User Manual

Vacuclave® 550

Steam sterilizer

from software version 4.0.1

EN

CE 0197

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.

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	Explanation
⚠	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
❗	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
☞	Draws your attention to important information.

Formatting rules

Example	Explanation
`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.

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 have been trained in the operation and safe handling of the device.

■ The operator must ensure that the users are regularly trained in the operation and safe handling of the device.

Setup, installation and commissioning

■ Check the device after unpacking for any damage suffered during transport.

■ The device should only be setup, installed and commissioned by MELAG authorised persons.

■ 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.

■ The device is not suitable for operation in explosive atmospheres.

■ Install and operate the device in a frost-free environment.

■ The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

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 unplug by pulling on the power cable. Always take a grip on the plug.

■ 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.

Spring safety valve

■ The free movement of the valve rod must be guaranteed. For example, the spring safety valve must not be taped or blocked. Install the device in such a way that the proper functioning of the spring safety valve is guaranteed.

Reprocessing and sterilization

■ Follow the manufacturer's instructions of your textile articles and instruments regarding their reprocessing and sterilization.

■ Comply with the relevant standards and directives applicable to the reprocessing and sterilization of textiles and instruments (in Germany e.g. from the ▶RKI and ▶DGSV).

Normal operation

- The door area and the area of the cooler and the safety valves at the rear of the device can become hot while the device is switched on and remain hot for a long time after it is switched 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.

Program abort

- Please observe that opening the door following a program abort can lead to hot steam leaving the sterilization chamber.

- Observe the instructions shown on the display of the device. Sterilize the affected ▸load after re-wrapping.

Maintenance

- Maintenance should only be performed by ▸authorised technicians.

- Maintain the specified servicing intervals.

- Only original MELAG spare parts may be used.

Repair

- 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.

Malfunctions

- 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.

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 product (e.g. death or serious deterioration in the state of health of a patient) which were presumably caused by the product, 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 steam sterilizer is mainly intended for use in the medical field, e.g. in physician and dental practices. The steam sterilizer is a small steam sterilizer according to ▶EN 13060 and works with the fractionated vacuum method, which ensures 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 the patient's environment and is not intended for the sterilization of liquids.

⚠️ **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/penetration of the load with saturated steam.

The steam sterilizer uses the 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 sterilization chamber from overheating. This especially effective procedure supports the quick ▶evacuation of the air from the sterilization chamber, the sterilization packaging and instrument cavities. This permits the sterilization of large quantities of instruments or textiles directly one after each other, thereby achieving excellent drying results.

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 sterilization 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 procedure is also called the fractionated vacuum procedure.
	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.

Program phase	Description
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.

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 (▸demineralized 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.

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 pressure and temperature in the sterilization chamber and prevents the door from being opened when over-pressure has built up in the sterilization chamber. The motor-driven automatic door locking mechanism opens the door slowly by turning the locking spindle. This also holds the door whilst it opens. Pressure equalisation will have been performed by the time that the door is completely open, even following pressure differences.

Automatic monitoring of the feed water

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

Performance characteristics of sterilization 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 body (▶Hollow body B)	X	X	X	X
▶Product with narrow lumen (▶Hollow body A)	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	05:30 min	03:30 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.

Standard scope of delivery

- Vacuclave 550
- User Manual
- Technical Manual
- User Manual Accessories for small steam sterilizers
- Manufacturer's inspection report and declaration of conformity
- Warranty certificate
- Record of installation and setup
- 2 tray lifters
- Power cable
- MELAG USB flash drive
- Allen key with which to open the door in an emergency
- Drain hose
- Oil for door lock bushing
- Test gauge TR20 for door lock nut
- Carrying handles
- Installation set
    - PTFE hose, 2.5 m
    - Nozzle G 1/4"
    - 2 Cu seal 13.5x20
    - 2 QSS- straight
    - Hose PUR (black) 6/4 mm, 2.5 m
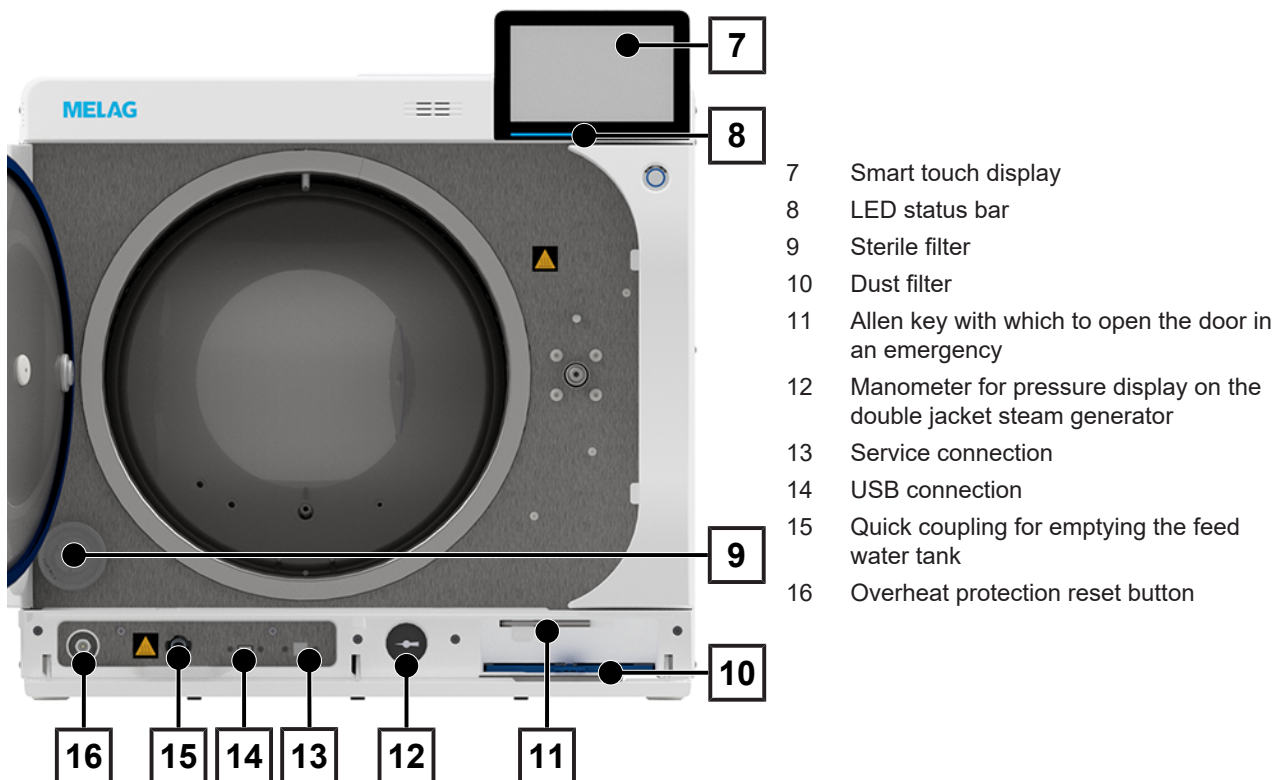   - Cold water adapter 3/4" to 1/4" (direct connection water hose)

Views of the device

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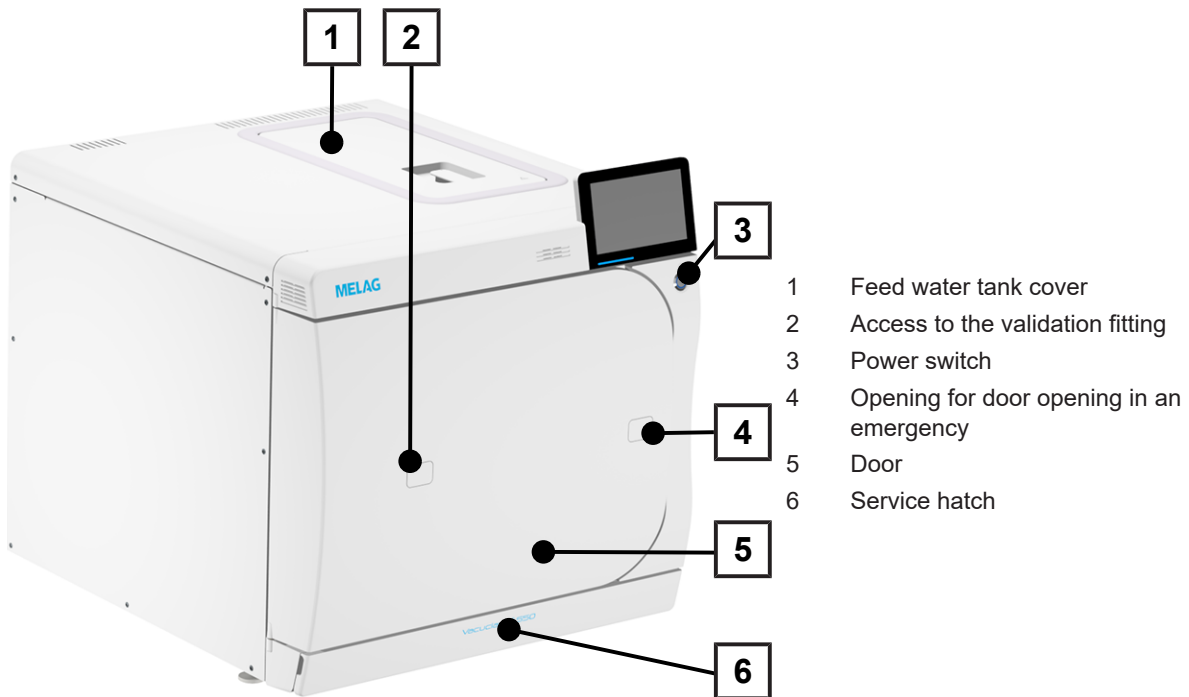
1	Feed water tank cover
2	Access to the validation fitting
3	Power switch
4	Opening for door opening in an emergency
5	Door
6	Service hatch

