage period when printing labels.
- Comply with the maximum storage duration in accordance with the packaging type. Comply with the manufacturer's information on the packaging.
- Store the sterile material in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterile material in an environment protected against moisture.
- Store the sterile material in an environment protected against excess temperature variations.

10 Logging

Batch documentation

The batch documentation serves as proof of the successful conclusion of the program and represents an obligatory part of quality assurance. The device internal log memory saves such data as the program type, batch and process parameters of all the programs completed.

To obtain the batch documentation, you can output the internal log memory and transfer its data to various output media. This can be performed immediately at the end of every program or at a later point, such as at the end of the day.

If Authentication [▸ Page 72] is activated, the user ID and the result of the approval process are documented in the log header and on a label if required.

Capacity of the internal log memory

The device is equipped with an internal log memory. All data of the programs run is stored in this automatically. The capacity of the internal log memory is sufficient for 100 logs.

If the internal log memory is full, a warning appears on the display. In this case, output the logs concerned onto the defined output medium [▸ Page 60]. If you continue the program without outputting the logs, the oldest log is overwritten automatically.

The number of free log memory locations can be viewed under **`Device status > Device`**.

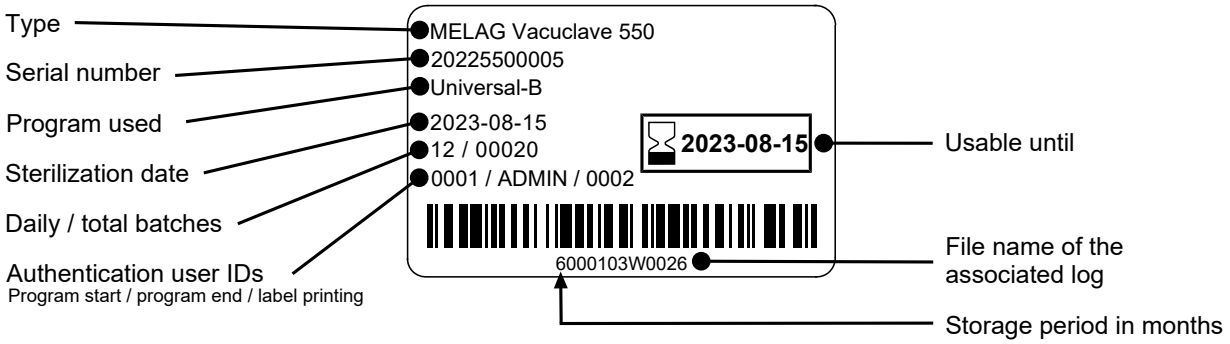
MELAG recommends outputting logs automatically, see Log output [▸ Page 69].

Label printer

The use of a label printer facilitates batch traceability. Using the sterilization date, the storage duration, batch number, user ID of the person approving the application for use, the device used and the file name it is possible to assign the sterilized instruments to the patient and sterilization batch.

For further information on setting up the label printer, see Label print [▸ Page 69].

Faultless packages containing sterile material are marked with labels after sterilization. As such, the preconditions for correct “approval” by the person conferred with the task of reprocessing are given. All information regarding the correct sterilization process can be attributed to the instruments used in patient records.



Logs menu

The **Logs** menu provides you with the following options:

- Display and output of program logs, see Log output [▶ Page 69]
- Display and output of malfunction logs
- Display and output of status log
- Display and output of system log
- Printing of labels, see Label print [▶ Page 69]

You can issue logs subsequently and independently of the time of a program end. Before the log output, you can select the output media.

Log types

Log type	Description
Program log	Log of a program
Malfunction logs	Log with faults that occurred outside a program run
Status log	Summary of all important settings and system statuses
System log	List of all the malfunctions and changes to the system in order of time (log book) The system log is output in English.

Log list

In the log list you can view all logs in detail. It displays all the logs present in the memory. You can sort the list by pressing the column headings.

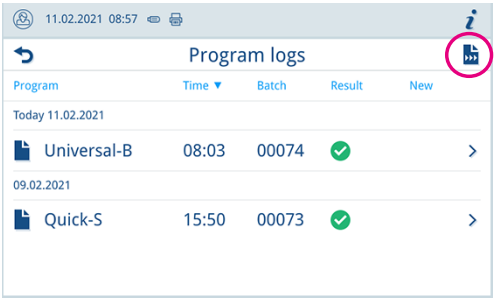
The **Result** column shows symbolically whether the program ended successfully or not.

Symbol	Description
	Program successfully completed
	Program not successfully completed

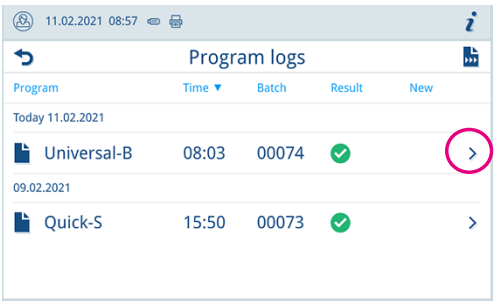
Logs that have not yet been output are marked with a dot in the **New** column.

Output logs and print labels

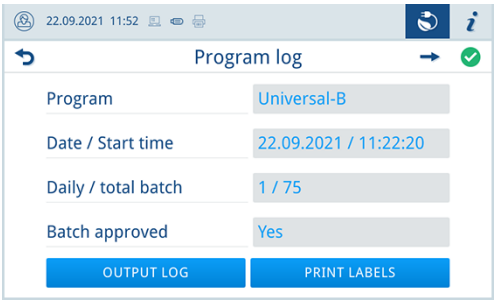
1. Press the button at the top right to customise the **Log output options** and output multiple logs.



2. Press the button with the arrow to view and output a log.

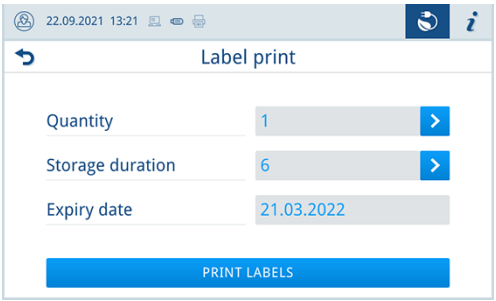


3. Press **OUTPUT LOG** to enter the **Log output options** and output the displayed log.



4. Press **PRINT LABELS** to open the label printing dialog.

5. Press the button with the arrow to change the **Quantity** or the **Storage duration**.



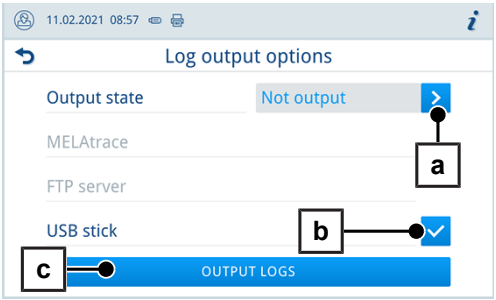
   ➥ Confirm the changes with **OK**.

6. Press **PRINT LABELS** to print labels for the displayed log.

Log output options

In the **Log output options** menu you can set the type of logs to be output and the output medium.

1. Press the button with the arrow (pos. a) to select the desired output status (see following table).



2. Activate at least one output medium (pos. b).

   ➥ Unavailable output media are greyed out.

3. Press **OUTPUT LOGS** (pos. c).

➥ The output takes place on the selected output media.

The following settings are possible:

Output status	Description
Not output	All logs that are not output will be output.
Last	The log of the last successful completed program is outputted.
All	All logs of the selected log type are output.

Output media

The following output media can be activated and configured in the menu **Settings** > **Log output**:

- MELAtrace
- FTP
- USB

For activated output media, the symbol in the information area is displayed faintly.

For activated and connected output media, the symbol is displayed in full.

Output media that are not activated are not displayed, even if they are connected.

PLEASE NOTE

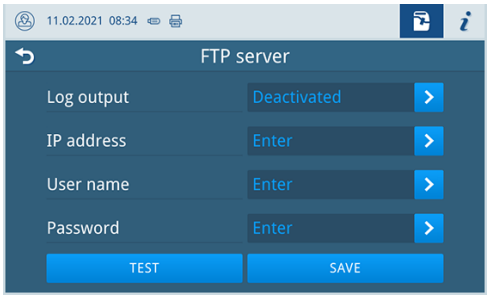
You can only connect one USB storage medium.

Symbol	Output media	Description
	USB flash drive	Output to a USB stick connected to the USB port
	FTP	Output to an FTP server
	MELAtrace	Output to MELAtrace
	Label printer	Output to a connected label printer

FTP server configuration

Under the **FTP** menu item, the FTP server is configured via the IP address, the user name and the password.

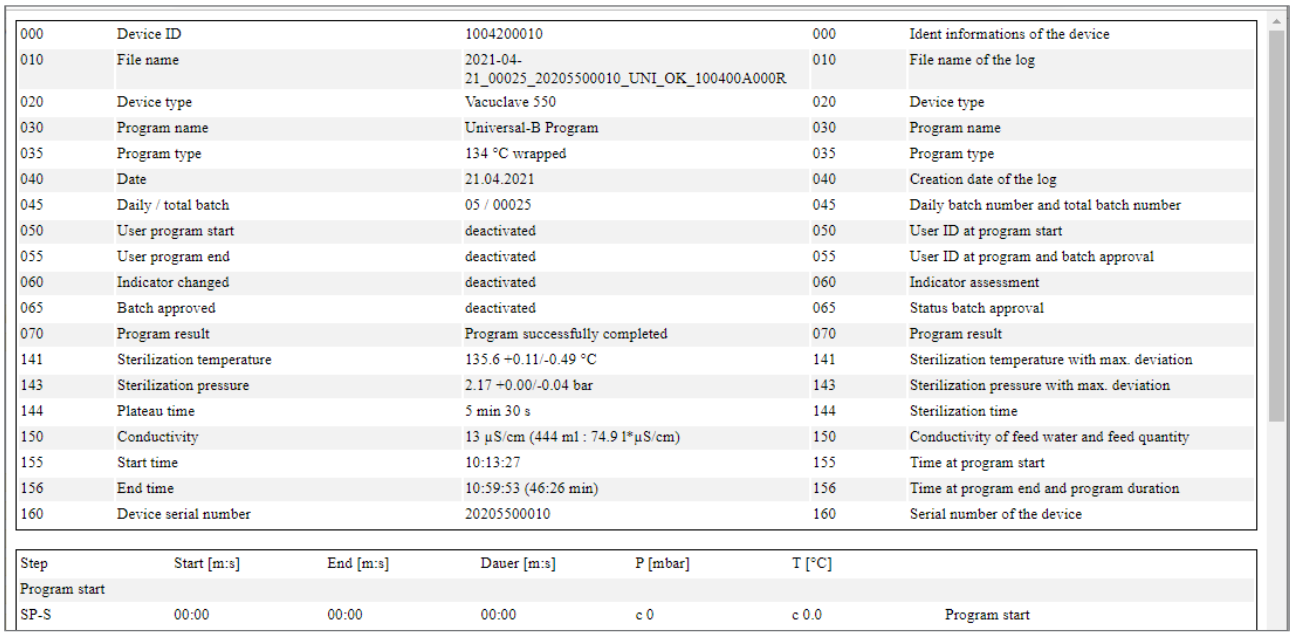
The **TEST** button can be used to test the set configuration.



