MELAG
competence in hygiene

User manual

Cliniclave® 45
Cliniclave® 45 M

Large steam sterilizer

from software version 3.240



EN

Dear customer,

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

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

The MELAG management and team.

CE 0197

Contents

1 General guidelines 5
Symbols used 5
Formatting rules 5
Disposal 5

2 Safety 6

3 Performance specifications 7
Intended use 7
Sterilization procedure 7
Type of the feed water supply 7
Safety equipment 7
Program runs 8

4 Description of the device 9
Scope of delivery 9
Views of the device 10
Symbols on the device 12
Colour touch display 13
LED status bar 15
Load mount 15

5 First steps 16
Setup and installation 16
Feed water supply 16
Use of high quality feed water 16
The feed water supply in the steam sterilizer 16
Switch on the device 17
Opening and closing the door 17
Opening the door 18
Closing the door 18
Manual door emergency-opening 18

6 Loading the steam sterilizer 20
Preparing the load 20
Reprocessing textiles 20
Reprocessing instruments 20
Loading the steam sterilizer 21
Closed sterile containers 21
Soft sterilization packaging 21
Multiple wrapping 22
Mixed loads 22
Load quantities and versions 22
Loading system Comfort 23

7 Sterilization 24
Important information regarding routine operation 24
Daily routine checks 24
Further routine checks 24
Selecting the program 25
Additional program options 27
Additional drying 27
Start time pre-selection 27
Automatic shutdown 28
Starting the program 29
Program in progress 29
Manual program abort 31
Program abort before the start of drying 31
Program abort after the start of drying 32
Program end 33
The approval process 33
Removing the sterile material 34
Storing sterile material 34

8 Logging 35
Batch documentation 35
Output media 35
Using the CF card as an output medium 35
Using the computer as an output medium 36
Label printer as output medium 37
Outputting text logs automatically after program end (immediate output) 37
Subsequent log output 38
Finding logs 40

9 Function checks 42
Service programs 42
Vacuum test 42
Bowie & Dick test 42
Test body systems 43
Feed water quality 43
Validation 43
Renewed performance qualification (requalification) 43

10 Settings 44
Setting the display position 44
Logging 44
Immediate log output 44
Outputting graphic logs (optional) 45
Log output in English 46
Using the computer as an output medium 47
IP addresses 48
Log formats 49
User administration 50
Adding a user 50
Deleting a user 51

Changing the Admin PIN ... 52
User authentication for sterilization ... 52
Formatting the CF card ... 53
Additional drying ... 54
Intelligent drying (DRYtelligence) ... 55
Date and time ... 55
Brightness ... 56
Volume ... 56
View ... 56
Key tone ... 57
Screensaver ... 58
Log printer MELAprint 42/44 ... 59
MELAprint 60 label printer ... 59
Sensitivity ... 59
Energy-saving mode ... 59
Switching off the display ... 60
11 Maintenance ... 61
Servicing intervals ... 61
Cleaning ... 61
Sterilization chamber, door gasket, mount, trays ... 61
Housing parts ... 62
Avoiding staining ... 62
Replacing of the door gasket ... 62
Checking and oiling the door lock ... 62
Replacing the sterile filter ... 63
Maintenance ... 63
Maintenance of the reverse osmosis unit ... 63
12 Pause times ... 64
Frequency of sterilization ... 64
Duration of the operating pause ... 64
Decommissioning ... 64
Emptying the double jacket ... 64
Transport ... 65
Preparing the steam sterilizer for transport ... 65
Transport within the practice ... 65
Transport over long-distance / dispatch ... 66
Recommissioning after relocation ... 66
13 Malfunctions ... 67
Messages ... 67
Warning and malfunction messages ... 68
14 Technical data ... 79
15 Accessories and spare parts ... 81
Glossary ... 83

1 General guidelines

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

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Symbols used

Symbol	Description
⚠ WARNING	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
⚠ CAUTION	Indicates a dangerous situation, which if not avoided, could entail slight to moderate injuries.
NOTICE	Indicates a dangerous situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
PLEASE NOTE	Draws your attention to important information.

Formatting rules

Example	Description
see **Chapter 2**	Reference to another text section within this document.
`Log`	Words or phrases appearing on the display of the device are marked as display text.
✓	Prerequisites for the following handling instruction.
▶	Reference to the glossary or another text section.
■	Information for safe handling.

Disposal

MELAG devices are synonymous with long-term quality. When you eventually need to decommission your MELAG device, the required disposal of the device can be carried out by MELAG in Berlin. Simply contact your stockist.

Dispose of ▶components, spare parts, ▶accessories, ▶equipment and consumables that you no longer need properly. Comply with all relevant disposal regulations regarding potentially contaminated waste.

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

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

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

2 Safety

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

Qualified personnel

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

Power cable and power plug

- Only the power cable included in the scope of delivery may be connected to the device.
- The power cable may only be replaced by an original spare part from MELAG.
- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- The power cable or plug should only be replaced by ▸authorised technicians.
- Never damage or alter the power plug or cable.
- Never bend or twist the power cable excessively.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Ensure that the power cable does not become jammed in.
- Never lead the cable along a source of heat.
- Never fix the power cable with sharp objects.
- The mains socket must be freely accessible after installation so that the device can be disconnected from the electrical mains at any time if necessary by pulling the mains plug.

Opening the housing

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

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

- Please note that all series incidents that occur in relation to a ▸medical device (e.g. death or a serious deterioration in a patient's state of health), which were presumably caused by the device must be reported to the manufacturer (MELAG) and the competent authority of the member state in which the user and/or the patient resides.