View from front, with open service hatch

7	Smart touch display
8	LED status bar
9	Sterile filter
10	Dust filter
11	Allen key with which to open the door in an emergency
12	Manometer for pressure display on the double jacket steam generator
13	Service connection
14	USB connection
15	Quick coupling for emptying the feed water tank
16	Overheat protection reset button

View from rear
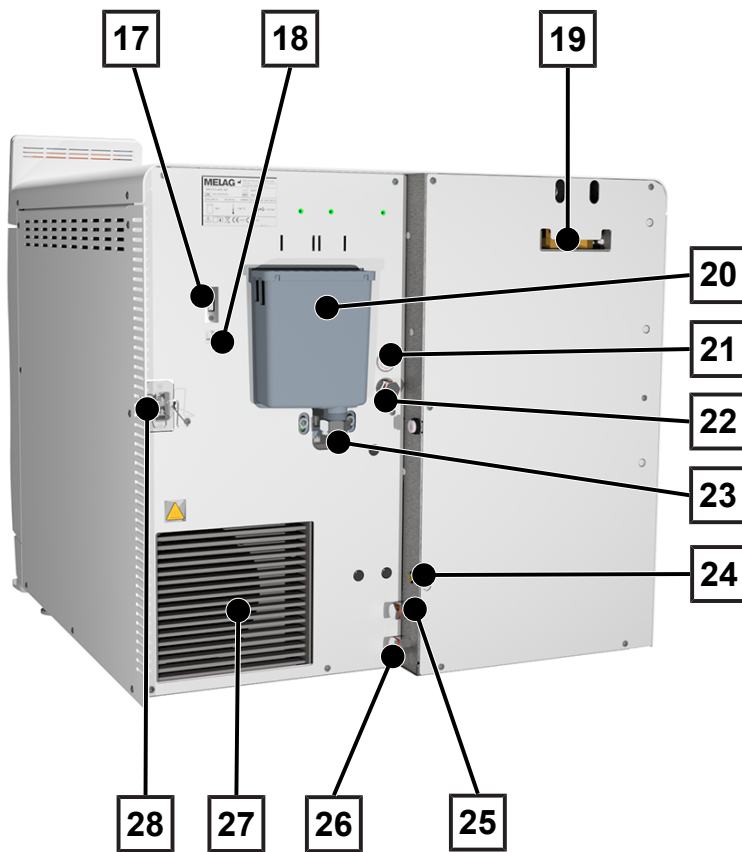
17	USB connection
18	Ethernet connection
19	Spring safety valves
20	Overflow funnel
21	Electrical connection of the filling pump
22	Feed water connection of the filling pump
23	Wastewater connection
24	Connection for level sensor for external wastewater container
25	Feed water connection, water treatment unit
26	Wastewater connection, water treatment unit
27	Cooler
28	Power cable connection

Symbols on the device

Type plate

	Manufacturer of the product
	Date of manufacture of the product
MD	Label as medical product
REF	Article number of the product
SN	Serial number of the product
	Observe user manual or electronic user manual
	Do not dispose of product in household waste

	CE marking
CE 0035	Identification number of the notified body responsible for conformity assessment according to Pressure Equipment Directive 2014/68/EU
CE 0197	Identification number of the notified body responsible for conformity assessment according to Regulation (EU) 2017/745 on medical products
(V)	Volume of the sterilization chamber
	Working overpressure in sterilization chamber
	Operating temperature in sterilization chamber
	Permissible temperature range of water supply
	Permissible pressure of water supply

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
	Drain connection, feed water		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	Connection, filling pump	**Drain**	Wastewater connection
Pump power	Electrical connection of the filling pump	**Sensor drain**	Sensor of the wastewater container

Service hatch

The service hatch is magnetic and can be opened by pulling on any side.
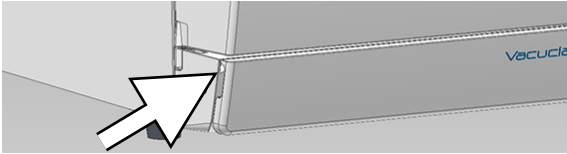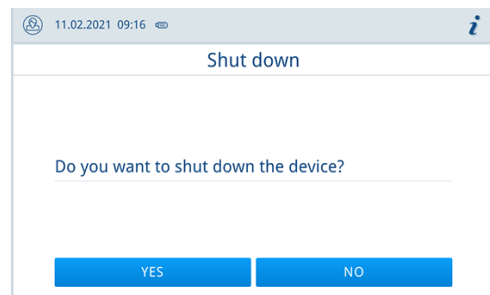
Power switch

☞ **PLEASE NOTE**
The device cannot be shut down during a running program.

By pressing the power switch, you can call up the shutdown dialogue.

By pressing the power switch again, you switch the device on again.

If the power switch is pressed for longer than 5 seconds, the device is restarted.

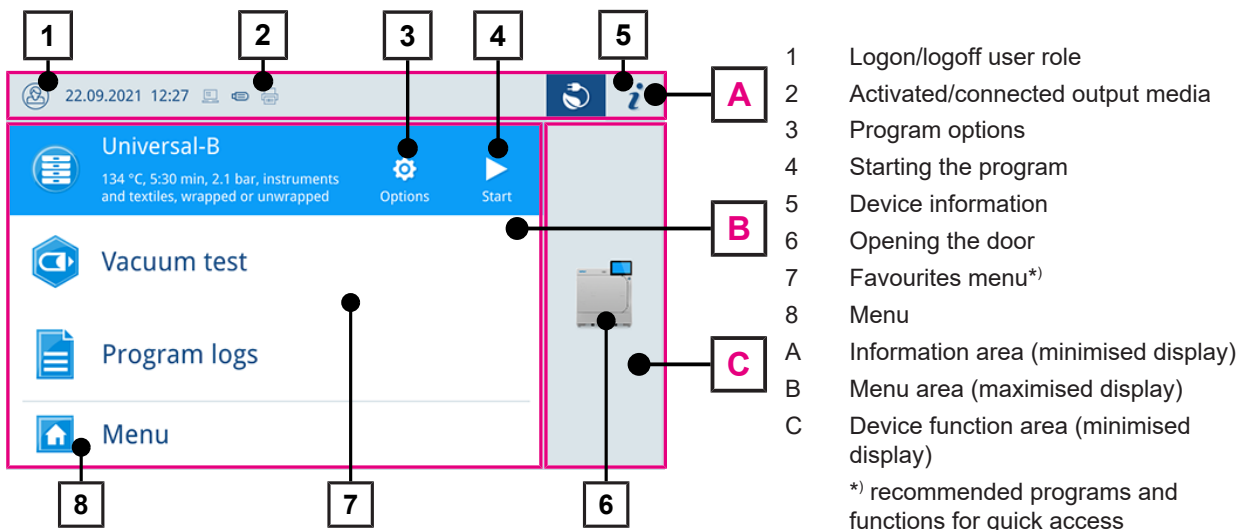The illumination of the power switch indicates the status of the device.

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.