Displaying logs on the computer

The log files are generated in html format and can be displayed and printed on the computer with a web browser or in MELAtrace.

The program, malfunction and status protocols contain a legend entry for each line. The program logs contain graphic data and can be displayed as graphic logs in MELAtrace.



000	Device ID	1004200010	000	Ident informations of the device
010	File name	2021-04-21_00025_20205500010_UNI_OK_100400A000R	010	File name of the log
020	Device type	Vacuclave 550	020	Device type
030	Program name	Universal-B Program	030	Program name
035	Program type	134 °C wrapped	035	Program type
040	Date	21.04.2021	040	Creation date of the log
045	Daily / total batch	05 / 00025	045	Daily batch number and total batch number
050	User program start	deactivated	050	User ID at program start
055	User program end	deactivated	055	User ID at program and batch approval
060	Indicator changed	deactivated	060	Indicator assessment
065	Batch approved	deactivated	065	Status batch approval
070	Program result	Program successfully completed	070	Program result
141	Sterilization temperature	135.6 +0.11/-0.49 °C	141	Sterilization temperature with max. deviation
143	Sterilization pressure	2.17 +0.00/-0.04 bar	143	Sterilization pressure with max. deviation
144	Plateau time	5 min 30 s	144	Sterilization time
150	Conductivity	13 µS/cm (444 ml : 74.9 l*µS/cm)	150	Conductivity of feed water and feed quantity
155	Start time	10:13:27	155	Time at program start
156	End time	10:59:53 (46:26 min)	156	Time at program end and program duration
160	Device serial number	20205500010	160	Serial number of the device

Step	Start [m:s]	End [m:s]	Dauer [m:s]	P [mbar]	T [°C]	
Program start						
SP-S	00:00	00:00	00:00	c 0	c 0.0	Program start

11 Function checks

Service programs

Program name	Program	Operating time	Use/function
Vacuum test		25 min	For measuring the leakage rate, test with a dry and cold device (test without load)
Bowie & Dick test		20 min	Steam penetration test with special test package (available from specialist stockists)
Draining		3 min	For emptying and pressure release of the double jacket steam generator, e.g. for service, decommissioning or before transport

Vacuum test

The device can be checked for leakages in the steam system using the ▸vacuum test. This determines the leakage rate at the same time.

Perform a vacuum test in the following circumstances:

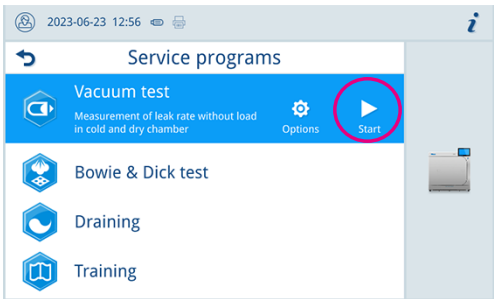
- Once a week in routine operation
- During commissioning
- Following longer operating pauses
- In the case of a corresponding malfunction (e.g. in the vacuum system)

PLEASE NOTE

Perform the vacuum test with the device in a cold and dry state.

1. Switch on the device.

2. Working in the **`Service programs`** menu, select **`Vacuum test`** and press **`Start`**.



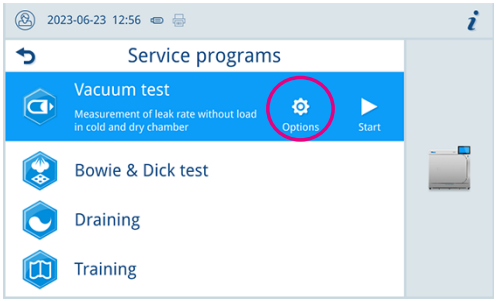
➥ The vacuum test is started in the **`Default`** program version.

➥ The evacuation pressure and the equilibration time or measurement time are shown on the display. The sterilization chamber is ventilated after the end of the measuring time. Then the message will be shown on the display with an indication of the leakage rate. Should the leakage rate be too high i.e. over 1.3 mbar, a corresponding message will appear on the display.

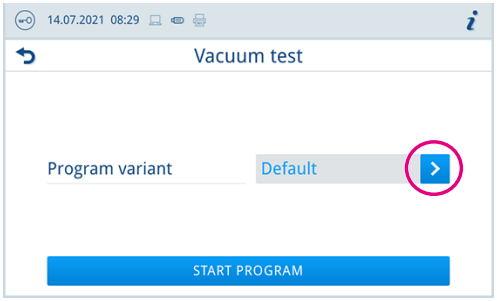
Options for the vacuum test

Under **Options**, you can extend the vacuum test to areas that are connected to the sterilization chamber. In this way, you can also evaluate their leak tightness.

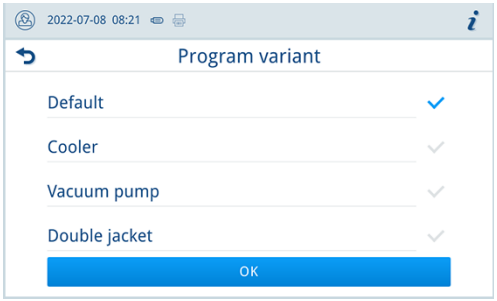
1. Working in the **Service programs** menu, select **Vacuum test** and press **Options**.



2. Press the button with the arrow to select another variant of the vacuum test.



3. Select the required variant and accept it with **OK**.



4. Start the vacuum test with **START PROGRAM**.

Bowie & Dick test

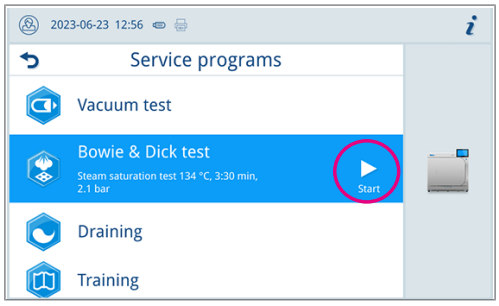
The ▸Bowie & Dick test serves as proof of steam penetration of ▸porous materials such as e.g. textiles. You can perform a routine function check for proof of steam penetration. To do so, use the Bowie & Dick Test service program. Specialist stockists provide various test systems for the Bowie & Dick test. Perform the test according to the test system manufacturer's specifications.

The following must be fulfilled or present:

✓ A new test system.

✓ The sterilization chamber is empty.

1. Place the test system in the sterilization chamber according to the manufacturer's instructions.
2. Close the door.
3. Working in the **`Service programs`** menu, select **`Bowie & Dick test`** and press **`Start`**.



12 Settings

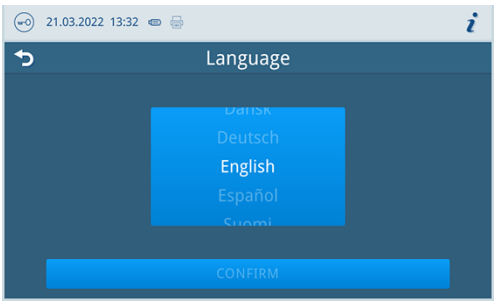
General settings

General settings can be changed by any user.

Language

In the **Settings** > **Language** menu, you can switch between the enabled languages.

1. Set the desired language.



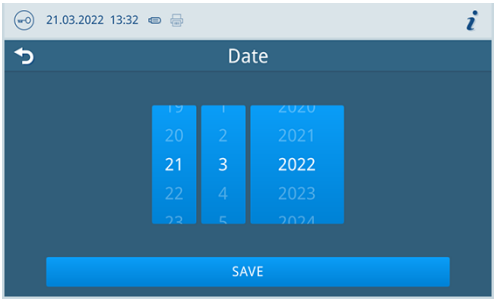
2. Press **CONFIRM** to accept the changes.

➥ The dialogues on the display and the log texts are changed to the selected language.

Date and time

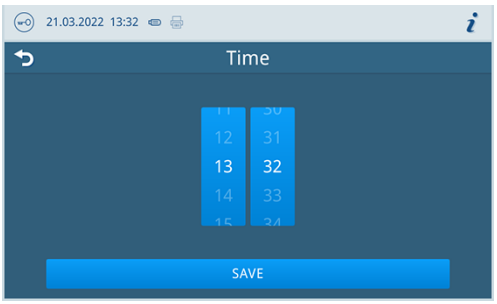
Date and time of the device must be correctly set for proper batch documentation. Ensure that you take into account any clock change in autumn and spring, as this is not adjusted automatically. Set the date and time as follows:

1. Open the **Settings** menu.
2. Select the **Date** menu item.
3. Set the date.



4. Press **SAVE** to accept the changes.
5. Select the **Time** menu item.

6. Set the time.



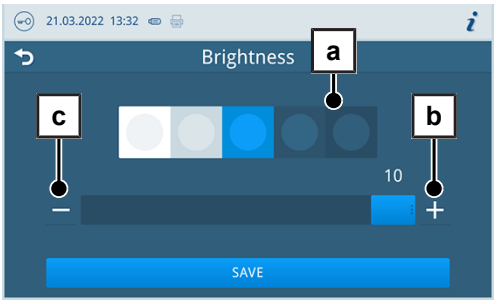
7. Press **SAVE** to accept the changes.

Display brightness

In the **Settings** > **Brightness** menu, you can set the brightness of the display.

The display brightness is adjusted immediately. The colour bar (pos. a) gives you an impression of the colour contrast.

1. Move the slider to the left or right or press the plus (pos. b) or minus (pos. c) buttons.



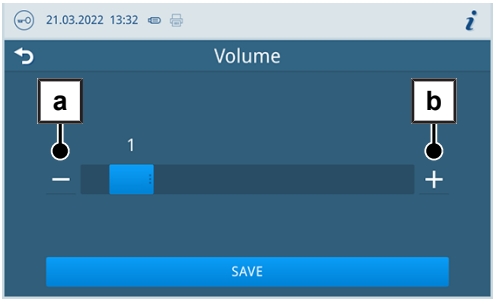
   ➥ The display brightness can be adjusted in ten steps.

2. Press **SAVE** to accept the changes.

Volume

In the **Settings** > **Volume** menu, you can set the volume of the sound output.