3 Performance specifications

Intended use

The steam sterilizer is designed for application in a medical context (e.g. general practitioners and dental practices, outpatient surgeries, outpatient centres, walk-in healthcare centres, group practices and hospitals). This steam sterilizer is a large sterilizer in accordance with EN 285. As a universal steam sterilizer it is suitable for complex sterilization tasks performed on the basis of the fractionated vacuum procedure. This enables the complete and effective penetration of the ▸load with saturated steam. It can be used to sterilize large quantities of instruments with narrow lumen and transmission instruments – both wrapped or unwrapped – and textiles. Typical users are physicians, trained medical assistants, and service technicians.

⚠ WARNING

Warning of material damage and injury

Any attempt to sterilize fluids can result in a ▸delay in boiling. This can cause damage to the device and/or scalding.

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

Sterilization procedure

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

This procedure enables the sterilization of loads produced in a doctor's practice or clinic in accordance with ▸EN 285.

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

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

Type of the feed water supply

The device works with a feed water one-way system. It uses fresh ▸feed water in the form of ▸demineralised or ▸distilled water for each 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 device.

Safety equipment

Internal process monitoring

A ▸process evaluation system is integrated in the electronics of the device. 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 and ensures a safe and successful program run. A monitoring system checks the device components of the device for their functionality and their plausible interaction. If one or more parameters exceeds pre-determined threshold values, the device issues warning or malfunction messages and if necessary, aborts the program. In the case of a program abort, follow the instructions on the display.

The device works with an electronic parameter control. This serves to optimise the total operating time of a program in dependence on the load.

The device constantly checks pressure and temperature in the sterilization chamber and prevents the door from being opened during the program run and when over-pressure has built up. The motor-driven automatic door lock opens the door slowly by turning the door lock nut and 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.

Independent Registration Device (URG)

The process data is registered using an Independent Registration Device (URG). The process data is determined entirely independently from the control and documented in a log.

Quantity and quality of the feed water

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

Automatic emergency shutdown

The steam sterilizer is equipped with an emergency shut-down mechanism; i.e. the steam sterilizer shuts down automatically if the internal process evaluation system registers a fault which represents a particular hazard situation. Reactivation of the steam sterilizer is only possible after the malfunction has been remedied.

Program runs

A program runs in three main phases: the de-aeration 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 sterilization / drying.

Program phases of a standard reprocessing program

Program phase	Description
1. De-aeration and heating phase	**De-aeration** The de-aeration phase comprises of the conditioning and the fractionating phase. During conditioning, steam is repeatedly injected into and removed from the ▸sterilization chamber. This generates over-pressure and the residual air is removed. Then, during fractionation, the mixture of air and steam is evacuated from the sterilization chamber and steam is injected. This method is also called the fractionated vacuum 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 program parameters (pressure and temperature) are held at sterilization level. The plateau time is indicated on the display.
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, so-called vacuum drying.
	Ventilation Upon program end, the sterilization chamber is filled with sterile air via the air filter and adjusted to the ambient pressure. A corresponding display message **`Ventilation`** is shown.

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 5 min will follow.
3. Measurement time	The measuring time is 10 min. 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 sterilization 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.

4 Description of the device

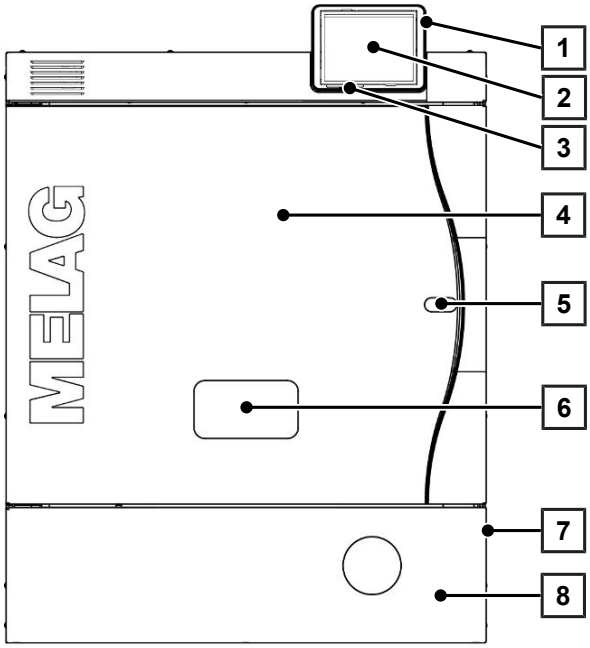
Scope of delivery

Check the scope of delivery before setting up and connecting the device.

- Cliniclave 45 M or Cliniclave 45
- User manual
- Technical manual
- Record of installation
- Manufacturer’s inspection report and declaration of conformity
- Warranty certificate
- CF card
- Slide rail Comfort or Slide rail Basic
- Protective gloves
- 4x Carrying handle
- Transport bars set (only for separate dispatch of the device and floor unit)
- 4x Screw M12x12
- Outlet hose
- Open-end spanner for the validation fitting connection/floor unit casters
- Ring spanner for the validation fitting retaining nut
- Allen key with which to open the door in an emergency
- MELAG oil for door lock nut
- Test gauge TR20 for door lock nut
- Test system for Bowie & Dick test
- Installation set (dispatched in advance)