Smart touch display

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

The selected menu item is always 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	Logon/logoff user role
2	Activated/connected output media
3	Program options
4	Starting the program
5	Device information
6	Opening the door
7	Favourites menu*)
8	Menu
A	Information area (minimised display)
B	Menu area (maximised display)
C	Device function area (minimised display)

*) recommended programs and functions for quick access

Buttons in the program selection

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

Buttons in the information area

Button	Description
i	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 dialogue

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

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`.
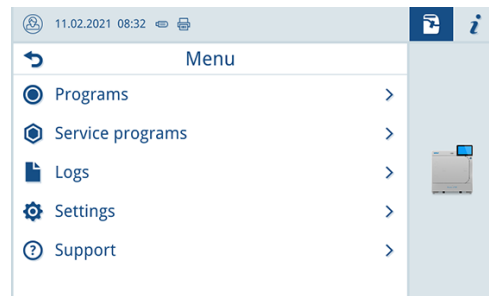
Program run

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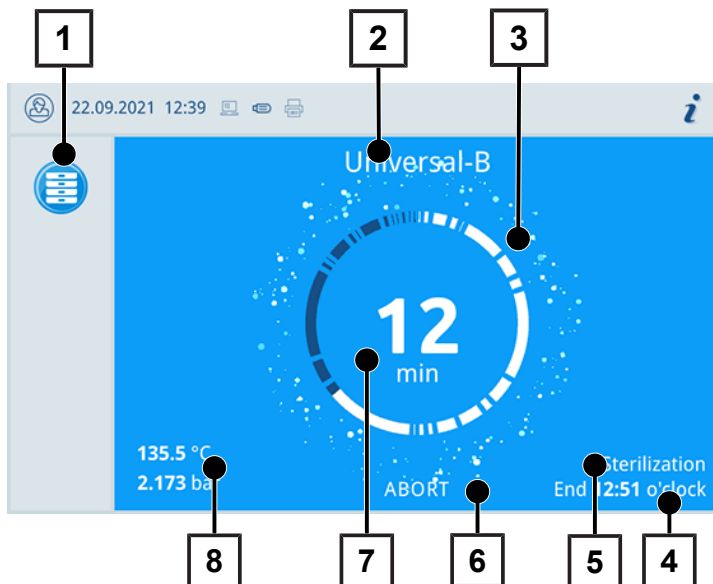
1	Program information for current program
2	Program name
3	Busy indicator
4	Estimated end of the program
5	Program phase
6	Abort/end button
7	Remaining run time (remaining program duration)
8	Program parameters (temperature/ pressure)

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 from the wastewater is transmitted to the feed water, reducing the need to heat the feed water. By recovering this heat, electricity consumption is significantly reduced.

The power recovered through heat recovery is shown in green.
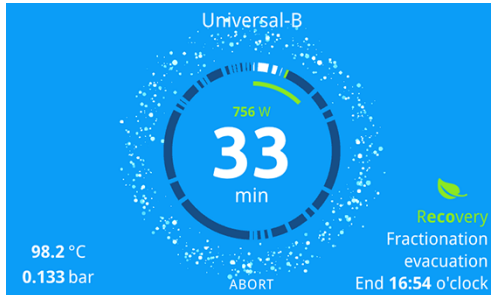
The energy saved over time can be displayed in the `Status log`.

Load mount

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

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

For detailed instructions on the use of the accessories and their combinability with different load holders, see the section Mounts and loading slide [▶ page 25] and the document "user manual accessories for small steam sterilizers ".

5 First steps

Setup and installation

☞ **PLEASE NOTE**
   Comply with the specifications of the technical manual during setup and installation. This contains all building-side requirements.

Record of installation and setup

The record of installation and setup 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.

Feed water supply

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

The steam sterilizer requires approx. five litres of feed water for the first filling of the steam sterilizer.

Use of a water treatment unit

A water treatment unit is connected to the drinking water supply. This obviates the need to fill the storage container. The respective system is selected in accordance with the number of sterilization runs per day and the type of the load. Every MELAG steam sterilizer can be fitted with a water treatment unit.

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

Use of external storage and wastewater container

Fill the storage container with feed water. The feed water is pumped into the device via the filling pump. Check the water level in the storage container before every program start. The wastewater container has a capacity of approx. 25 litres and is sufficient for at least ten sterilizations.

! **NOTICE**
   Danger of algae development
   ■ To prevent the development of algae, never expose the storage container to sunlight.

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.

   ➥ The double jacket steam generator is ventilated, whereby the air flow can cause a hissing noise.

2.   The welcome screen is displayed. The display then switches to the Favourites menu.

➥ The feed water level is checked and pre-heated immediately after activation.

After device activation, a ▸heating up time of a maximum of 18 minutes is required. This time is required for the pre-heating of the double jacket steam generator.

☞ **PLEASE NOTE**

You can start a program immediately without waiting for the heating up time.

---

6 Opening and closing the door

The device is fitted with a motor-driven automatic door locking mechanism with a 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 opens automatically.

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

   ➥ The door opens automatically.

2. Grasp the door by the lateral grip to move it.

Closing the door

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

- Never slam the door.

- Press the door closely to the housing.

- Hold the door closed for min. 3 s until the door lock engages.

1. Grasp the door by the lateral grip to move it.

2. To close the door, press it firmly inwards until the automatic door lock engages.

➥ 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

In emergency situations e.g. power failure, the door can be opened in the following fashion:

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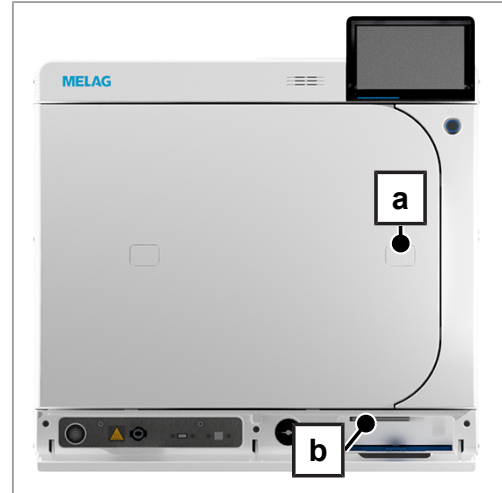
3. Insert the Allen key (5 mm) included in the scope of delivery into the opening. The Allen key can be stored in the specially designed bracket behind the service hatch (pos. b).

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. Turn the Allen key to open the door in a clockwise direction.

   ➥ The door opens a crack.

5. Remove the Allen key.

6. Open the door and return the cover cap.

7   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

8 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.

Reprocessing the 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.

Ensure the following when reprocessing used and brand-new instruments:

■ Observe both the instrument manufacturer's instructions regarding reprocessing and sterilization as well as the relevant standards 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 cleaning and disinfecting, where possible with demineralised 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 ultrasonic 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 putting the textiles in sterilization containers:

■ Comply with both the manufacturer's instructions of the textiles regarding reprocessing and sterilization as well as the relevant standards and directives (in Germany e.g. from 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 sterilization 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.
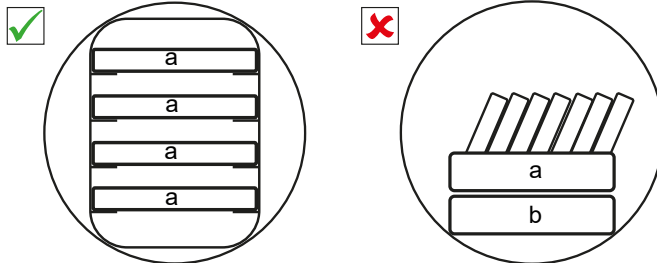

a   Tray
b   Sterilization container

■ 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.

■ The use of paper tray inserts can result in poor drying results.

■ Wherever possible, ensure the separate sterilization of textiles and instruments in separate sterilization containers or sterilization packaging. This leads to better drying results.
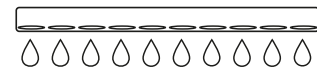
Packaging

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 packaging, paper bags, sterilization paper, textiles or fleece.

Mounts and loading slide

Note the following depending on the use of the accessories:

Loading without mounts or loading slides

For loading with containers or MELAstore Boxes 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-packed goods (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 Boxes at the rear end of the slide. You can stack up to 4 MELAstore Boxes 100 crosswise on top of each other.

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.

Closed sterilization containers

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

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

Please comply with the following when using closed sterilization containers:

- ■ Use aluminium sterilization containers. Aluminium retains and conducts heat and thus accelerates drying.

- ■ Closed sterilization containers must be either perforated or have a valve on at least one side. MELAG sterilization containers (e.g. MELAstore Boxes) fulfil the requirements for successful sterilization and drying.

- ■ Wherever possible, ensure that sterilization 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 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 packaging can be used in both sterilization containers and on trays. Please comply with the following when using soft sterilization packaging e.g. MELAfol:

- Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.

- Place transparent sterilization packages on their edge wherever possible and 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 bags are facing each other.

- If the seam seal tears during sterilization, this could be caused by the choice of undersized packaging. Re-pack the instruments with larger packaging and perform sterilization again.

- Should the seam seal rip during sterilization, extend the sealing pulse on the sealing device or make a double seam.

Multiple wrapping

The steam sterilizer works with a fractionated vacuum procedure. This permits the use of ▶multiple wrapping.

Mixed loads

Observe the following when sterilizing ▶mixed loads:

- Always place textiles at the top.