1. Move the slider to the left or right or press the minus (pos. a) or plus (pos. b) buttons.



   ➥ The volume can be adjusted in ten steps.

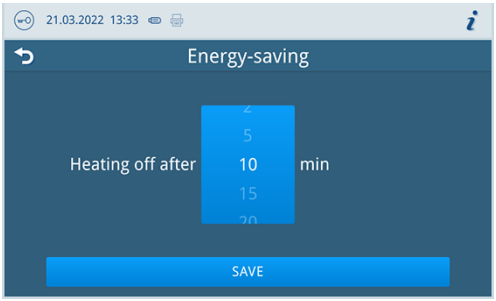
   ➥ At level 0, the sound is switched off.

2. Press **SAVE** to accept the changes.

Energy-saving

In the **Settings** > **Energy-saving** menu, you can set after how long the device is inactive the heater is switched off.

1. At the number wheel set after how many minutes the heater is switched off automatically.



2. Press **SAVE** to accept the changes.

Water management

Water supply

You can set the feed water supply to **Automatic** or **Manual**.

Designation	Description
Automatic	The feed water is supplied automatically via the MELAdem feed water connection or the filling pump feed water connection.
Manual	The manual feed water supply is only used for emergency operation. Before each program start the feed water tank must be filed manually up to the MAX mark. The required amount is about 3 l.

Water disposal

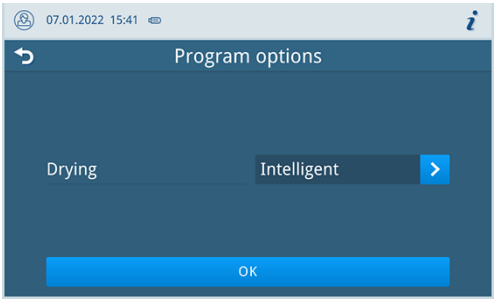
You can set the disposal of wastewater to **Automatic** or **Manual**.

Designation	Description
Automatic	The wastewater is automatically disposed of via the overflow funnel into the building's wastewater installation.
Manual	The wastewater is disposed of via the overflow funnel into an external wastewater container. The container is monitored by a level sensor and must be emptied regularly. MELAG recommends daily emptying. The capacity of the wastewater container is at least 10 cycles.

Program options

In the **Settings** > **Program options** menu, you can make default settings for program options.

1. Press the button with the arrow to make changes.



2. Activate or deactivate the desired setting by selecting or deselecting it.
3. Confirm the changes with **OK**.
4. Press **SAVE** to accept the changes.

The following settings are possible:

Designation	Short description
Drying: Intelligent	Automatically monitors and ends the drying phase once the load is dry.
Drying: Time-controlled	Ends the drying phase after a specified duration.

Drying

You can change the preset drying mode once via **Program options**.

Time-controlled drying

With time-controlled drying, the duration of the drying phase is determined by the program.

If you want to activate time-controlled drying, proceed as follows:

- Press the drying button to select the option **Time-controlled** if you want time-controlled drying to take place during the next program run.

Intelligent drying

In contrast to time-controlled drying, the duration of the intelligent drying is automatically calculated using the residual moisture in the sterilization chamber. The drying phase is ended as soon as the load is dry. A number of factors play a role in this process including e.g. the type of the load, wrapped or unwrapped, the load quantity, the distribution of the load in the sterilization chamber etc.

If you want to activate intelligent drying, proceed as follows:

- Press the drying button to select the **Intelligent** option if you want intelligent drying to take place during the next program run.

PLEASE NOTE

Intelligent drying is activated in the delivery state.

Log output

In the **Settings** > **Log output** menu, you can set how the log should be output by default for each output medium [▶ Page 60].

The following settings are possible:

Option	Description
Deactivated	No log output possible, even with output medium connected
Manual	Manual log output possible via the log list
Automatic (immediately after program run)	Automatic log output after end of the program for the defined programs

For the option **Automatic** a dialog follows for the definition for which programs the automatic log output should take place.

You can activate the log output for several output media at the same time.

Label print

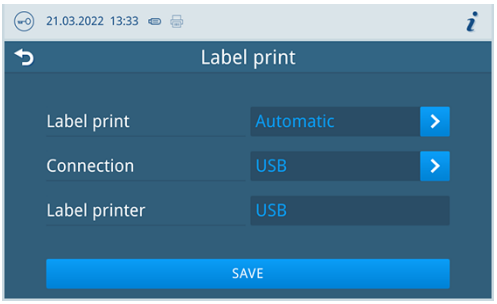
PLEASE NOTE

No labels can be printed if the program run has not been completed successfully or the batch has not been released.

In the **Settings** > **Label print** menu, you can configure the label printer and set default settings.

The label printer can be connected via USB or via integration into a local network (LAN). If several devices access the label printer, it must be integrated via a local network (LAN).

1. Press the button with the arrow to make changes.



2. Activate or deactivate the desired setting by selecting or deselecting it.

   ➥ For the option **Automatic** a dialogue follows for the definition for which programs the automatic label print should take place.

3. Confirm the changes with **OK**.

4. Press **SAVE** to accept the changes.

The following settings are possible:

Option	Description
Deactivated	No label print possible, even with label printer connected
Manual	Manual label print possible via the log list
Automatic (immediately after program run)	Label printing dialogue is displayed for the specified programs after each program run.

The number of labels to be printed can be set in the label printing dialog. The storage period can also be set for successfully completed reprocessing programs.

The last storage time set during label printing is taken over individually for each program as a presetting for the next label printing.

Administrative settings

To make administrative settings, such as changes to the user administration, you must log in as an administrator or a service technician, see Logging on user role [▸ Page 71].

User administration

An individual ID and user PIN can be issued to every user to facilitate reliable traceability via the approval process after the end of a sterilization program. With the user PIN, the user can authenticate himself before the batch is approved, see Authentication [▸ Page 72].

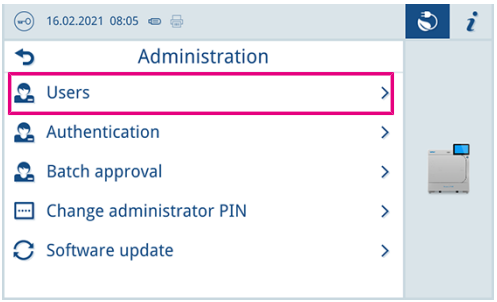
Only created users are authorised to approve and can approve a batch with their user PIN, see Batch approval [▸ Page 73].

In the **`Settings`** > **`Administration`** you can create or edit users.

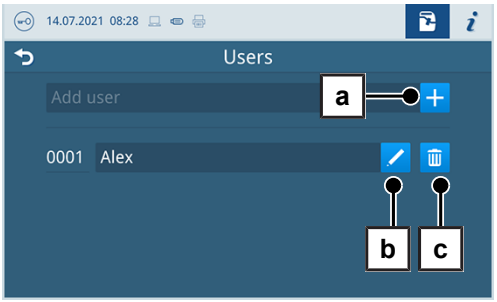
The following must be fulfilled or present:

✓ The logged-in user role is: administrator or service technician.

1. Select the **`Users`** menu.

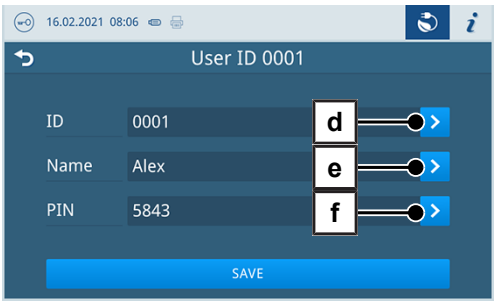


2. Press the plus button (pos. a) to create a new user.



3. Edit (pos. b) or delete (pos. c) the user using the buttons next to the user name.

4. Press the buttons with the arrow to change the ID (pos. d), the user name (pos. e) or the PIN (pos. f).



5. Confirm the changes with **OK** and accept the changes with **SAVE**.

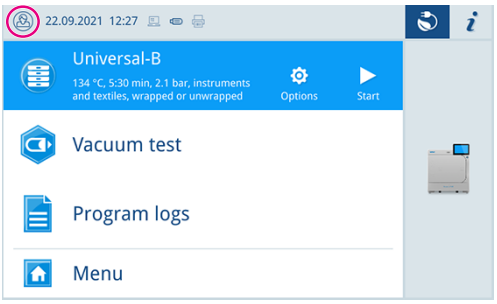
PLEASE NOTE

You can determine the necessity of user authentication via a PIN in the `Authentication` menu.

Logging on user role

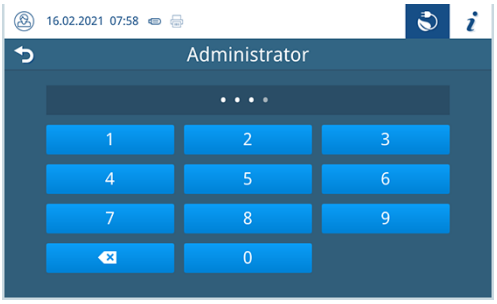
To log on a user role, proceed as follows:

1. Press the user role button.



2. Select the desired role, e.g. administrator.

3. Enter the associated PIN.



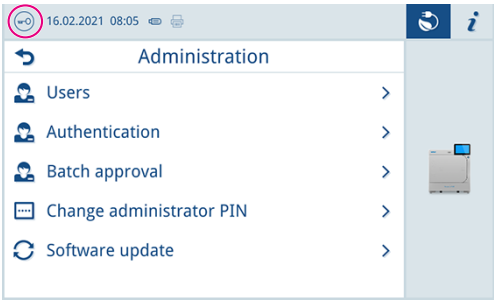
➥ The symbol of the user role button changes.

➥ Further setting options are now available in the menu.

Logging off a user role

In order to log off a user role, proceed as follows:

1. Press the user role button.



2. Press **LOGOUT**.

➥ The symbol of the user role button changes.

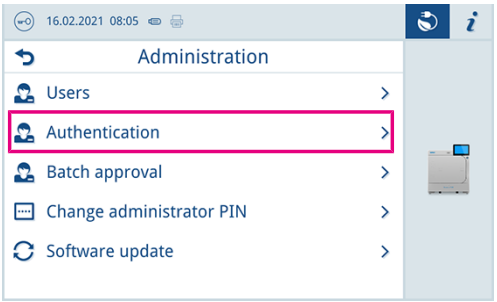
Authentication

In the **Settings** > **Administration** menu, you can activate authentication (PIN entry) for the start or end of the program.