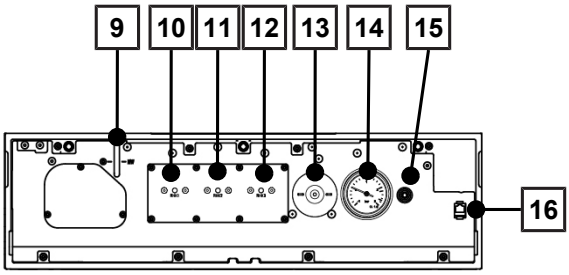
Views of the device

Front



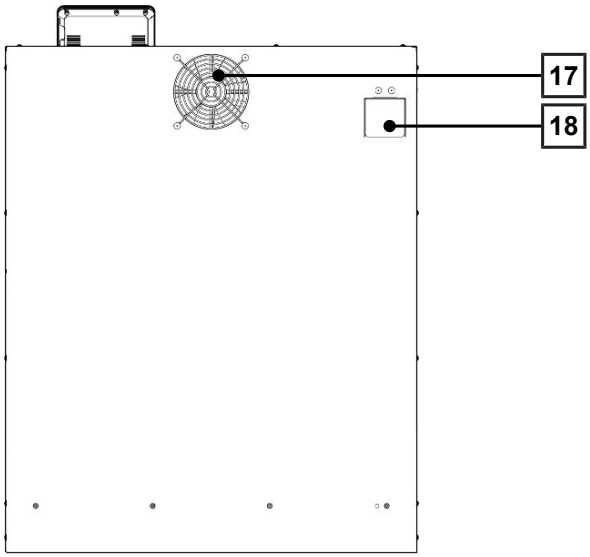
1 CF card slot
2 Colour touch display
3 LED status bar
4 Door (swings open left/right)
5 Opening for door opening in an emergency*)
6 Validation fitting*)
7 Power switch (covered, accessible from the side)
8 Service hatch
*) behind cover

Detailed fore view with service hatch open



9 Steam generator level gauge
10 Reset button overheat protection RHK1 (safety temperature limiter)
11 Reset button overheat protection RHK2 (safety temperature limiter)
12 Reset button overheat protection RHK3 (safety temperature limiter)
13 Sterile filter
14 Manometer (double jacket steam generator)
15 Opening for emergency activation of the vacuum pump
16 Service connection of network cable (RJ45)

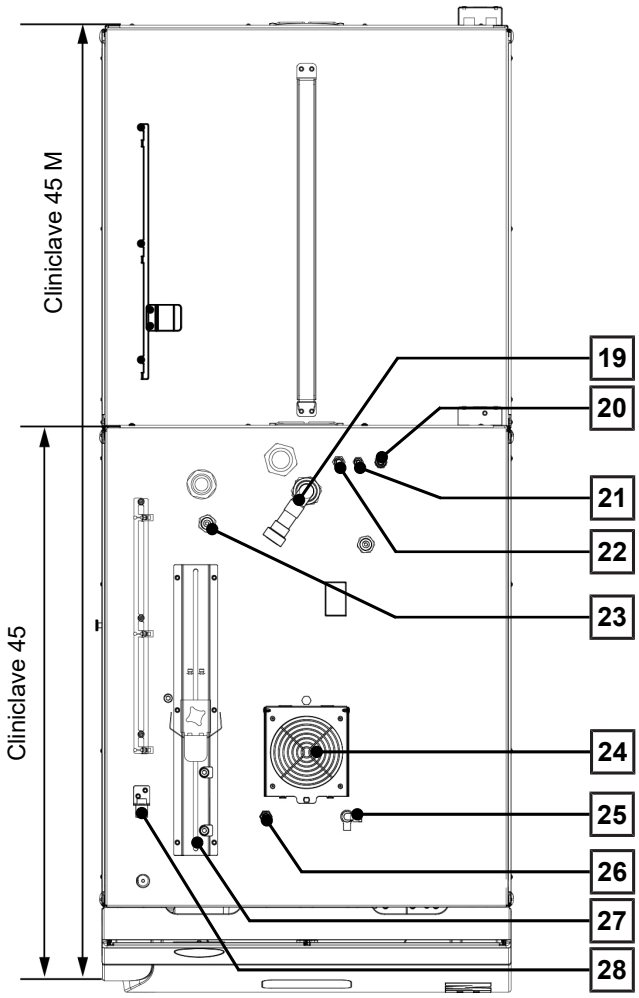
Rear



17 Fan

18 Pressure and emergency release behind cover plate

Underside



19 Wastewater connection

20 Feed water inflow of water treatment unit

21 Connection of the concentrate line water treatment unit

22 Cold water inlet of water treatment unit

23 Power plug connection MELAdem 56/56 M

24 Fan

25 Tap for manual emptying of the air gap

26 Connection for decalcifying the vacuum pump (for service technicians only)

27 Bracket and tensioning carriage for the outlet hose

28 Connection of the network cable

Symbols on the device

The following overview lists all possible symbols. Only the symbols specific to the device are attached on the device or its packaging.