- Place the sterilization containers at the bottom.

- Place unwrapped instruments at the bottom.

- Place the heaviest loads at the bottom.

- Place transparent sterilization packaging and paper bags at the top - except in combination with textiles. In this case, place them at the bottom.
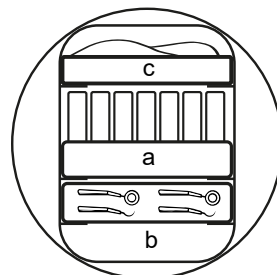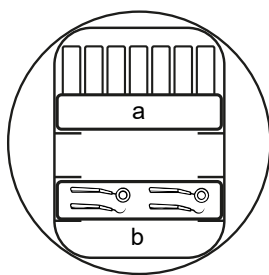
a   Packaging
b   Heavy load/instruments
c   Textiles

Load quantities and versions

Max. weight per component

Load type	Instruments	Textiles
Max. weight per component	2 kg	2 kg

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 100 8 x 1.75 kg	MELAstore 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`.
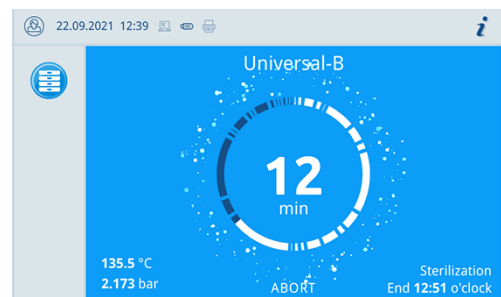
Selecting the program

Now select the sterilization program according to how and whether the ▶load is packed. It is also necessary to take into account the temperature resistance of the load. All sterilization programs are displayed in the `Programs` menu. The following tables list the correct program for each ▶load.

Starting the program

With the start of the program, the door closes pressure-tight and the device checks the quantity of feed water and its conductivity.

1. Press `START PROGRAM`.

2. Confirm the subsequent dialogue window with `START PROGRAM`.

3. With enabled `Authentication at Reprocessing program start`, authenticate by entering a PIN.

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

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

Program options

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

1. Press the `Options` button.
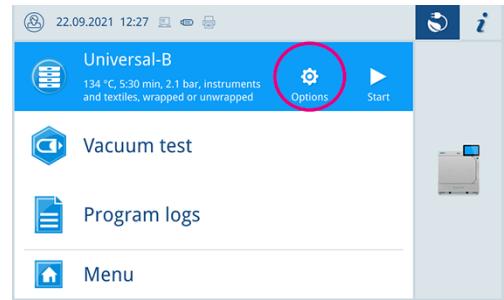
2. Select the desired option, see Program options [▶ page 44].

3. Start the program with `START PROGRAM`.

4. With enabled `Authentication at Reprocessing program start`, authenticate by entering a PIN.

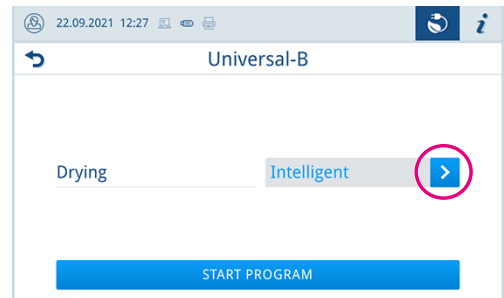5. Confirm the subsequent dialogue window with `START PROGRAM`.

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.

1. Press `ABORT` to abort a program.
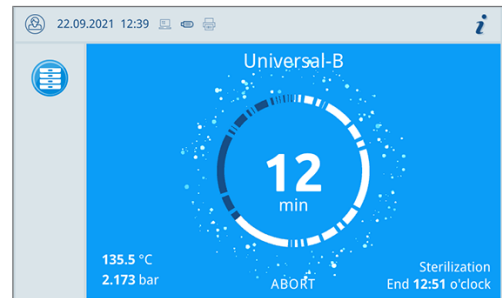
2. Confirm the security query with `YES`.
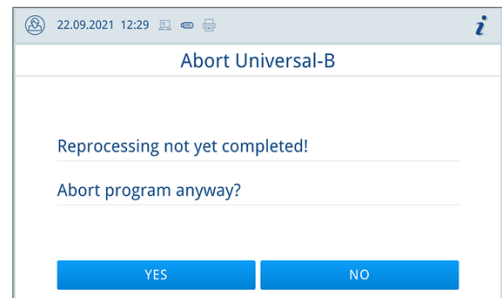
➥ The load is not sterile.

➥ Aborting the program may take a few minutes as steam and condensate are removed from the chamber.

⚠ **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.

---

3. Press `OPEN DOOR` to remove the load.
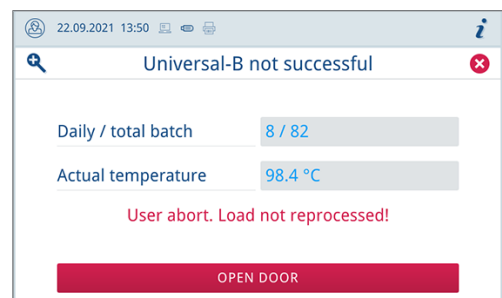
Ending the program prematurely

You can end the program prematurely. If you abort the program before the end of the drying phase, the load is not completely dried and should be used immediately.

The following must be fulfilled or present:

✔ The drying phase has been reached.

1. To end the program prematurely, press **END**.
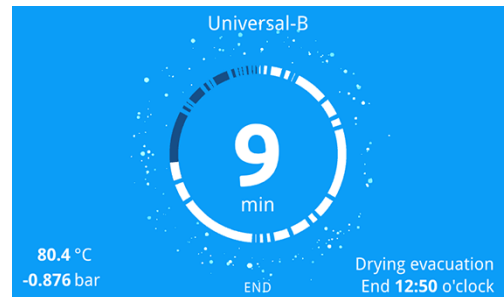
2. Confirm the termination of the drying process with **YES**.
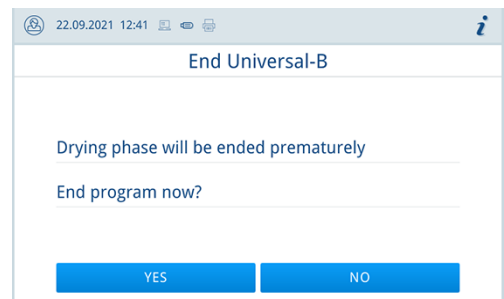
➥ The program will be aborted prematurely.

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, you can view further values for the program that has just been completed (e.g. the plateau time or the conductivity) by pressing the magnifying glass symbol.

2. Press **OPEN DOOR** to remove the load.
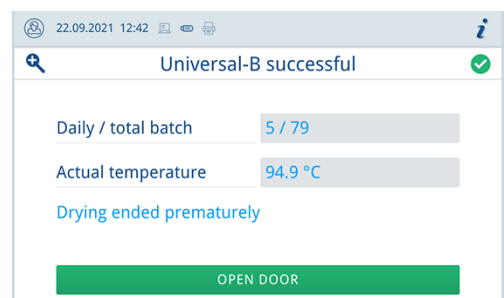
3. With enabled **Authentication at Reprocessing program end**, authenticate by entering a PIN.

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 treatment of medical products", instrument reprocessing ends with the documented release for storage and application of the ▶sterile material. The approval process consists of ▶batch indication and batch approval and must be performed by authorised and expert personnel.

Batch approval comprises the checking of the process parameters using the sterilization results on the device and the sterilization log as well as checking of the individual packaging for damage and residual moisture. The sterilization log records the release of the ▶batch and any indicators, see Logging [▶ page 34]. Depending on the setting in the user administration, release of the ▶sterile material requires the user PIN of the person who provides approval for the batch and the indicators.
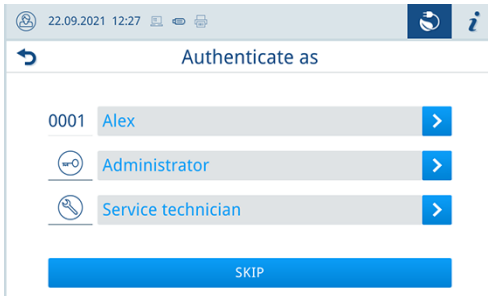

Removing the sterile material

⚠	**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.

■ Hold the tray level when removing it from the steam sterilizer. 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.

■ Do not store the ▸sterile material in the reprocessing room.

■ 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.

9 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 is activated, the user ID and the result of the approval process are documented in the log header and, if required, on a label.

Capacity of the internal log memory

The device is equipped with an internal log memory. This saves all the data regarding the programs automatically. The capacity of the internal log memory is sufficient for at least 4000 logs. If the internal log memory is full, a warning appears at program start and the oldest log is overwritten.

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

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 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.