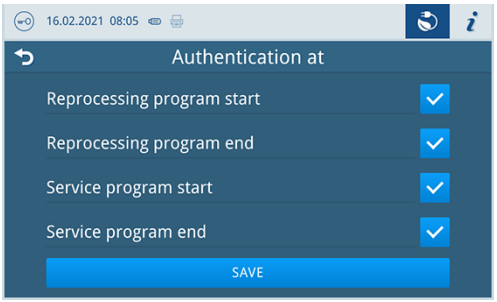
The following must be fulfilled or present:

✓ The logged-in user role is: administrator or service technician.

1. Select the **Authentication** menu.



2. Activate or deactivate the desired setting by selecting or deselecting it.



3. Press **SAVE** to accept the changes.

The following settings are possible:

Designation	Description
Reprocessing program start	PIN entry required to start a program
Reprocessing program end	PIN entry required to open a door
Service program start	PIN entry required to start a service program
Service program end	PIN entry required to open door after a service program

PLEASE NOTE

All options are disabled in the delivery state.

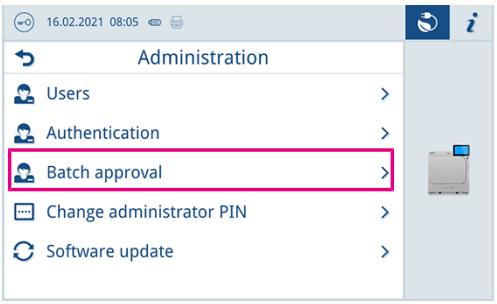
Batch approval

In the **Settings** > **Administration** menu you can activate the batch approval and the indicator assessment.

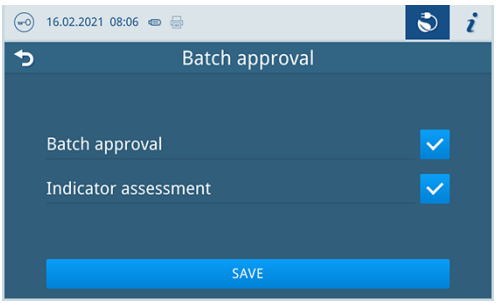
The following must be fulfilled or present:

✓ The logged-in user role is: administrator or service technician.

1. Select the **Batch approval** menu.



2. Activate or deactivate the desired setting by selecting or deselecting it.



3. Press **SAVE** to accept the changes.

The following settings are possible:

Log type	Description
Batch approval	Batch approval after successful program end
Indicator assessment	Indicator assessment after successful program end

Administrator PIN

You can change the administrator PIN in the **Settings** > **Change administrator PIN** menu.

The administrator PIN (default: 1000) can be edited like every other user PIN and should be changed after delivery.

Software update

In the **Settings** > **Administration** menu, you can perform a software version update.

NOTICE

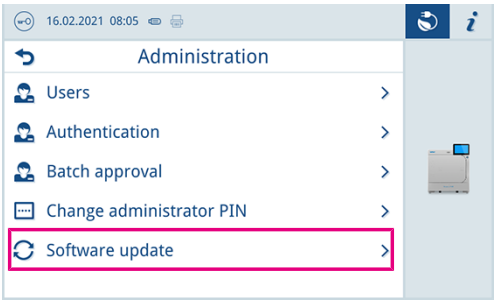
During a software update, all program logs are deleted.

- Check whether all required logs have been output to an output medium.

The following must be fulfilled or present:

- ✓ The logged-in user role is: administrator or service technician.
- ✓ A USB stick in FAT 32 format with installation data.
- ✓ All required logs have been output.

1. Select the **Software update** menu.



2. Insert a USB stick with the installation data into any USB port.
3. Press **NEXT** to perform the software update.

   ↪ During the software update, the device independently performs one or more restarts.

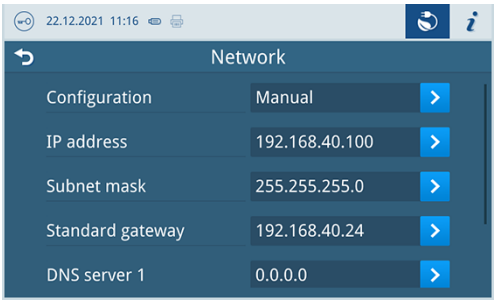
Network

In the **Settings** > **Network** menu, you can select an automatic configuration via DHCP or enter the required address details manually.

The following must be fulfilled or present:

- ✓ The logged-in user role is: administrator or service technician.

1. Press the button with the arrow to make changes.



2. Press **SAVE** to accept the changes.

13 Maintenance

PLEASE NOTE

The maintenance work described below can be performed by the user as part of in-house maintenance.

All maintenance activities beyond this may only be carried out by an authorised technician.

Servicing intervals

Interval	Measure	Device component
Daily	Check for soiling, deposits or damage	Sterilization chamber including door seal and chamber seal face, door lock, mount for the load
	Check the operating media - electricity, water, wastewater	Operating media
	Check the documentation media - printer, network, USB	Documentation media
Weekly	Cleaning	All device components
	Vacuum test (in the morning before starting work when the device is cold and dry)	Vacuum system
After 2 months	Checking and oiling the door lock	Door mechanism
Annually	Clean the sieve	Feed water tank
After 1000 cycles	Replace the dust filter	Behind the service hatch
After 24 months or 4000 cycles	Maintenance	By the authorised customer services working in accordance with the maintenance instructions
As required	Cleaning the surfaces	Housing parts
	Clean or replace the suction filter **PLEASE NOTE:** Only relevant for installation of a filling pump	Suction filter

Checking and oiling the door lock

NOTICE

Wear of the door lock

Only use MELAG oil.

Check and oil the door lock every two months as follows:

1. Clean the locking spindle and nut with a non-fuzzing cloth.
2. Insert the check gauge into the door lock nut as far as it will go and turn it 180°. If this is not possible or resistance can be felt, the door lock nut is worn. Have the door lock nut replaced by an authorised technician.
3. Put two drops of oil in the door lock nut.

   ↪ The oil will be distributed automatically by closing the door.

Changing the dust filter

The following must be fulfilled or present:

✓ A new and dry dust filter.

1. Open the service flap.
2. Press down the centre of the grip and pull out the dust filter.

3. Insert the new dust filter until it snaps into place.
   The latch nose of the grip must point upwards.
4. Close the service flap.

Cleaning

NOTICE

Inappropriately performed cleaning can lead to the scratching of and damage to surfaces and the development of leaks in sealing surfaces.

This also favours the development of soiling deposits and ▸corrosion in the ▸sterilization chamber.

- Comply with all information regarding cleaning of the part affected.
- Do not use any hard objects for cleaning such as a metal saucepan cleaner or a steel brush.

Sterilization chamber, door seal, mount, trays

To maintain the value of your device and to avoid persistent contamination and deposits, MELAG recommends weekly cleaning of the surfaces.

PLEASE NOTE: Also follow the additional application instructions for Chamber Protect or, if not available, of the liquid cleaner or spirit.

The following must be fulfilled or present:

✓ Chamber Protect (if not available: neutral liquid cleaner or spirits)

✓ The door is open.

✓ The device has been switched off.

✓ The device has been completely cooled.

✓ Trays or sterile containers and the associated mount have been removed from the sterilization chamber.

1. Apply the cleaning agent on a lint-free cloth.
2. Use the lint-free cloth to spread the cleaning agent uniformly on the surfaces to be cleaned.
   PLEASE NOTE: You should not allow cleaning fluid to enter the piping coming from the sterilization chamber.
3. Allow the cleaning fluid to act and evaporate for a sufficient time. This may take a few minutes.
4. Wet a new lint-free cloth with plenty of demineralised water.
5. Wipe the cleaned surfaces thoroughly to remove cleaning residues. Repeat this process as necessary after wringing out the cloth.
   NOTICE! Residues of cleaning agents can ignite or cause deposits on the instruments.
6. Allow the cleaned surfaces to dry completely. This may take a few minutes.
7. Wipe the cleaned surfaces with a dry, lint-free microfibre cloth.

Housing parts

Where necessary, clean the housing parts with a neutral fluid cleaner or spirit.

Comply with the following specifications when disinfecting the housing parts:

- Use wipe disinfectants and not spray disinfectants. This prevents disinfectant from getting into inaccessible places or ventilation slots.
- Only use alcohol-based surface disinfectants (ethanol or isopropanol) or alcohol-free disinfectants based on quaternary ammonium compounds.
- Do not use disinfectants containing secondary and tertiary alkylamines or butanone.

Feed water tank

Drain the feed water tank

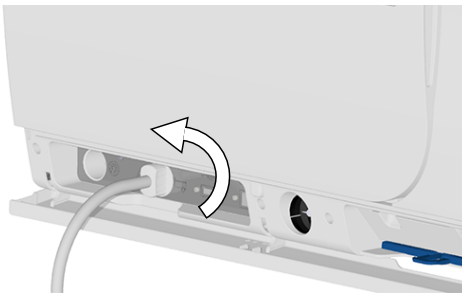
The following must be fulfilled or present:

✓ A collection container with at least 5 l capacity

✓ A drain hose (included in the scope of delivery).

✓ The device is switched off and has cooled down completely.

1. Open the service hatch.
2. Place the collection container in front of the device and place the end of the drain hose in the collection container.
3. Fit the other end of the hose onto the drain valve of the feed water tank until it noticeably latches into position.
   To do this, the valve must be in a horizontal position.
4. Open the drain valve by turning it, together with the drain hose, by a 1/4 turn in the anti-clockwise direction.



5. Drain the water into the collection container.
   PLEASE NOTE: It is advisable to lee the drain hose connected until after the cleaning so that any cleaning fluid residues can be flushed out.

Cleaning the feed water tank

PLEASE NOTE

The cover of the feed water tank is engaged.

- Press the cover backwards before lifting it.

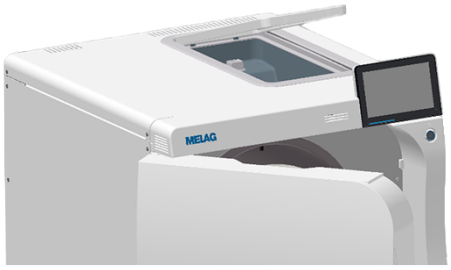
The following must be fulfilled or present:

✓ Solvent-free, non-alkaline cleaning agent (e.g. washing-up liquid).

✓ The device is switched off and has cooled down completely.

✓ The tank is completely empty.

1. Open the cover cap on the top of the device.
   If the cover is difficult to open, let the device cool down.



2. Check the tank for contamination and, if necessary, clean it with a sponge and solvent-free, non-alkaline cleaner (e.g. washing-up liquid).
3. Rinse any cleaning agent residue from the tank with demineralised water.
4. **CAUTION! Danger of burns.** Fold up the heat exchanger.