Type plate


Manufacturer of the product


Date of manufacture of the product



Label as medical device



Article number of the product



Serial number of the product


Observe user manual or electronic user manual


Do not dispose of product in household waste


CE marking



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



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



Volume of the sterilization chamber


Working overpressure in sterilization chamber


Operating temperature in sterilization chamber


Electrical connection of the product: Alternating current (AC)

Other symbols

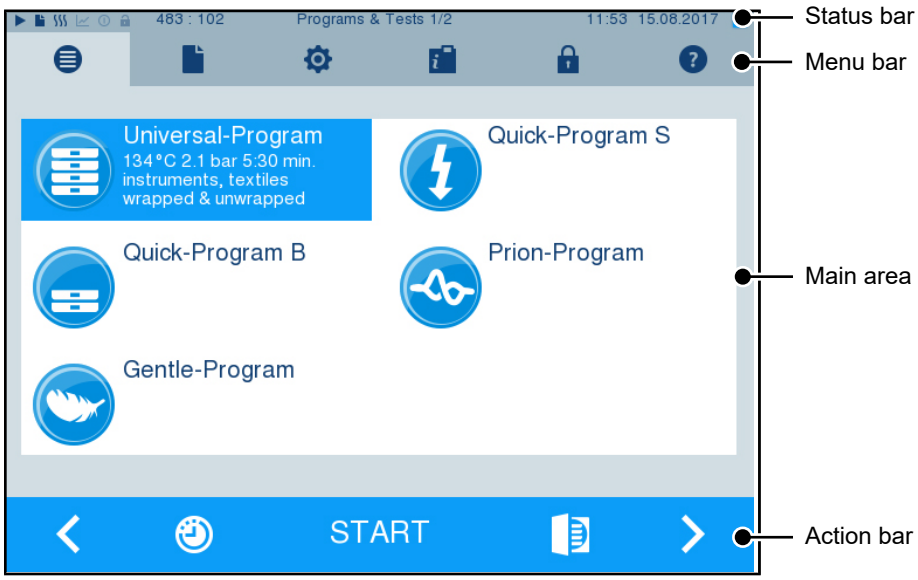
XX REP	Authorised representative of the relevant federal state or area of responsibility
	This symbol indicates that the device is live. Contact with live parts result in serious injury and danger to life.
	This symbol indicates areas are subject to the influence of high temperatures. Contact with these areas can result in burns. This symbol also indicates the possibility of steam egress. Sign in the door area: “Attention hot surfaces”.
	This symbol draws attention to an increased danger of crushing resulting from the improper closure of the door. Comply with the instructions outlined in the corresponding chapter.

Symbols on the power switch

	Switching on device
	Switching off device

Colour touch display

The operating panel consists of a colour 5.7 inch touch display.



Symbols in the status bar		Description
	Program/tests	Indicates whether a program/test is running
	Immediate output	Indicates whether immediate output is activated/deactivated
	Additional drying	Indicates whether additional drying is activated/deactivated
	Graphic logs	Indicates whether the graphic log recording is activated/deactivated
	Energy-saving mode	Indicates whether the steam sterilizer is currently in energy-saving mode
	Service area	Indicates whether a service technician is logged-in to the service area
	CF card status	Indicates whether a CF card has been inserted and whether a reading or writing action is in process

Symbols in the menu bar		Description
	Program/tests	Lists all reprocessing programs and tests, e.g. Vacuum test, Bowie & Dick test.
	Log output	Here you can display the entire log list or the list of logs from a restricted time (e.g. day, month). You can also delete specific log types and logs.
	Settings	Here you can perform various settings (e.g. date and time, brightness). It also enables one-time setting of the standard logging settings regarding log output.
	Info/status window	Displays information regarding the software version and device data, e.g. total number of batches, maintenance counter, log settings, log memory, and further technical values.
	Service area	Only for service technicians.
	Help menu	Depending on the window selected and the operating situation, gives information regarding operation or the function of the window currently selected.

Symbols in the action bar		Description
	Door open	Opens the door of the steam sterilizer
	Back	Navigates to the previous window
	Forwards	Navigates to the next window
	Cancel/return without saving	Navigates to the superordinate menu, leaves the window without saving
	Zoom (+)	Displays further details such as further values after a completed program
	Start time pre-selection	Navigates to the menu **`Start time pre-selection`**
	Delete	Deletes logs from the internal log memory/deletes the log printer or label printer stored as standard
	Search	Search for label printer / log printer
	Skip	Navigates to the next window without entry of the required data

LED status bar

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

Colour	Description
Blue	Standby, program running, drying has not yet begun
Green	Drying running, program completed successfully
Yellow	Warning message, software update is running
Red	Malfunction message, program not completed successfully

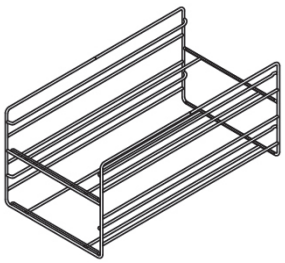
Load mount

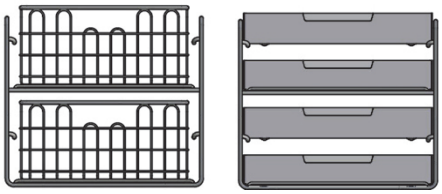
PLEASE NOTE

We do not recommend using the mounts in the rear half of the Cliniclave 45 M with the loading system Basic. In this case, use the loading system Comfort.

Mount for 2 instrument baskets or 4 large trays

One mount of this type can be used in the Cliniclave 45 and two mounts of this type can be used in the Cliniclave 45 M.





for 2 instrument baskets or 4 large trays

5 First steps

Setup and installation

PLEASE NOTE For setup and installation, observe the information in the technical manual. This contains all building-side requirements.

Comply with the following for safe handling:

- Check the device after unpacking for any damage suffered during transport.
- The device should only be setup, installed and commissioned by MELAG authorised persons.
- Have the electrical connection and the water supply and waste water connections installed only by trained personnel.
- Using the optional electronic leak detector (water stop) minimises the risk of water damage.
- Do not install or operate the device in potentially explosive areas.
- 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.
- The documentation media (computer, CF card reader etc.) must be placed in such a way that they cannot come into contact with liquids.

Record of installation

As evidence of proper setup, installation and initial commissioning as well as your warranty claim, the record of installation must be completed by an authorised specialist and a copy sent to MELAG.