1. Press the button at the top right to customise the `Log output options` and output multiple logs.
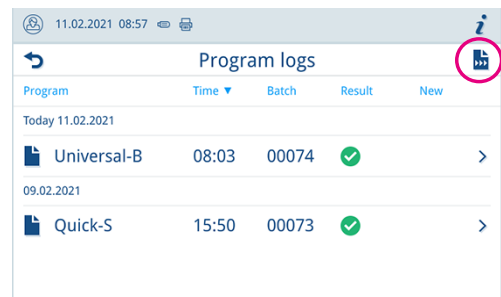
2. Press the button with the arrow to view and output a log.
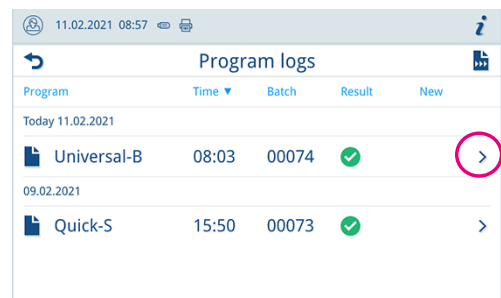
3. Press `OUTPUT LOG` to enter the `Log output options` and output the displayed log.
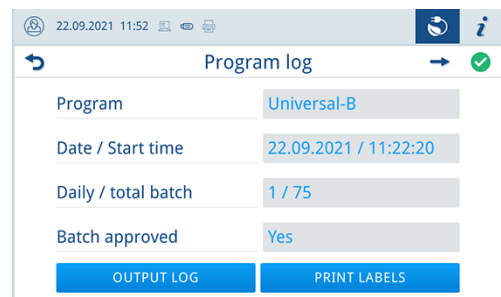
4. Press `PRINT LABELS` to open the label printing dialogue.

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 which logs are to be output and then output the logs.

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

(icon) 11.02.2021 08:57			*i*
↩	Log output options		
Output state		Not output	**>** [a]
MELAtrace			
FTP server	[c]	[b]	
USB stick			✓
	OUTPUT LOGS		
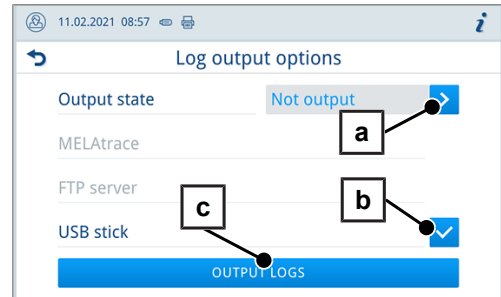
2. Activate the desired output medium (pos. b).

➥ Unavailable output media are displayed greyed out.

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

➥ The output takes place on the selected output media.

Output status

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	The logs of all successfully completed programs will be outputted.

MELAG

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/MELAview.

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

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

Output media

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

- MELAtrace
- FTP
- USB on USB stick

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.
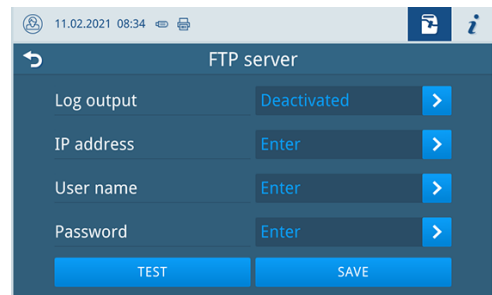
☞ **PLEASE NOTE**
   You can only connect one USB storage medium.

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 configuration of the FTP server is also carried out via the IP address, the user name and the password.

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

10 Function checks

Service programs

Program	Program name	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`.
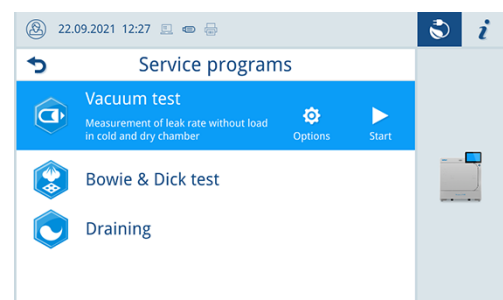
↪ The vacuum test is started in the `Default` program version.

↪ 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. Press the button with the arrow to select another variant of the vacuum test.
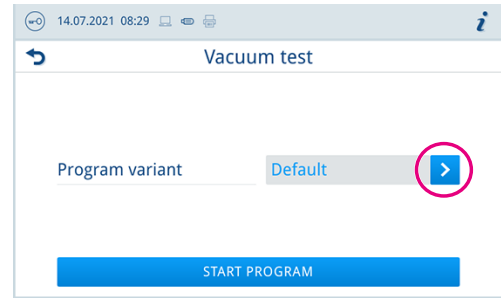
2. Select the desired variant and accept it with `OK` at the end of the list.
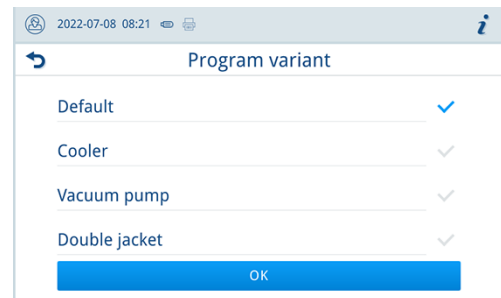
3. Start the vacuum test with `START PROGRAM`.

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. Use the Bowie & Dick test program to this end. 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` select `Bowie & Dick test` and press `Start`.
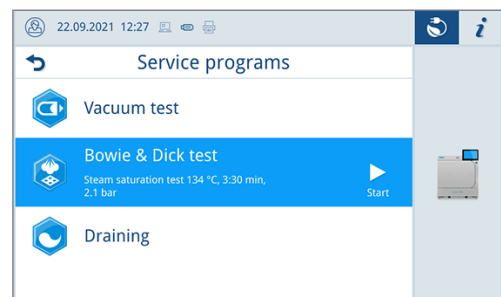
11 Settings

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 desire language.
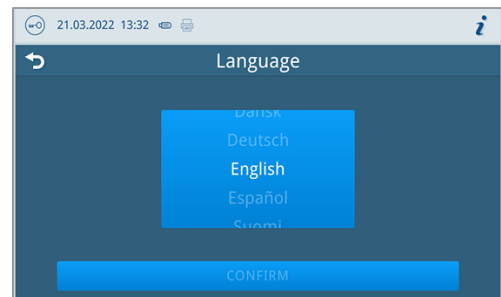
2. Press `CONFIRM` to accept the changes.

➡ 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.
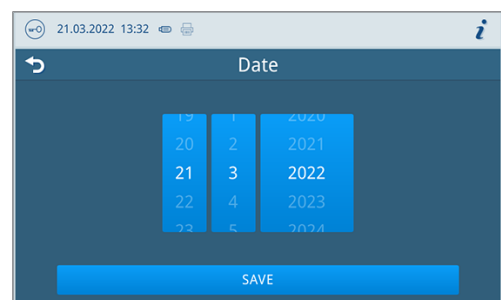
4. Press `SAVE` to accept the changes.

5. Select the `Time` menu item.

6. Set the time.
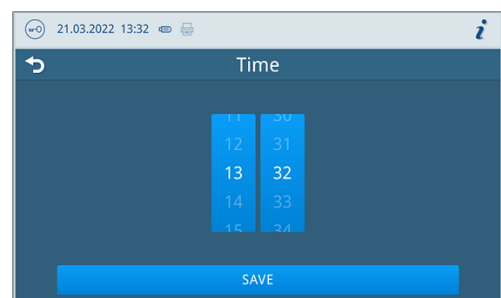
7. Press `SAVE` to accept the changes.

Display brightness

In the `Settings` > `Brightness` menu, you can individualise 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.
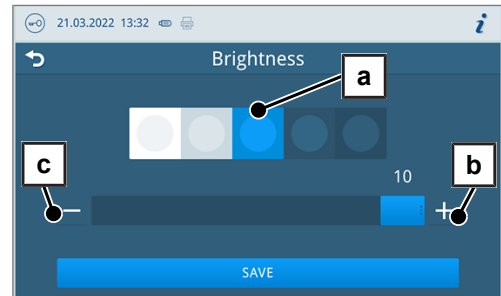
   ➥ The display brightness can be adjusted in ten steps.

2. Press `SAVE` to accept the changes.

Volume

In the `Settings` > `Volume` menu, you can individualise the sound output.

1. Move the slider to the left or right or press the minus (pos. a) or plus (pos. b) buttons.
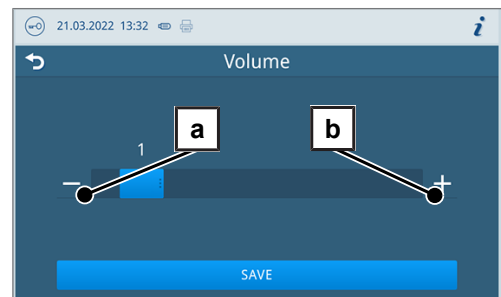
   ➥ The volume can be adjusted in ten steps.