5. Pull the tank filter out of the bottom of the feed water tank.

6. Clean the tank filter under running water or with the MELAjet spray pistol.
7. Check the cleaning result against the light.
8. Reinsert the tank filter.
9. Reinsert the tank lid correctly and close it.
10. To remove the drain hose after cleaning the feed water tank, turn the drain valve back to the horizontal position.
11. Close the service hatch.

Maintenance

NOTICE

Continuing operation beyond the maintenance interval can result in malfunctions in the device!

- Maintenance should only be performed by trained and authorised technicians.
- Maintain the specified maintenance intervals.

Regular maintenance is vital to ensure reliable operation and value retention of the device. All function and safety-relevant components and electrical units must be checked during maintenance and replaced where necessary. Maintenance must be performed in accordance with the pertinent maintenance instructions of the device.

Maintenance work is to be performed regularly after 4000 program cycles but must be performed after 24 months. The steam sterilizer will issue a maintenance message at the relevant time.

Carry out maintenance with an original maintenance set prepared by MELAG. Only original MELAG spare parts may be used.

14 Pause times

Duration of the operating pause

Duration of the operating pause	Measure
Short pauses between two sterilization processes	• Keep the door closed to save energy • Set Energy-saving as required, see Energy-saving [▸ Page 67]
Pauses which last longer than an hour	• Switch off device
Longer pauses e.g. over night or the weekend	• Leave the door ajar to prevent premature wear and the sticking of the door seal • Switch off device • If present, shut off the water inflow of the water treatment unit
Longer than two weeks	• Perform the **Draining** service program, see Service programs [▸ Page 62] • Perform a **Vacuum test** • After a successful vacuum test, perform an empty sterilization in a reprocessing program

Decommissioning

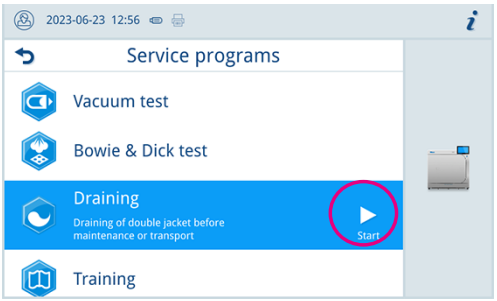
When decommissioning the device for a long pause (e.g. due to holiday), proceed as follows:

1. Empty the double jacket steam generator, see Draining [▸ Page 80].
2. Switch on the device at the power switch.
3. Disconnect the power plug from the socket and if necessary, allow the device to cool.
4. Empty the internal storage tank via the drain hose.
5. Shut off if present, the water inflow of the water treatment unit.

Draining

You can drain the water in the double jacket steam generator via the **Draining** program. In order to do so, the device is heated once, building up pressure in the double jacket so that the water can be emptied fully from the double jacket steam generator.

1. Working in the **Service programs** menu, select the **Draining** program and press **Start**.



2. Confirm the dialogue window.

   ➥ The double jacket steam generator is emptied.

3. Confirm the **Draining successful** message.
4. Switch off the device.

Transport

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 carrying system to carry the device.

PLEASE NOTE

Allow ▸authorised technicians only to transport and install the carrying system.

Symbols on the packaging

Indicates the temperature limits to which the device can be safely exposed.

Denotes a device that may break or be damaged if handled carelessly.

Indicates a device that must be protected against moisture.

Indicates the upper limit of humidity to which the device can be safely exposed.

On-site transport

To transport the device within a room or floor, proceed as follows:

1. Decommission the device, see Decommissioning [▸ Page 80].
2. Disconnect the connection hoses connected on the rear of the device.
3. Install the carrying system.

Off-site transport

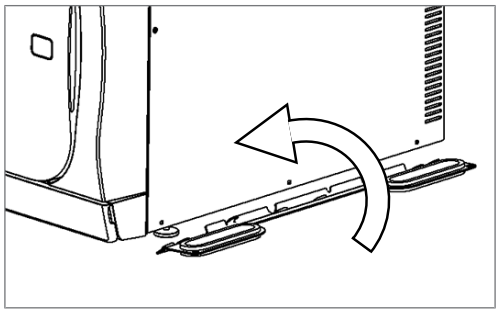
To transport the device over longer distances, to different floors or for shipping, proceed as follows:

1. Decommission the device, see Decommissioning [▸ Page 80].
2. Pack the device so that it is protected from mechanical hazards (e.g. blows) and moisture.
3. Observe the transport and storage conditions, see Technical data [▸ Page 93].

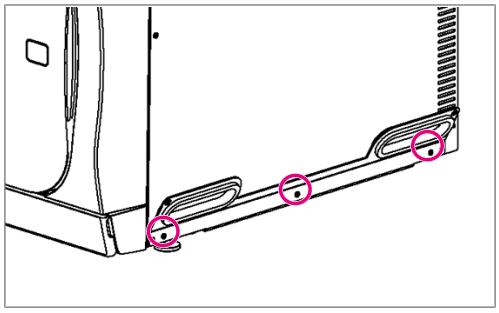
Installing the carrying system

1. Undo the three bottom housing screws.

2. Hook the carrying system up into the baseplate.



3. Secure the carrying system on the device with the three screws.



15 Malfunctions

Not all notifications on the display are malfunction messages. Warnings and malfunction messages are issued on the display with an event number. This number serves identification purposes.

Comply with the following for safe handling:

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.
- The device may only be serviced by ▸authorised technicians.

	Nature of the display notification	Description
	Notifications	Many messages are notifications. Notifications provide you with information and help you to operate the device.
	Warnings	Warnings are displayed when necessary. Warnings contain instructions that help you to ensure smooth operation and to identify undesirable states. Comply with these warnings early in order to avoid malfunctions.
	Malfunction messages	Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after activating the steam sterilizer or during a program run. If a malfunction occurs during a program run, the program will be aborted.

Troubleshooting online

All messages with current descriptions can be found in the Troubleshooting portal on the MELAG website (https://www.melag.com/en/service/troubleshooting).

Before contacting the technical service

Follow the instructions that appear on the device's display that relate to a warning or malfunction message. The following table contains a summary of the most important events. Should you be unable to find the relevant event, or your efforts do not redress the problem, you can contact your stockist or the MELAG customer service. Have the number of your device, the event number and a detailed description of the malfunction to hand so that we can help you.

Malfunction logs

In the **`Logs`** > **`Malfunction logs`** menu, you can view malfunction logs and output them to a USB flash drive.

Warning and malfunction messages

Event	Possible cause	What you can do
10059	The external wastewater container is full.	Empty the external wastewater container before the next program start.
10062	The lack of water in the feed water tank could not be remedied within the monitoring time.	Secure the water supply (main tap) or fill the external storage container if using the filling pump.
10063	The manual feed water supply is activated. The device must be filled with at least 1.5 l of demineralised water.	Supply the device with sufficient demineralised water before starting the program or ensure an automatic water supply via a water treatment unit. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10081	The emptying of the double jacket was skipped regularly by cancelling the drying.	Do not cancel the drying. If this occurs repeatedly, please contact the technical service. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10082	At program start, the counter for the feed water quantity is evaluated. The limit value is exceeded. A program start not possible. The automatic emptying was skipped several times because the drying was ended manually. The program cannot be started until the double jacket has been emptied.	To do this, start the **`Draining`** service program. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10093	At program start, the counter for the rinse value is evaluated. The limit value is exceeded. A program start is not possible. The automatic emptying was skipped several times because the drying was ended manually. The program cannot be started until the double jacket has been emptied.	To do this, start the **`Draining`** service program. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10094	At program start, the system checks whether the vacuum test can be performed successfully at the current ambient temperature. The ambient temperature of the device is very high.	Allow the device to cool down. Observe the installation conditions and ensure sufficient ventilation of the device.
10098	A supply voltage failure was detected during the program run.	Connect the device to a specially fused power supply to which no other electrical device is connected. Check the mains connection cable at the rear of the device to ensure that it is firmly seated and put on the safety bracket.
10099	A supply voltage failure was detected during the program run.	Connect the device to a specially fused power supply to which no other electrical device is connected. Check the mains connection cable at the rear of the device to ensure that it is firmly seated and put on the safety bracket.

Event	Possible cause	What you can do
10101	Short-term wastewater blockage. The float switch (S13) in the overflow funnel detected a short-term impermissible water level, which indicates a blockage in the wastewater system.	Check whether the outlet hose is bent or the shut-off valve is possibly closed. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10102	Long-term wastewater blockage. The float switch (S13) in the overflow funnel detected a continuous impermissible water level, which indicates a blockage in the wastewater system.	Check the wastewater hose for kinks or, if applicable, a closed shut-off.
10109	Door process. The automatic opening of the door is disturbed. The limit current for the door motor was exceeded during opening. The door locking mechanism or the door motor is possibly blocked.	Allow the device to cool down and open the door using the tool behind the service hatch. Ensure regular oil maintenance of the door spindle and door nut. If this occurs repeatedly, please contact the technical service.
10117	Door process. The automatic opening of the door is disturbed. The monitoring time on opening the door has expired and both the door contact switch K1 and K2 signal a closed door.	Allow the device to cool down and open the door using the tool behind the service hatch. Ensure regular oil maintenance of the door spindle and door nut. If this occurs repeatedly, please contact the technical service.
10120	Door process. The automatic opening of the door is disturbed. The limit current for the door motor is exceeded when opening from the steam-tight status (Z4) to the vapour-tight status (Z3). The door may be blocked.	Allow the device to cool down and open the door using the tool behind the service hatch. Ensure regular oil maintenance of the door spindle and door nut. If this occurs repeatedly, please contact the technical service.
10130	Double jacket feeding. The maximum feed quantity or feed duration when feeding feed water into the double jacket has been exceeded.	Remove and clean the filter in the feed water tank.
10134	Vacuum system cooling. The temperature at the cooler cannot be lowered sufficiently within the monitoring time. The cooling system may be faulty.	Allow the device to cool down. Observe the installation conditions and ensure sufficient ventilation of the device.
10137	Evacuation/test during vacuum test. The maximum permissible pressure was exceeded in the waiting or test phase of the vacuum test.	Allow the device to cool down. Check the door seal for visible defects. Clean the door seal with a damp cloth.