Feed water supply

Use of high quality feed water

▸Distilled or ▸demineralised/deionised water is required for the steam sterilisation. ▸EN 285 recommends compliance with the guide values in Annex B, Table B.1 when using feed water, see Technical manual. For normal operation of the steam sterilizer, the value of 5 µS/cm recommended in Table B.1 of EN 285 should not be exceeded.

The feed water from the MELAdem 56/MELAdem 56 M reverse osmosis unit fulfils the requirements placed on feed water.

Because of the design of the steam generator and the process used for steam generation with integrated degassing, higher conductivity values are permissible for short periods in exceptional cases. This also keeps the practice running:

- Regularly check the current conductivity of the feed water.
- Plan for a prompt replacement of the mixed bed resin cartridge if the conductivity is above 5 µS/cm.
- The display issues a warning message once conductivity has reached 20 µS/cm. Replace the mixed bed resin cartridge, or check the system.

The feed water supply in the steam sterilizer

The feed water is preferably supplied via the MELAdem 56 or MELAdem 56 M water treatment units. These water treatment units produce the optimum feed water quality for the steam sterilizer. The water treatment units are supplied via the air gap integrated in the steam sterilizer. This prevents the water from flowing back into the drinking water supply and corresponds fully to the requirements of ▸EN 1717 (fluid category 5). For more information, see the user manual of the water treatment unit.

PLEASE NOTE If you would like to use a water treatment unit from another manufacturer, please contact MELAG first and observe the installation instructions.

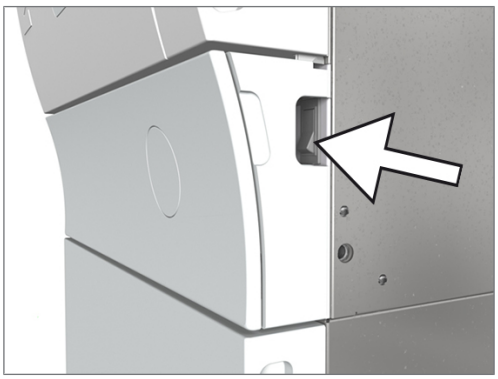
Switch on the device

The following must be fulfilled or present:

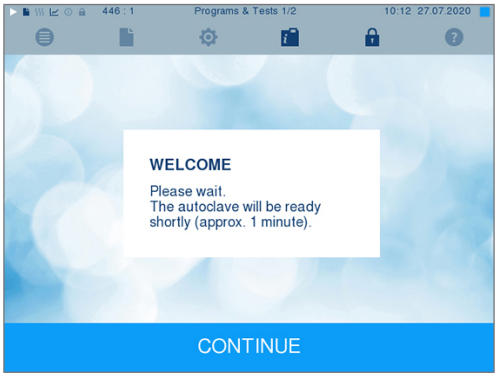
✓ The device is connected to the power supply.

✓ The feed water supply is secure.

1. Switch on the device at the power switch.



2. When the welcome screen appears, press CONTINUE. The display changes to the main menu.



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

After device activation, a ▸pre-heating time of approx. 20 min is required depending on the device type. This time is required for the pre-heating of the double jacket steam generator.

Opening and closing the door

The steam sterilizer is fitted with a motor-driven automatic door locking mechanism with a threaded spindle. Entry on the display is only possible when the door is closed.

⚠ CAUTION

Warning of injury

Swinging the door can cause crushing or bruising.

- Always hold the door on the lateral grips intended for this purpose.

Opening the door

The door is opened by pressing on the door symbol  on the display.

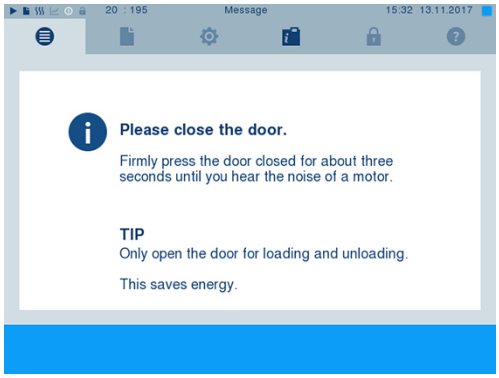
When opening the door, comply with the following instructions, so as to ensure faultless operation of the door locking mechanism.

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

PLEASE NOTE The door is to be left open only whilst loading and unloading the steam sterilizer. Keeping the door closed saves energy.

Closing the door

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



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

- Make sure that the brakes on the casters have been engaged.
- Do not slam the door.
- Keep pressing the door closed until the door lock engages.

Manual door emergency-opening

CAUTION

Warning of scalding

On opening the door, steam and hot water can escape from the sterilization chamber. e.g. if it is necessary to open the door immediately after the end of a program. This could result in scalding.

- Should steam be issued from the rear of the device after its deactivation, wait until the procedure has finished. Wait a further 5 min before opening the door.
- Stand to one side of the door and maintain sufficient distance.
- Allow the sterilization chamber to cool before removing the load.

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

1. Switch off the device at the power switch.

2. Remove the cover cap in order to enable the door emergency-opening by pressing the cover cap that is on the side of the door towards the centre, inwards (i.e. on a door closing to the right on the right-hand side; on a door closing to the left on the left-hand side of the cover cap).



3. Lever the cover cap out of the opening at an angle. Observe the retaining brackets whilst doing so.



4. Remove the 10 mm Allen key included in the scope of delivery from its bracket in the floor unit. Insert it in the door lock nut behind the opening.