   ➥ 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 heating is switched off.

1. Set the desired switch-off time in minutes on the number wheel.
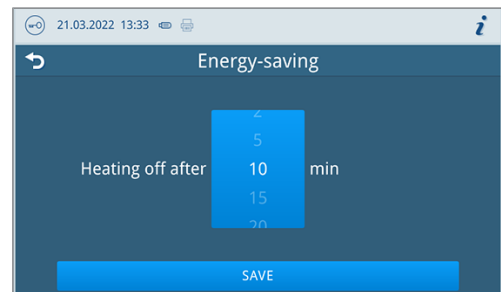
2. Press `SAVE` to accept the changes.

Program options

In the `Settings` > `Program options` menu, you can set default settings for program options.

1. Press the button with the arrow to make changes.
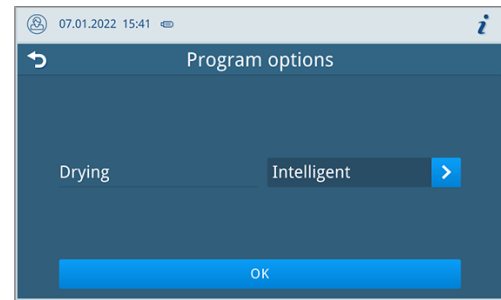
2. Activate or deactivate the desired setting by selecting or deselecting it.

3. Confirm the changes with `OK`.

4. Press `SAVE` to accept the changes.

The following settings are possible:

Device mode	Designation	Short description
Vacuclave	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 have the option to change the preset drying mode once at the program start via `Program options`.

Time-controlled drying

In the case of timed 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 a conventional time-controlled drying process, 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 option `Intelligent` 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.

The following output media can be activated and configured:

▪ MELAtrace

▪ FTP

▪ USB on USB stick

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

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

- 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.

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

FTP server configuration

Under the FTP menu item, the configuration of the FTP server is also carried out via the IP address, the user name and the password.

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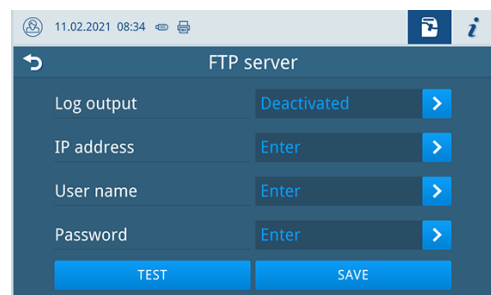
USB

You can only connect one USB stick. Output to multiple USB sticks is not possible.

Label print

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, see Label printer as output medium [▶ page 35].
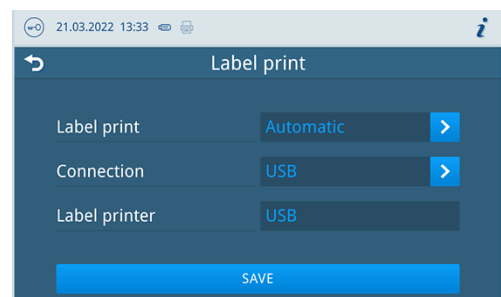
2. Activate or deactivate the desired setting by selecting or deselecting it.

   ➥ 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

Option	Description
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 dialogue. 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.

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

Water management

In the **Settings** > **Water management** menu you can change the water supply and disposal.

Water supply

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

Designation	Description
Automatic	The feed water is automatically supplied via the *MELAdem feed water connection*.
Manual	Before starting the program, the feed water tank must be filled manually.
	The required amount is about three litres.
	PLEASE NOTE: The feed water tank must be filled up to the MAX mark before each program start.

Water disposal

You can set the wastewater disposal to Automatic or Manual.

Designation	Description
Automatic	The wastewater is automatically disposed of via the wastewater funnel into the building's wastewater installation.
Manual	The wastewater is disposed of via the overflow funnel into an external wastewater container. The tank is monitored by a level sensor and must be emptied regularly. Emptying every working day is recommended. The capacity of the wastewater container is at least 10 cycles.

Administrative settings

To make administrative settings, such as changes to the user administration, you must log in as an Administratoror a Service technician, see Logging on user role [▶ page 50].

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 released, see Authentication [▶ page 47].

Only created users are authorised to approve and can approve a batch with their user PIN, see Batch approval [▶ page 49].

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.
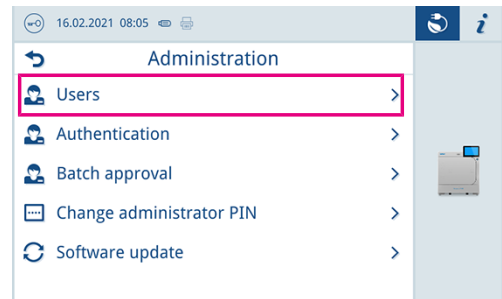
2. Press the plus button (pos. a) to create a new user.
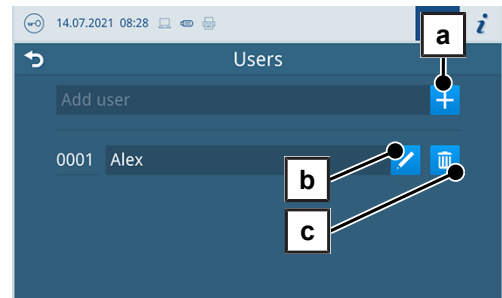
3. Edit (pos. b) or delete (pos. c) the user using the buttons next to the user name.

4. Press the buttons with the arrow to change the ID (pos. d), the user name (pos. e) or the PIN (pos. f).
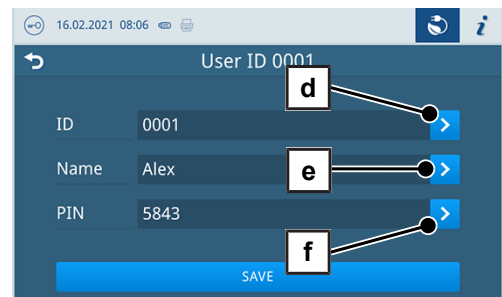
5. Confirm the changes with `OK` and accept the changes with `SAVE`.

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

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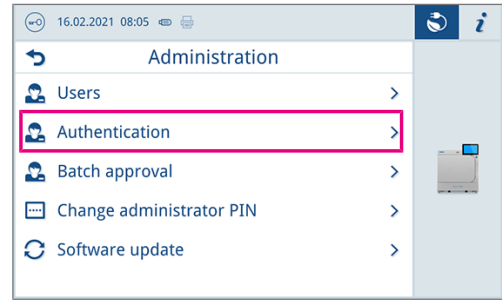
2. Activate or deactivate the desired setting by selecting or deselecting it.
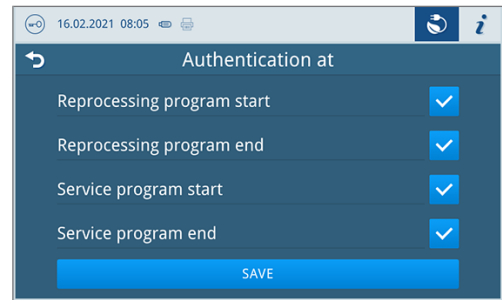
3. Press **SAVE** to accept the changes.

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 factory settings.

Batch approval

In the `Settings` > `Administration` menu you can activate the batch approval after the program has ended successfully 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.
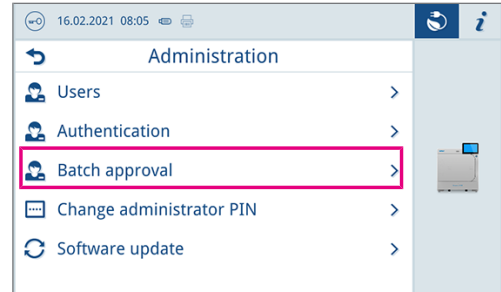
2.   Activate or deactivate the desired setting by selecting or deselecting it.
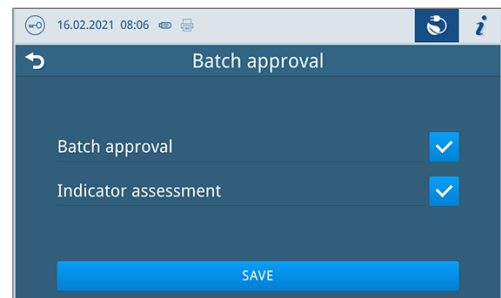
3.   Press `SAVE` to accept the changes.