Event	Possible cause	What you can do
10145	Monitoring time only runs when evacuation in negative pressure is started. The malfunction is triggered if evacuation cannot be completed within the monitoring time.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or the like underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.
10165	Double jacket emptying. The maximum runtime for emptying has expired.	Allow the device to cool down. Observe the installation conditions and ensure sufficient ventilation of the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10169	Abort routine. The abort routine was terminated with an emergency drain, so there may still be hot condensate in the chamber.	Please contact technical services. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10179	Chamber pressure release. The pressure release valve had to be opened several times before a pressure drop occurred.	Check the chamber to see if any debris from loading or packaging is clogging the fittings. Remove and check the coarse filter at the back bottom of the chamber for blockages. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10184	During the program run, the maximum filling level of the external wastewater container was reached during manual water disposal.	Empty the wastewater container before starting a new program. The wastewater container can still receive the wastewater from the currently running program.
10185	The external wastewater container is full.	The wastewater container must be empty for the **`Draining`** program. Empty the external wastewater container.
10186	With a manual water supply, the filling level of the feed water tank is undershot.	Replenish the feed water tank.
10218	An actuator/sensor error has occurred.	In case of malfunction (open load) at ACOUT 1 and 2: Press the reset button of the overheating protection behind the service flap. If the error persists, please contact the technical service and state which sensor/actuator is affected by the malfunction.
10224	There is not enough feed water in the tank.	Fill the feed water tank up to the maximum mark (MAX) of the level increase before the next program start.

Event	Possible cause	What you can do
10226	There is not enough feed water in the tank.	Fill the feed water tank up to the maximum mark (MAX) of the level increase.
10241	Pressure-controlled evacuation. This is triggered when, in a gradient-monitored process, the gradient falls below the termination gradient, resulting in termination of the program. The vacuum performance is insufficient.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.
10242	This is triggered when, in a gradient-monitored process, the gradient falls below the termination gradient, resulting in termination of the program. The vacuum performance is insufficient.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.
10256	Monitor pressure gradient during evacuation. The pressure change at pressure sensor S1 is too low during evacuation.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.

Event	Possible cause	What you can do
10257	Monitor pressure gradient during evacuation in the vacuum test. The pressure change at pressure sensor S1 is too low during evacuation.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.
10266	Pressure-controlled evacuation. The pressure change is less than expected; the vacuum performance is decreasing.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage. This is only a warning. The reprocessing result is not affected. You can continue to use the device.

Event	Possible cause	What you can do
10267	Clock-controlled evacuation. The pressure change is less than expected; the vacuum performance is decreasing.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10268	Steam intake. The pressure change is less than expected; the steam intake performance is decreasing.	Check whether the permissible load quantities of the device have been observed. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10269	Ventilation. The volume flow during ventilation is lower than expected.	Check the sterile filter behind the service flap. Replace it in case of heavy soiling or blockage. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10270	Pressure release. The pressure change is less than expected; the pressure release speed is decreasing.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage. This is only a warning. The reprocessing result is not affected. You can continue to use the device.

Event	Possible cause	What you can do
10271	Conductivity monitoring. The warning value for poor conductivity was exceeded. A program start is still possible.	Have a regenerated cartridge ready for your water treatment unit. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10273	Conductivity monitoring. The limit value for insufficient conductivity was exceeded in the program start. A program start is not possible.	Ensure the supply of demineralized water of suitable quality. Insert a regenerated cartridge into your water treatment unit.
10275	This is triggered when the measuring turbine (S9) of the feed pump (P1) indicates that the volume flow is too low.	Please remove and clean the filter in the storage tank.
10283	Pressure-controlled evacuation. This is triggered when, in a gradient-monitored process, the gradient falls below the termination gradient, resulting in termination of the program. The vacuum performance is insufficient.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check whether the permissible load quantities of the device have been observed. Check the pressure release filter in the chamber for blockage.
10286	Pressure-controlled evacuation. This is triggered when, in a gradient-monitored process, the gradient falls below the termination gradient, resulting in termination of the program. The vacuum performance is insufficient.	Check the dust filter for contamination and replace it if necessary. The intake area of the cooling system under the device must be free. Check whether paper or similar underneath the device is blocking the air flow. Ensure that the device has sufficient ventilation so that the heat can dissipate freely. Mounting the device is not recommended. Observe the setup conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible load quantities. Check the pressure release filter in the chamber for blockage.
11000	The log output was aborted due to a connection error.	Please check the connection of the device to the practice network via the network interface on the back of the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.

Event	Possible cause	What you can do
11001	Several USB sticks are directly connected to the device	Please connect only one USB stick to the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11002	The USB stick is not plugged in although write access to the USB stick has been requested.	Insert a USB stick behind the service flap. If necessary, use the USB port on the rear of the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11003	The USB flash drive does not have enough free space to store the required log data.	Backup the log data located on the USB stick onto the practice network. Then delete the files from the USB stick to create storage space for the new logs. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11004	The writing of the log data on the USB stick has failed.	Insert a USB stick behind the service flap. If necessary, use the USB port on the rear of the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11006	The maximum number of program logs not output has been reached. The oldest log will be overwritten during the next program run.	Output the internally stored logs to a USB stick or to your practice network. The logs can also be output automatically. You have to configure this in the Settings menu. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11007	The printer cover is open while a print job was being sent.	Close the printer cover. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11008	The paper of the printer is used up.	Place a new roll of labels in the printer. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11009	A printer is configured but not connected.	Please connect the printer via the network interface on the back of the device. Please restart the printer. First start the device and then the printer. This is only a warning. The reprocessing result is not affected. You can continue to use the device.

Event	Possible cause	What you can do
11011	Several printers are directly connected to the device.	Please connect only one printer to the device. Please restart the printer. First start the device and then the printer. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11012	The paper of the printer will be used up soon.	Please have a new roll ready. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11013	General printer error	Please restart the printer. First start the device and then the printer. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
11100	The log output was aborted due to a connection error.	Please check the connection of the device to the practice network via the network interface on the back of the device. This is only a warning. The reprocessing result is not affected. You can continue to use the device.

16 Technical data

Device type	**Vacuclave 550**
Device dimensions (H x W x D)	65.0 x 63.6 x 71.5 cm
Empty weight	98 kg
Operating weight	127 kg
Floor loading (normal operation)	2.71 kN/m²
Floor load (hydraulic pressure test)	3.53 kN/m²
Sterilization chamber	
Chamber diameter	38 cm
Chamber depth	45 cm
Chamber volume/steam generator	53 l/12.5 l
Electrical connection	
Power supply	220-230 V 50/60 Hz
Max. voltage range	198-255 V
Max. power consumption in operation	3400 W (15 A operation) 2700 W (13 A operation)
Building fuse protection	16 A, RCD with rated residual current = 30 mA (15 A operation) 13 A, RCD with rated residual current = 30 mA (13 A operation)
Length of the power cable	2 m
Overvoltage category	transient overvoltages up to the values of overvoltage category II
Degree of contamination (in accordance with EN 61010)	2
Ambient conditions	
Installation location	interior of a building
Installation surface	level, horizontal and waterproof/sealed
Noise emission LP(a) in 1 m distance	64 dB(A)
Heat emission per hour (with maximum load)	2.25 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)
Degree of protection (in accordance with IEC 60529)	IP20
Transport and storage conditions	temperature: -18 to +50 °C, air humidity: < 80 %
Max. altitude	3000 m
Feed water	
Max. water consumption	5.5 l/cycle
Average water consumption	2 l/cycle
Max. water temperature	35 °C (ideal 15-20 °C)
Min. flow pressure	0.5 bar at 1.0 l/min
Min. static water pressure	1 bar
Max static water pressure	10 bar
Water quality	distilled or demineralised water in accordance with EN 13060, Appendix C
Cold water (for connection of the water treatment unit)	
Min. static water pressure[2)]	2 bar
Max static water pressure	10 bar
Water quality	potable water

[2)] When using a MELAdem 47, the minimum static water pressure is 3.0 bar. If less than 3.0 bar, the pressure increase pump must be used on the MELAdem 47.

Wastewater	
Max. throughflow volume	2 l/min
Max water temperature	90 °C for 30 s, max. 98 °C for 1 s
Working and operating pressures	
Permissible operating pressure chamber	-1 bar to + 3 bar relative
Permissible operating pressure jacket	-1 bar to + 3 bar relative
Working pressure chamber/jacket	2.2 bar relative

17 Accessories and spare parts

You can obtain the specified articles and an overview of further accessories from your stockist.

Accessories for the device

Category	Article	Art. no.
Mounts	Basic mount for 9 tray levels	ME22486
	Loading slide for up to 10 MELAstore Box 100	ME22606
	Comfort mount for 8 tray levels	ME22485
Trays	Tray, short, standard (29 x 19 cm)	ME00280
	Tray, long standard (42 x 19 cm)	ME00230
	Tray, long (41 x 29 cm)	ME00550
Sterilization container with disposable paper filter according to EN 868-8	15K (18 x 12 x 4.5 cm)	ME01151
	15M (35 x 12 x 4.5 cm)	ME01152
	15G (35 x 12 x 8 cm)	ME01153
	17K (20 x 14 x 5 cm)	ME01171
	17M (41 x 14 x 5 cm)	ME01172
	17G (41 x 14 x 9 cm)	ME01173
	23M (42 x 16 x 6 cm)	ME01231
	23G (42 x 16 x 12 cm)	ME01232
	28M (32 x 16 x 6 cm)	ME01284
	28G (32 x 16 x 12 cm)	ME01285
MELAstore System	MELAstore Tray 50 (18 x 11.8 x 3 cm)	ME01180
	MELAstore Tray 100 (27.5 x 17.6 x 3 cm)	ME01181
	MELAstore Tray 200 (27.5 x 17.6 x 4.3 cm)	ME01182
	MELAstore Box 100 (31.2 x 19 x 4.6 cm)	ME01191
	MELAstore Box 200 (31.2 x 19 x 6.5 cm)	ME01192
Films	MELAfol 501	ME00501
	MELAfol 502	ME00502
	MELAfol 751	ME00751
	MELAfol 752	ME00752
	MELAfol 1001	ME01001
	MELAfol 1002	ME01002
	MELAfol 1502	ME01502
	MELAfol 2002	ME02002
	MELAfol 2051	ME02051
	MELAfol 2502	ME02502
Package holder	Package holder, short, (18.4 x 28 x 8.7 cm)	ME22410
	Package holder, long, (18.4 x 37 x 8.7 cm)	ME22420

General accessories

Category	Article	Art. no.
Test body system	MELAcontrol Helix	ME01080
	MELAcontrol Pro	ME01075
	MELAcontrol Pro refill pack (250 indicator strips)	ME01076
Water treatment	MELAdem 47 reverse osmosis unit	ME01047
	MELAdem 53 C with 2 containers (15 l each)/MELAdem 53 with 2 containers (20 l each)	ME01036/ME01038
Water supply	Filling pump	ME65010
	Pressure increase pump for MELAdem 47	ME22500
Water disposal	External wastewater container	ME65020
For the documentation	USB flash drive	ME19901
	MELAprint 60 label printer	ME01160
	Network cable (1:1), 5 m	ME15811
	Network cable (cross-over), 2 m	ME15813
	Network cable (cross-over), 5 m	ME15814
	Network cable (cross-over), 10 m	ME15815
	Fast Ethernet Switch	ME76600
Other	Water stop (leakage water detector with shut-off valve and probe)	ME01056
	Surface-mounted siphon	ME37410
	Chamber Protect chamber cleaning set	ME01081