5. Turn the Allen key in an anti-clockwise direction to open the door.

6. Remove the Allen key after opening and return the cover cap.

6 Loading the steam sterilizer

Preparing the load

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

Comply with the following for safe handling:

- Only ever use packaging material and systems which have been cleared by their manufacturer for steam sterilization.
- Only use original MELAG articles or third-party articles approved by MELAG. No warranty can be provided for non-approved third-party articles, even if validation has been successfully carried out.

Reprocessing textiles

The incorrect reprocessing of textiles, e.g. a textile package can prevent steam penetration or produce poor drying results. This may result in the textiles **not** being sterile.

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

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

Reprocessing instruments

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

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

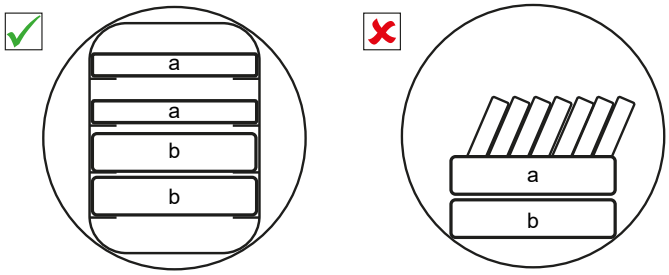
- Always observe both the instrument manufacturer's reprocessing instructions and the relevant standards, guidelines and directives (in Germany, for example, from ▸RKI, ▸DGSV and ▸DGUV Regulation 1).
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with demineralised or distilled water, and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- Re-dry the spray, air and water channels using medical compressed air.
- 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. MELAG recommends the use of MELAG Care Oil Spray.
- When using ultrasound devices, care equipment for handpieces and washer-disinfectors, comply with the manufacturer's reprocessing instructions.
- Remove any residual disinfection and cleaning fluids to avoid corrosion. Otherwise, this could result in increased maintenance requirements and a restriction of the device function.

Loading the steam sterilizer

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

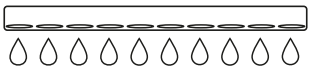
Ensure the following during loading:

- Insert trays or sterile containers in the sterilization chamber only with their appropriate mount.



a Tray
b Sterile container

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



Packaging

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

Closed sterile containers

Please comply with the following when using closed sterile containers:

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

PLEASE NOTE: For very heavy loads (e.g. orthopaedic instruments) that can produce large quantities of condensate, MELAG recommends the use of containers with condensate drains, e.g. from Wagner.

Soft sterilization packaging

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

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

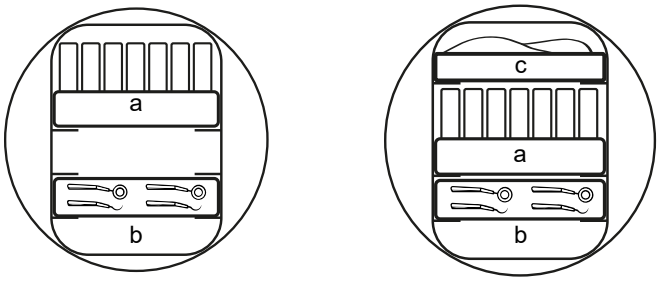
Multiple wrapping

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

Mixed loads

Please observe the following when sterilizing mixed loads:

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



a Wrappings
b Heavy loads/instruments
c Textiles

Load quantities and versions

Max. weight per component

Load	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.

For more information, see Selecting the program [▸ page 25].

Loading variants per sterilization module (StM)

Type of mount*)	Loading version
Mount for 2 instrument baskets or 4 large trays	max. 4 large trays max. 2x ½ StM sterilization container 2x ½ StM instrument baskets
Mount for 8 small trays**)	max. 24 dental trays (8 per mount)
Without mount	max. 1 sterilization module (1 StM)

*) For mounts, trays, etc. from MELAG, see Load mount [▸ page 15]

**) We do not recommend using the mounts in the rear half of the Cliniclave 45 M with the loading system Basic. In this case, use the loading system Comfort.

Loading system Comfort

MELAG provides a loading system Comfort consisting of a loading trolley, slide rail, batch slider and loading hook. This enables effortless and ergonomic loading and unloading of the steam sterilizer. For information on setting and using the loading trolley see User manual Accessories for large steam sterilizers.

Refer to the user manual of the sterilization containers used. Never exceed the max. permissible load quantity and weight specified by the manufacturer.



7 Sterilization

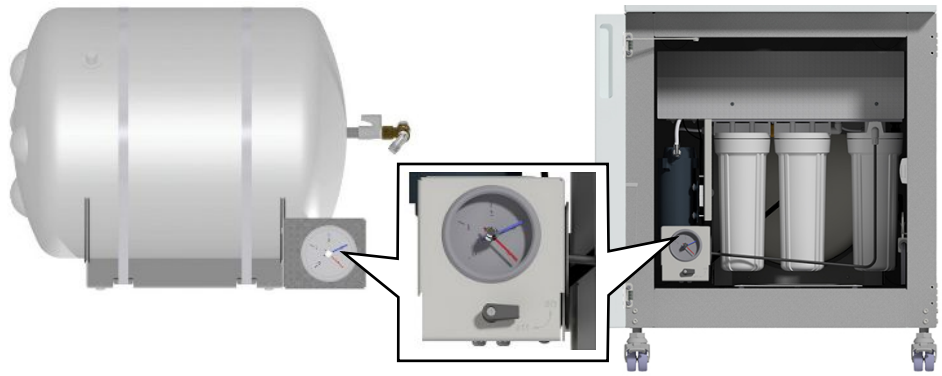
Important information regarding routine operation

Daily routine checks

- Check the sterilization chamber and seal for proper condition, see Maintenance [▸ page 61].
- Check the operational readiness of the recording equipment, see Logging [▸ page 35].
- Perform a Bowie & Dick test (steam penetration test), see Function checks [▸ page 42].