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.
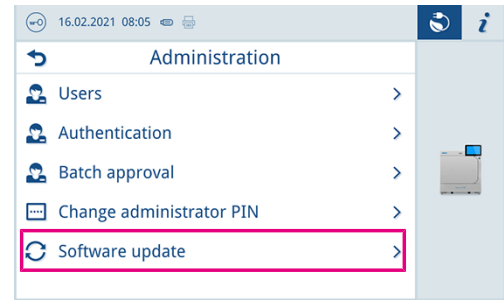
2. Insert a USB stick with the installation data into any USB port.

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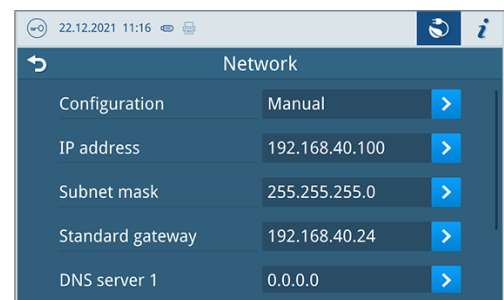
2. Press `SAVE` to accept the changes.

Logging on user role

To log on a user role, proceed as follows:

1. Press the user role button.
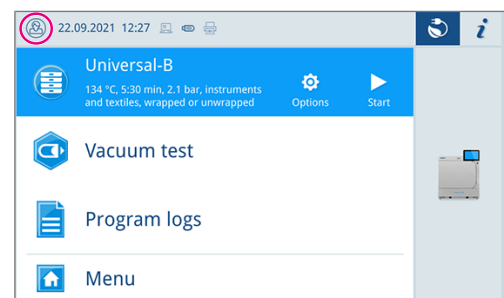
2. Select the desired role, e.g. Administrator.

3. Enter the associated PIN.
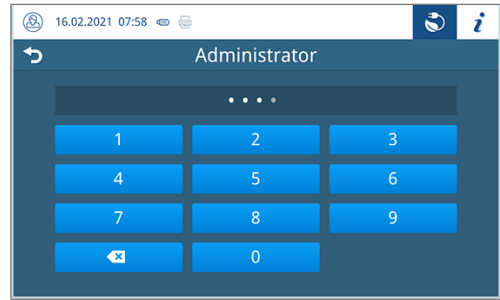
> The symbol of the user role button changes.

> 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.
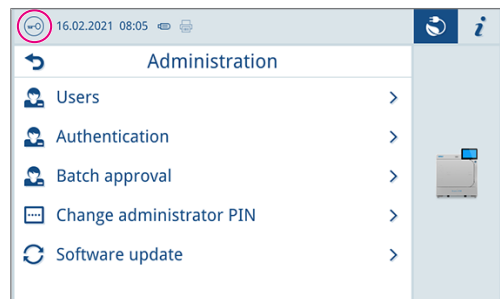
2. Press **LOGOUT**.

> The symbol of the user role button changes.

Service settings

Only ▶authorised technicians have access to the further service documents required for this purpose.

12 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 must only be carried out by an ▶authorized technician.

Servicing intervals

Interval	Measure	Device components
Daily	Check for soiling, deposits or damage	chamber inc. door seal and chamber sealing face, door lock, mount for the load
Daily	Check the operating media - electricity, water, wastewater	Operating media
	Check the documentation media - printer, network, USB	Documentation media
Weekly	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
Annually or following 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

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 test 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 hatch.

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 hatch.

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, chamber sealing face, mount, trays

To maintain the value of your device and to avoid persistent contamination and deposits, MELAG recommends daily cleaning of the surfaces (e.g. with the MELAG chamber cleaning set).

Cleaning the sterilization chamber, chamber sealing face, mount and trays

The following must be fulfilled or present:

✓   The device has been switched off and the power plug has been unplugged from the socket.

✓   The device has been completely cooled.

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

1.   Wet the surfaces to be cleaned completely with the cleaning fluid.
     PLEASE NOTE: You should not allow cleaning fluid to enter the piping coming from the sterilization chamber.

2.   Spread the cleaning fluid evenly with a non-fuzzing cloth.

3.   Allow the cleaning fluid to act and evaporate for a sufficient time.

4.   Using a new non-fuzzing cloth, spread ample amounts of demineralised water over the cleaned surfaces.

5.   Wipe the surfaces thoroughly to remove cleaning residues. Repeat this process as necessary after wringing out the cloth.

     ➥   Residues of cleaning fluids can ignite or cause deposits on the instruments.

6.   Allow the cleaned areas to dry completely. This may take a few minutes.

7.   Finally, wipe the cleaned surfaces with a dry, non-fuzzing microfibre cloth.

8.   Clean the door seal with neutral liquid detergent.

MELAG

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.

Cleaning the feed water tank

Drain the feed water tank

The following must be fulfilled or present:

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

✓ A collection container (with a capacity of up to 5 l, normally 2000 ml flows out).

✓ The device is not in operation. The device should cool down for approx. 15 min after switching off.

1. Switch off the device.

2. Open the service hatch.

3. Place the collection container in front of the device and the end of the drain hose in the collection container.

4. Push the drain hose onto the drain valve until it noticeably snaps into place. The knob must be horizontal.

5. Open the drain valve by turning the knob 1/4 in an anti-clockwise direction.

6. Drain the water into the collection container.

7. To remove the drain hose, turn the drain valve into the vertical position again.

8. Close the service hatch.

Cleaning the feed water tank

☞ **PLEASE NOTE**

The cover of the feed water tank is engaged.
- ■ Press the cover backwards before lifting it.

---

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

2. Put the cover aside.

3. Check the tank for contamination and, if necessary, clean it with a sponge and solvent-free, non-alkaline cleaner (e.g. washing-up liquid).

4. **CAUTION! Danger of burns.** Fold up the heat exchanger.

5. Remove the tank filter from the base of the feed water tank by pulling it out.
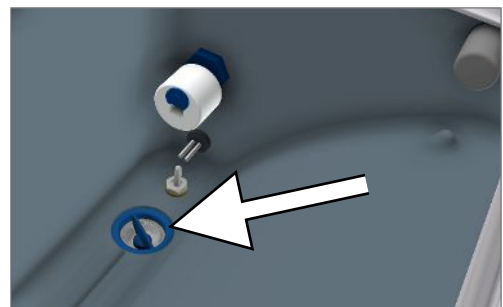
6. Clean the tank filter under running water or with the MELAjet spray pistol for MELAdem 40.

7. Check the cleaning result against the light.

8. Reinsert the tank filter.

9. Reinsert the cover cap correctly and close it.

Maintenance

! **NOTICE**

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

- Maintenance should only be performed by trained and authorised service technicians or stockist technicians.
- Maintain the specified servicing 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.

13 Pause times

Starting after long pauses

After a long period of non-use, the device will heat up after being switched on.

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 Emptying [▶ page 57].
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.

Emptying

You have the option of emptying the water in the double jacket steam generator easily 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`.

⊗ 11.11.2021 09:34 👓 🖨		_i_
↩	**Service programs**	
🔲	Vacuum test	
✳	Bowie & Dick test	
🛡	**Draining** Draining of double jacket before maintenance or transport	▶ Start
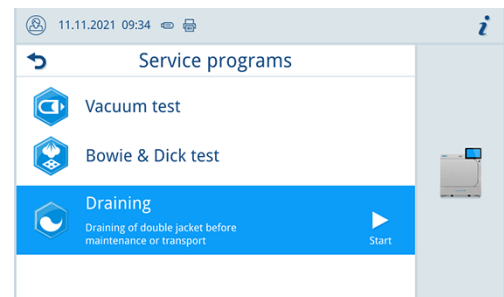
2. Confirm the dialogue window.

   ➥ The double jacket steam generator is emptied.

3. Confirm the message `Draining successful`.

   ➥ The device switches to door mode.

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 handles to carry the device.

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 57].
2. Disconnect the connection hoses connected on the rear of the device.
3. Install the carrying aid.

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 57].
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 69].

14 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.

	Nature of the display notification	Description
ℹ	Messages	Many messages are notifications. They serve to inform and provide assistance in the operation of the device.
⚠	Warnings	Warning messages are displayed when necessary. Warning messages contain instructions that help to ensure smooth operation and to recognise undesirable conditions. 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

Ensure that you have complied with all instructions relating to a warning or malfunction message issued on the display of the device. 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. To enable us to give the best possible service, please have the serial number of your device, the malfunction number and a detailed description of the malfunction to hand.

Malfunction logs

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

Warning and malfunction messages

Event	Possible cause	What you can do
10059	The external wastewater container is full.	Please 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.	Ensure water supply (main valve) or fill in case of supply from canisters
10063	The manual feed water supply is activated. The device must be filled with at least 1.5 l of demineralised water.	Please 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.