Spare parts

Category	Article	Art. no.
Device	MELAG oil for door lock nut	ME27515
	Test gauge TR20 for door lock nut	ME27521
	Sterile filter	ME20160
	Tank filter	ME21358
	Dust filter	ME82260
	Tank cover	ME21985
	Carrying system	ME80025
	Power cable with hot device plug	ME21301

18 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

Nominal value tolerances

Step			Universal-B	Prion-B	Gentle-B	Quick-S	Program phase
	P [$mbar_a$]	T [°C]		Pressure (P) / Temperature (T) tolerance			
SP-S	--	--	--	--	--	--	Program start
SV1	c 500	--	x	x	x	x	Pre-evacuation
SK13	c 1500	--	x	x	x	x	Steam intake sterilization chamber
SH1	c 1500	--	x	x	x	x	Hold conditioning
SF2	c 500	--	x	x	x	x	Fractionation evacuation
SK11	c 1900	--	+100/-20	+100/-20	c 1800	c 1800	Conditioning steam intake
SK12	c 1900	--	+100/ -500	+100/ -500	c 1800	◀	Hold conditioning
SK13	c 1300	--	+20/-50	+20/-50	◀	◀	Conditioning pressure release
SF12	c 300	--	+30/-30	+30/-30	◀	c 225	Fractionation evacuation
SF13	c 2100	--	+100/-20	+100/-20	c 1800	--	Fractionation steam intake
SF21	c 1300	--	+20/-50	+20/-50	◀	◀	Fractionation pressure release
SF22	c 200	--	+30/-30	+30/-30	◀	c 150	Fractionation evacuation
SF23	c 2100	--	+100/-20	+100/-20	c 1800	x	Fractionation steam intake
SF31	c 1300	--	+20/-50	+20/-50	◀	x	Fractionation pressure release
SF32	c 500	--	+30/-30	+30/-30	◀	x	Fractionation evacuation

Step			Universal-B	Prion-B	Gentle-B	Quick-S	Program phase
	P [mbar$_a$]	T [°C]		Pressure (P) / Temperature (T) tolerance			
SF33	c 2000	--	+100/-20	+100/-20	c 1500	◄	Fractionation steam intake
SH1	c 2950	--	+60/-60	+60/-60	c 1850	◄	Hold steam intake
SH2	c 2950	--	+60/-60	+60/-60	c 1950	◄	Hold control
SS1	c 3031	c 134	+60/-60	+60/-60	c 2080	◄	Sterilization entry
SS2	c 3170	c 135.3	+60/-60	+60/-60	c 2150	◄	Sterilization
SA2	c 1943	--	+60/-60	+60/-60	◄	◄	Pressure release
VAT	c 190	--	+60/-60	+60/-60	x	x	Drying evacuation
TDL	c 741	--	+60/-60	+60/-60	x	x	Compressed air drying
ST12	c 80	--	--	--	--	--	Drying hold
ST13	c 180	--	--	--	--	--	Drying ventilation
ST21	c 80	--	--	--	--	--	Drying evacuation
ST22	c 80	--	--	--	--	--	Drying hold
ST23	c 180	--	--	--	--	--	Drying ventilation
ST31	c 80	--	--	--	--	--	Drying evacuation
ST32	c 80	--	--	--	--	--	Drying hold
SB12	c *)	--	--	--	--	--	Ventilation
SP-E	--	--	x	x	x	x	Program end

Key:

◄ as in the Universal-B

-- not specified

*) Ambient pressure

x Not applicable

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

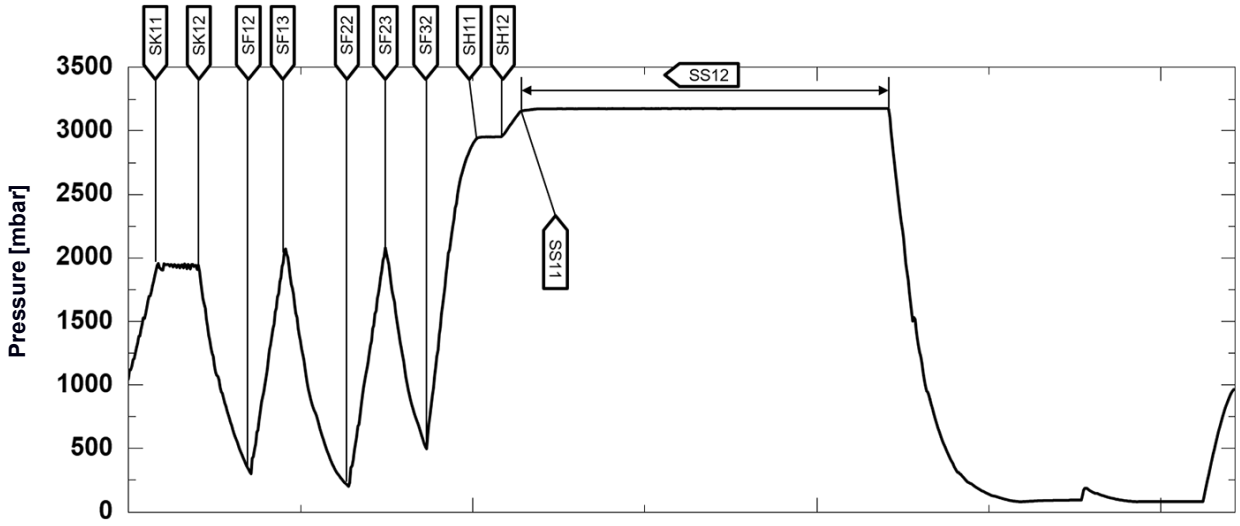
Precision (at 135 °C)	at pure addition of individual errors approx. ± 0.70 K
Precision (at 135 °C)	according to Gauss' law of propagation approx. ± 0.47 K

Entire measuring chain of the pressure measurement

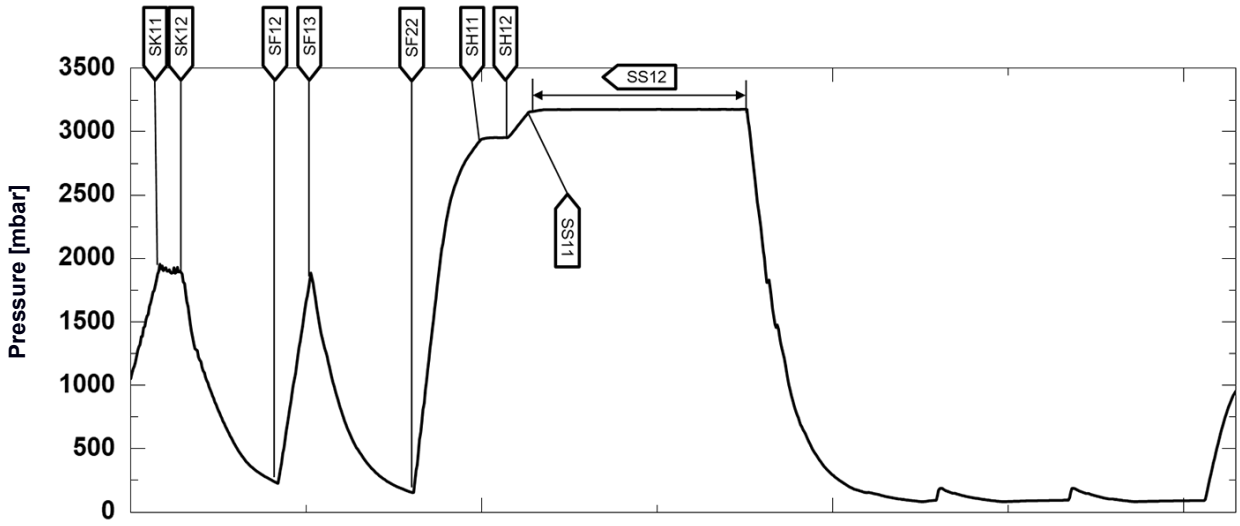
Precision	at pure addition of individual errors	± 0.70 % corresponds to ± 28.0 mbar corresponds to approx. ± 0.30 K steam temperature
Precision	per Gauss' law of propagation	± 0.41 % corresponds to ± 16.5 mbar corresponds to approx. ± 0.18 K steam temperature

Pressure-time chart

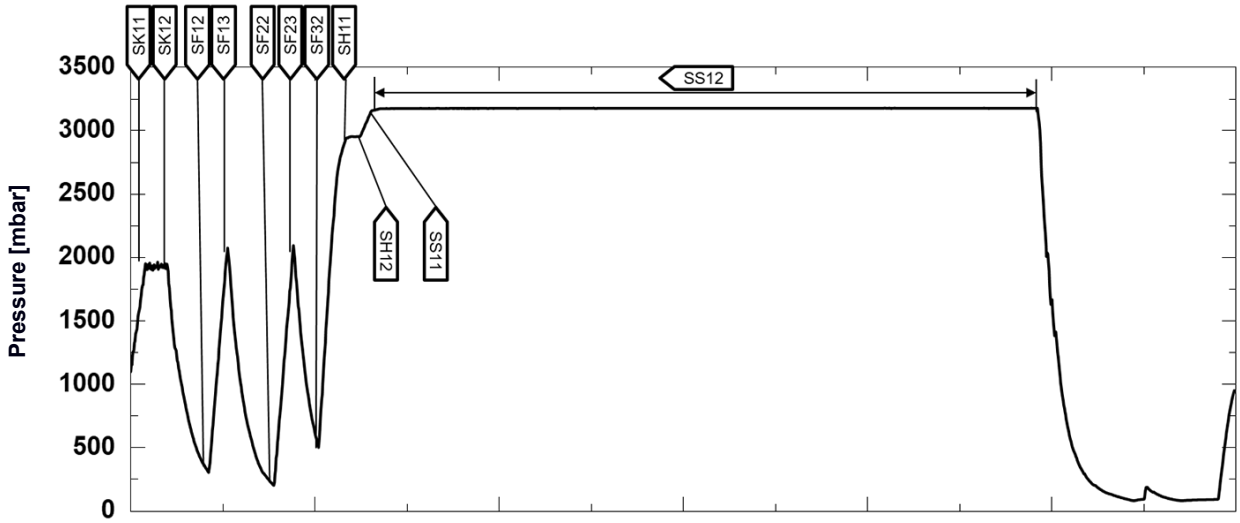
Pressure-time diagram for Universal-B, 134 °C and 2.1 bar