When using the MELAdem 56/56 M water treatment unit

- Perform regular checks of the pressure on the pressure tank manometer before first program start. With daily operation, the pressure tank is still sufficiently full from the previous day.
- The blue pointer shows the current pressure of the water treatment unit.
- The red pointer is used to check the maximum pressure of the water treatment unit.



left: pressure tank MELAdem 56 | right: MELAdem 56 M

Pressure in the pressure tank (blue indicator)	Description	Measure
3-4 bar	Recommended operating pressure	--
< 2.5 bar	Little feed water in the pressure tank	Leave the steam sterilizer switched on so that the water treatment unit can produce feed water.
< 1 bar	No or insufficient feed water in the pressure tank	Leave the steam sterilizer switched on so that the water treatment unit can produce feed water. A warning or malfunction message will be displayed.

Further routine checks

EN ISO 17665-1 and ▸DIN 58946-7 prescribe the following fundamental procedures for routine operation:

When is it necessary to make checks?	How should the checks be made?
Before starting routine operation	Installation qualification (IQ); Operational qualification (OQ); Performance qualification (PQ)
Monthly	Vacuum test
After 4000 cycles but after 12 months at the latest	Maintenance

When is it necessary to make checks?	How should the checks be made?
After changes to the steam sterilizer and its supply	Operational qualification (OQ)
After changes to the configuration	Renewed performance qualification (PQ) for a particular reason
At fixed intervals after 12-24 months*)	Renewed performance qualification (PQ)
*) In accordance with the stated standards and according to the assessment of the person performing the validation.	

Selecting the program

Select the reprocessing program according to whether and how the ▸load is wrapped. It is also necessary to take into account the temperature resistance of the load. All sterilization and additional programs are displayed in the **Programs & Tests** menu. The following tables show you which program you use for which load and which additional programs are also available to you.

The stated operating time does not include drying and depends on the load and the setup conditions, e.g. mains voltage and air pressure. The device requires an additional one-off heating-up time to pre-heat the double jacket steam generator after activation. For normal operation, this amounts to approx. 20 min.

When taking into account the specified load quantity, the program-specific drying times (time-controlled drying) ensure excellent drying of the sterile material. Additional drying [▸ page 54] can be activated for particularly difficult drying tasks. Intelligent drying [▸ page 55] is activated in the as-delivered state.

Drying for 35 kg or 70 kg loads was tested with dental containers and MELAstore Box. Drying of other large weights (20-40 kg/40-80 kg wrapped) or other load configurations must be checked on site for each case. Activate additional drying if necessary.

Universal-Program

	134 °C 2.1 bar 5:30 min	Suitable for	• Transmission instruments • Products with narrow lumen • Simple hollow bodies

Load type	Load quantity		Operating time		Drying	
	45	45 M	45	45 M	Time-controlled	Intelligent
Partial load: • unwrapped • single wrapped • multiple wrapping	15 kg	30 kg	approx. 23 min	approx. 27 min	20 min	4-30 min
Full load: • unwrapped • single wrapped • multiple wrapping	40 kg 35 kg 35 kg	80 kg 70 kg 70 kg	approx. 35 min	approx. 48 min	20 min	4-30 min
Textiles: • single wrapped	max. 7 kg	max. 14 kg	approx. 26 min	approx. 35 min	20 min	4-30 min

Quick-Program B

	134 °C 2.1 bar 5:30 min	Suitable for	• Transmission instruments • Products with narrow lumen • Simple hollow bodies

Load type	Load quantity		Operating time		Drying	
	45	45 M	45	45 M	Time-controlled	Intelligent
Partial load: • unwrapped • single wrapped • multiple wrapping	15 kg	30 kg	approx. 22 min	approx. 27 min	approx. 10 min	4-30 min
No textiles	--	--	--	--	--	--

Quick-Program S

	134 °C 2.1 bar 3:30 min	Suitable for	• Simple solid instruments • Simple hollow bodies

Load type	Load quantity		Operating time		Drying	
	45	45 M	45	45 M	Time-controlled	Intelligent
Partial load: • unwrapped	15 kg	30 kg	approx. 17 min	approx. 22 min	approx. 6 min	4-30 min
No textiles	--	--	--	--	--	--

Gentle-Program

	121 °C 1.1 bar 20:30 min	Suitable for	• Thermo-unstable equipment (e.g. plastic, rubber, textiles) • Products with narrow lumen • Simple hollow bodies

Load type	Load quantity		Operating time		Drying	
	45	45 M	45	45 M	Time-controlled	Intelligent
Partial load: • single wrapped • multiple wrapping	15 kg	30 kg	approx. 36 min	approx. 45 min	20 min	4-30 min
Textiles: • single wrapped	7 kg	14 kg	approx. 42 min	approx. 53 min	20 min	4-30 min

Prion-Program

	134 °C 2.1 bar 20:30 min	Suitable for	• Instruments with more stringent sterilization requirements*) • Transmission instruments • Products with narrow lumen • Simple hollow bodies

*) The Prion-Program provides an extended plateau period at 134 °C to help reduce the risk of prion transmission - particularly when users comply with the applicable national or institutional requirements for handling potential prion contamination. The Prion-Program does not ensure complete inactivation of prions and does not claim prion inactivation.