Event	Possible cause	What you can do
10082	In the program start, the counter for the feed quantity is evaluated. The limit value is exceeded. Therefore, starting the program is not possible.	The automatic emptying was skipped several times because the drying was ended manually. Starting the program is not possible before the "Empty double jacket" service program has been carried out. Please start the "Empty double jacket"service program. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10093	In the program start, the counter for the rinse value is evaluated. The limit value is exceeded. Therefore, starting the program is not possible.	The automatic emptying was skipped several times because the drying was ended manually. Starting the program is not possible before the "Empty double jacket" service program has been carried out. Please start the "Empty double jacket"service program. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10094	In the 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 set-up conditions. Ensure that the device is sufficiently ventilated. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10098	A failure of the supply voltage was detected in the program run.	Connect the device to a specially fused power supply to which no other electrical device is connected. Check the power cable on the rear of the device to ensure that it is firmly seated. Attach the safety latch.
10099	A failure of the supply voltage was detected in the program run of a service program.	Connect the device to a specially fused power supply to which no other electrical device is connected. Check the power cable on the rear of the device to ensure that it is firmly seated. Attach the safety latch.
10101	The float switch (S13) in the overflow funnel detects a short-term impermissible water level, which indicates a blockage in the wastewater system.	Short-term wastewater blockage - please check wastewater hose for kinks or, if applicable, a closed shut-off. This is only a warning. The reprocessing result is not affected. You can continue to use the device.
10102	The float switch (S13) in the overflow funnel detects a permanently impermissible water level, which indicates a blockage in the wastewater system.	Permanent wastewater blockage - please check wastewater hose for kinks or, if applicable, a closed shut-off.

Event	Possible cause	What you can do
10109	Door process. The limit current for the door motor was exceeded during opening. Apparently, the door locking mechanism or the door motor is blocked.	The automatic opening of the door is disturbed. Please allow the device to cool down and open the door using the tool in the media board. Please ensure regular oil maintenance of the door spindle and door nut. If this occurs repeatedly, please contact the technical service.
10117	Door process. The monitoring time when opening the door has expired and both the door contact switch K1 and K2 signal a closed door.	The automatic opening of the door is disturbed. Please allow the device to cool down and open the door using the tool in the media board. Please ensure regular oil maintenance of the door spindle and door nut. If this occurs repeatedly, please contact the technical service.
10120	Door process. The limit current for the door motor is exceeded when opening from the pressure-tight status (Z4) to the vapour-tight status (Z3). Apparently, there is a blockage of the door.	The automatic opening of the door is disturbed. Please allow the device to cool down and open the door using the tool in the media board. Please 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 reduced sufficiently within the monitoring time. Apparently, the cooling system has a fault.	Please allow the device to cool down. Please observe the set-up conditions. Please 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.	Please allow the device to cool down. Check the door seal for visible defects. Please clean the door seal with a damp cloth.
10145	Monitoring time only runs when evacuation is started in negative pressure. Malfunction is triggered if evacuation cannot be completed within the monitoring time.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.

Event	Possible cause	What you can do
10165	Double jacket emptying. The maximum runtime for emptying has expired.	Please allow the device to cool down. Please observe the set-up conditions. Please 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	Please contact technical services	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 packing 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	In the program run, the maximum filling level of the external wastewater container is reached during manual water disposal.	Please 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.	For the Empty program, the wastewater container must be empty. Please empty the external wastewater container.
10186	With a manual water supply, the filling level of the feed water tank is undershot.	Please fill up the feed water tank.
10224	There is not enough feed water tank in the tank.	Please fill the feed water tank up to the maximum marking of the level increase before the next program start.
10226	There is not enough feed water tank in the tank.	Please fill the feed water tank up to the maximum marking of the level increase.
10241	Pressure-controlled evacuation. This is triggered when the termination gradient is violated in a gradient-monitored process, which leads to an abort of the program run (in the context of pressure-controlled evacuation/pressure gradient monitoring). The vacuum performance is insufficient.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.

Event	Possible cause	What you can do
10242	This is triggered when the termination gradient is violated in a gradient-monitored process, which leads to an abort of the program run (in the context of clock-controlled evacuation VT/pressure gradient monitoring). The vacuum performance is insufficient.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.
10256	Monitoring pressure gradient during evacuation. The pressure change at pressure sensor S1 is too low during evacuation.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.

Event	Possible cause	What you can do
10257	Monitoring pressure gradient during evacuation in the vacuum test. The pressure change at pressure sensor S1 is too low during evacuation.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. 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.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. 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.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. 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 the loading of the device for compliance with the loading quantities. 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 air filter in the media board; if it is heavily worn or blocked, replace it. 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.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. 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 DI water of suitable quality. Insert a regenerated cartridge into your water treatment system.
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 the termination gradient is violated in a gradient-monitored process, which leads to an abort of the program run (in the context of pressure-controlled evacuation/pressure gradient monitoring). The vacuum performance is insufficient.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure that the device is sufficiently ventilated. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.
10286	Pressure-controlled evacuation. This is triggered when the termination gradient is violated in a gradient-monitored process, which leads to an abort of the program run (in the context of pressure-controlled evacuation/pressure gradient monitoring). The vacuum performance is insufficient.	Please 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 for paper or similar items underneath the device which could stop the air flow. Please ensure sufficient ventilation of the device. Heat dissipation must be able to take place freely, ensure ventilation; conversion cabinets are not recommended. Please observe the set-up conditions (e.g. ambient temperature). Check the loading of the device for compliance with the permissible loading quantities. Check the pressure release filter in the chamber for blockage.

Event	Possible cause	What you can do
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.
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.	Please insert the USB stick. If necessary, use the USB connection 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 storage medium does not have enough free space to store the required log data.	Please save the log data on the USB stick in the practice network and then empty the USB stick to output 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 to the USB storage medium has failed.	Please insert the USB stick in the media board. If necessary, use the USB socket 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 was reached. The oldest log will be overwritten the next time the program is run.	Please output the internally stored logs to a USB stick or to your practice network. The log output can also be done automatically; this must be configured 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.	Please 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.	Please load a new roll of labels into 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.
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.

15 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
Sterilization chamber	
Chamber diameter	380 mm
Chamber depth	450 mm
Chamber volume/steam generator	53 l/12.5 l
Electrical connection	
Power supply	220-230 V 50/60 Hz
	max. voltage range 198-253 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
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 supply	
Max. water consumption	5.5 l/cycle
Average water consumption	2 l/cycle
Water temperature	1 to 35 °C
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 supply (for connection of the water treatment unit)	
Min. static water pressure	2 bar
Max. static water pressure	10 bar
Water quality	potable water
Wastewater connection	
Max. throughflow volume	0.5 l/min
Max. water temperature	90 °C for 30 s, max. 98 °C for 1 s

Device type **Working and operating pressures**	**Vacuclave 550**
Perm. operating pressure, sterilization chamber	-1 bar to + 3 bar relative
Perm. operating pressure, jacket	-1 bar to + 3 bar relative
Working pressure chamber/jacket	2.2 bar relative

16 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 Boxes 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 consisting of a Helix test body and 250 indicator strips	ME01080
	MELAcontrol Pro consisting of a Helix test body and 40 indicator strips	ME01075
	MELAcontrol Pro refill pack (250 indicator strips)	ME01076
Water treatment	MELAdem 47 reverse osmosis unit	ME01047
	MELAdem 53/MELAdem 53 C	ME01036/ME01038
Water supply	Filling pump P10	ME65010
Water disposal	External wastewater container	ME65020
For the documentation	USB flash drive	ME19901
	MELAprint 60 label printer	ME01160
	Network cable (1:1), 2,5 m	ME15817
	Network cable (1:1), 3 m	ME15818
	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	ME01056
	Surface-mounted siphon	ME37410
	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 appliance plug	ME21301

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" (Instrument Reprocessing Working Group)

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.

Authorised technician

The term "authorised technician" refers to an employee of a customer service provider or stockist who has been trained and authorised by MELAG 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 recognized 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 also 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.

Heat-up phase
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.

Hollow body A
See product with narrow lumen

Hollow body B
See simple hollow body

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.

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

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

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

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: $1 \leq L/D \leq 750$ and $L \leq 1500$ mm or an article with an opening on both sides which is: $2 \leq L/D \leq 1500$ and $L \leq 3000$ mm and which does not correspond to a hollow body article B; L…length of hollow body article; D…Diameter of hollow body article [see also 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].

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: $1 \leq L/D \leq 5$ and $D \geq 5$ mm or an article with an opening on both sides which is: $2 \leq L/D \leq 10$ and $D \geq 5$ 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 massive instruments designed for sterilization in a sterilizer in accordance with EN 13060.
[see also EN 13060]

Sterile barrier system
A closed minimum packaging which prevents the entrance of micro-organisms e.g. through sealing bags, 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 Medizintechnik GmbH & Co. KG

Geneststraße 6-10
10829 Berlin
Germany

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

Original instructions

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

Your stockist