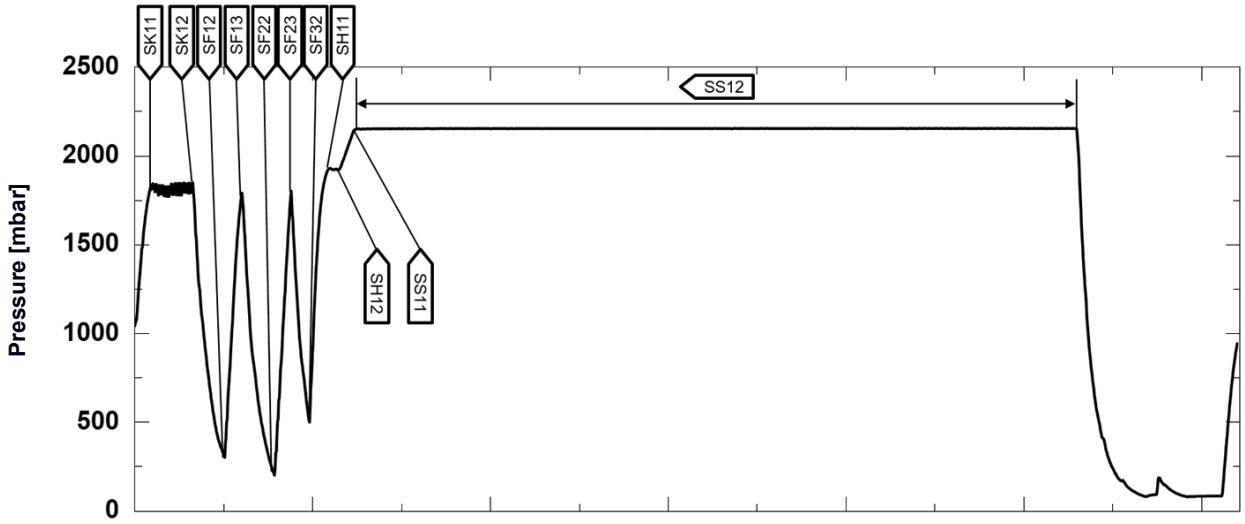
Pressure-time diagram for Quick-S, 134 °C and 2.1 bar



Pressure-time diagram for Prion-B, 134 °C and 2.1 bar



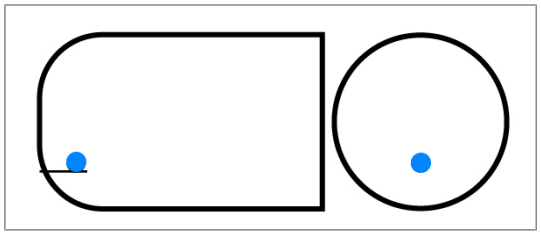
Pressure-time diagram for Gentle-B, 121 °C and 1.1 bar



Empty chamber test

The coldest point in the sterilization chamber during the empty chamber test lies directly on the temperature sensor (see blue dot in the following figure). The temperature in the remaining three area of the sterilization chamber is almost the same all over (0.8 K range).

Schematic side and fore view of the sterilization chamber



Glossary

Air leakage
is a location through which air can pass in and out without this being desired. Verification of the leakage serves to prove that the volume of air ingress in the chamber during the vacuum phase does not exceed a value which would prevent steam penetration of the sterilizer load and that the air leakage does not cause the possible contamination of the sterilizer load during the drying phase.

AKI
AKI is the abbreviation for “Arbeitskreis Instrumentenaufbereitung”

Authorised technician
An authorised technician is a person intensively trained and authorised by MELAG who has sufficient specific device and technical knowledge. to perform maintenance and installation work on MELAG devices. Only they may carry out this work.

Batch
The batch is the composition of items which has been subject to the same reprocessing procedure.

Bowie & Dick test
Steam penetration test with a standard test package; described in EN 285; the test is usually recognised in the large-scale sterilization industry

Competent personnel
Trained personnel in accordance with national specifications for the respective area of application (dentistry, medicine, podiatry, veterinary medicine, cosmetics, piercing, tattoo) with the following contents: knowledge of instruments, hygiene and microbiology, risk assessment and classification of medical devices and instrument reprocessing.

Condensate
Fluid (e.g. water) produced by the cooling of and resultant separation from the vaporous state.

Conductivity
is the ability of a conductive chemical substance or mixture of substances to conduct or transfer energy or other substances or particles in space.

Corrosion
The chemical alteration or destruction of metal materials by water and chemicals

Delay in boiling
This refers to the phenomenon that it is possible under certain circumstances to heat a fluid beyond its boiling point without them boiling. This represents an unstable state; even low-level agitation can produce a large bubble within the shortest period, which expands explosively.

Demineralised water
Water without the minerals usually found in normal spring or tap water; is produced through ion exchange of normal tap water. It is used here as feed water.

DGSV
Abb.: “Deutsche Gesellschaft für Sterilgutverordnung” (German Association for the Sterilized Equipment Ordinance). The DSGV training centres are specified in DIN 58946, part 6 as “Requirements of personnel”.

DGUV Regulation 1
DGUV is the abbreviation for “Deutsche Gesetzliche Unfallversicherung” (German Statutory Accident Insurance). The regulation 1 governs the principles of prevention.

DIN 58946-7
Standard – sterilization - steam steam sterilizers - part 7: Building requirements and requirements placed on the operating agents and the operation of steam sterilizers in the health-care branch

DIN 58953
Standard – sterilization, sterile equipment supply

Distilled water
From the Latin aqua destillata; also referred to as aqua dest; water which to a great extent is free from salts, organic material and micro-organisms, is produced from normal tap water or pre-cleaned water through the process of distillation (evaporation and subsequent condensation). Distilled water is used, for example, as feed water for steam sterilizers.

Dynamic pressure test of the sterilization chamber
Serves to prove that the rate of pressure variations during a sterilization cycle does not exceed a particular value which could result in the damage of the packaging material. [see EN 13060]

Empty chamber test
Test run without a load, performed to assess the performance of a sterilizer without the influence of a load; facilitating verification of the temperatures maintained in comparison to the temperatures set. [see EN 13060]

EN 13060
Standard – small steam sterilizers

EN 867-5
Standard – non-biological systems for use in sterilizers – part 5: The determination of indicator systems and test bodies for the performance inspection of type B and type S small sterilizers.

EN ISO 11140-1
Standard – the sterilization of products for use in medical treatment – chemical indicators – part 1: General requirements

EN ISO 11607-1
Standard - packaging for medical devices to be sterilized in the final packaging - Part 1: Requirements placed on materials, sterile barrier systems and packaging systems

Evacuation
Creation of a vacuum in a vessel

Feed water
Feed water is required to produce steam for sterilization. Guide values for water quality in accordance with EN 285 / EN 13060 – Appendix C

Fractionated vacuum procedure
A technical procedure in steam sterilization; the repeated evacuation of the sterilization chamber in alternation with steam injection.

Load
Products, devices or materials that are reprocessed together in one operating cycle.

Mixed loads
wrapped and unwrapped load within a single batch

Multiple wrapping
e.g. wrapped instruments sealed in a double layer of film or wrapped in film and placed in an additional container or a container wrapped in textiles.

pH Value
The pH value is a measure of the strength of the acid or alkali effect of a watery solution.

Porous
Pervious to liquids and air, e.g. textiles

Porous full load
Serves to prove that the values set at the control satisfy the necessary sterilization conditions in porous loads with the maximum density for whose sterilisation a sterilizer is designed to EN 13060 [see also EN 13060].

Porous partial load
Serves to prove that the values set at the control allow steam to enter the pre-determined test package quickly and uniformly [see also EN 13060]

Pre-heating time
The time required after the steam sterilizer has been switched on / after the start of a sterilization program, to heat the double jacket steam generator before the sterilization procedure starts. The duration is dependent on temperature at which sterilization takes place.

Process evaluation system
Also known as the self-monitoring system – this observes itself and compares the various sensors during a current program.

Product with narrow lumen
An article open on one side to which the following applies: 1 ≤ L/D ≤ 750 and L ≤ 1500 mm or an article with an opening on both sides which is: 2 ≤ L/D ≤ 1500 and L ≤ 3000 mm and which does not correspond to the hollow body B L…hollow body length D…hollow body diameter [see EN 13060]

Qualified electrician
Person with suitable technical training, knowledge and experience so that he or she can recognise and avoid hazards that can be caused by electricity [see IEC 60050 or for Germany VDE 0105-100].

Reprocessing
Reprocessing is a measure to prepare a new or used healthcare device for its intended purpose. Reprocessing includes cleaning, disinfection, sterilization and similar procedures.

RKI
Abbreviation for “Robert Koch Institute”. It is one of the most important bodies for the safeguarding of public health in Germany.

Simple hollow bodies
An article open on one side to which the following applies: 1 ≤ L/D ≤ 5 and D ≥ 5 mm or an article with an opening on both sides which is: 2 ≤ L/D ≤ 10 and D ≥ 5 L…hollow body article length D… hollow body article diameter [see EN 13060]

Single wrapping
Wrapped once e.g. instruments sealed in foil – in opposition to: Multiple wrapping

Soft sterilization packaging
e.g. a paper bag or transparent sterilization packaging

Solid
Without hollows or gaps, solid, compact, closed

Solid load
Serves to prove that the necessary sterilization conditions have been reached within the entire load with the values set in the control. The load must represent the largest weight of solid instruments for whose sterilization a sterilizer is designed to EN 13060. [see EN 13060]

Sterile barrier system
A closed minimum packaging which prevents the entrance of micro-organisms e.g. through sealing pouches, sealed and re-usable containers and folded sterilization towels etc.

Sterile material
Also referred to as a batch: a load which has already been sterilized, i.e. is sterile

Sterilization chamber
The interior of a sterilizer accommodates the load

Vacuum
In common parlance, an area devoid of all materialIn the technical sense: volumes with a reduced gas pressure (at least air pressure)

MELAG
competence in hygiene

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:	Vacuclave® 550
Type of device:	Steam sterilizer
Classification:	Class IIa
Device type acc. to EN 13060:	Type B

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

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

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 EN ISO 17664-1.

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

- **MELA*control*® and MELA*control*® PRO**

Berlin, 07.09.2023

Dr. Steffen Gebauer
(Management)

Quality - made in Germany

MELAG Medizintechnik GmbH & Co. KG

Geneststraße 6-10
10829 Berlin
Germany

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

Original instructions

Your stockist

BA_VC550_EN.pdf | Rev. 6 - 23/2543 | Modification date: 2023-09-15