Use the Prion-Program only as part of a validated overall reprocessing procedure, including thorough pre-cleaning and, where required, chemical prion decontamination in accordance with the applicable guidelines.

Use the Prion-Program only in accordance with the national or international guidelines applicable to you, e.g. “Hygiene requirements for the reprocessing of medical devices. Recommendation of the Commission for Hospital Hygiene and Infection Prevention (▸KRINKO) at the Robert Koch Institute (▸RKI) and the Federal Institute for Drugs and Medical Devices (▸BfArM)” (2012, PMID: 23011095; German national guideline).

Always discard reusable medical instruments that have been in contact with high- or medium-risk tissue from patients with suspected or confirmed Creutzfeldt-Jakob disease - whether owned or borrowed. Prion proteins may be resistant to conventional sterilization processes!

Load type	Load quantity		Operating time		Drying	
	45	45 M	45	45 M	Time-controlled	Intelligent
Partial load: • unwrapped • single wrapped • multiple wrapping	15 kg	30 kg	approx. 38 min	approx. 42 min	20 min	4-50 min
Full load: • unwrapped • single wrapped • multiple wrapping	40 kg 35 kg 35 kg	80 kg 70 kg 70 kg	approx. 50 min	approx. 63 min	20 min	4-50 min
Textiles: • single wrapped	7 kg	14 kg	approx. 41 min	approx. 50 min	20 min	4-50 min

Additional program options

Additional drying

The program-specific drying times ensure excellent drying of the sterile items. For difficult drying tasks, you can activate the additional drying – also subsequently during a running program, see Additional drying [▸ page 54].

Start time pre-selection

NOTICE

Warning of material damage to the device or the equipment

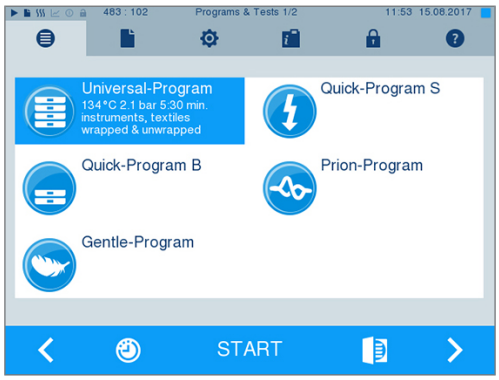
Unsupervised operation can result in material damage to the device and the equipment. Unattended operation is performed at the operator’s risk. In such a case, MELAG does not accept any liability.

- Never operate the device unattended.

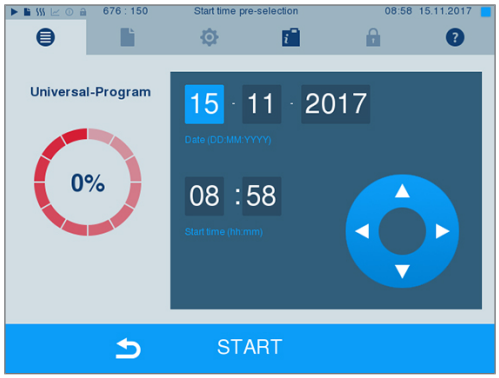
This function enables you to select any program and start it at a time of your choice. The start time pre-selection is only active for the unique time and program selection. This means that after completion of the program, the pre-selected start time expires. You can switch off the steam sterilizer during the start time pre-selection. However, the steam sterilizer must be switched on before the timer runs out.

Note that this function is not possible for the Quick-Program S due to the confirmation prompt. To set a program start to a particular time, proceed as follows:

1. After selecting the program, press the  symbol in the action bar. The display switches to the settings window.



2. For example, to change the time, directly tap the parameter **`Hour`** or **`Minutes`**. The selected field is highlighted light blue.



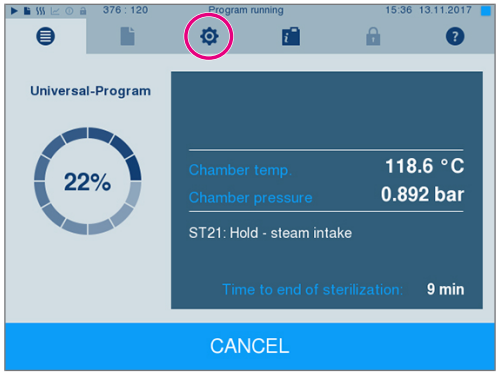
3. Change the hour, for example, by pressing the  or  buttons.
4. Then press START. The display remains in the start time pre-selection window.

➥ After the start of the start time pre-selection no other menu apart from the **`Info & Status`** menu can be selected.

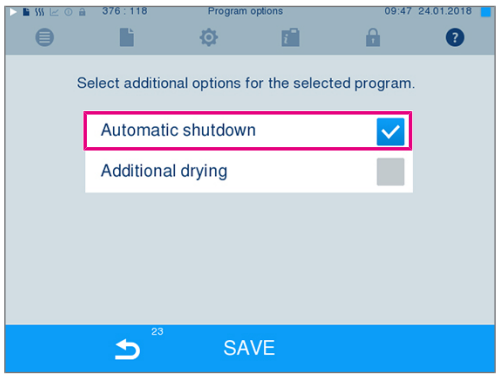
Automatic shutdown

Activating the automatic shutdown function enables the automatic deactivation of the steam sterilizer at the end of a program, e.g. after the last batch at the end of the day. Batch approval can be performed by reactivating the steam sterilizer as usual. Proceed as follows to activate automatic shutdown for the next program run:

1. Select the desired program.
2. Press START.
3. Select the **`Settings`** menu. The display switches to the following window.

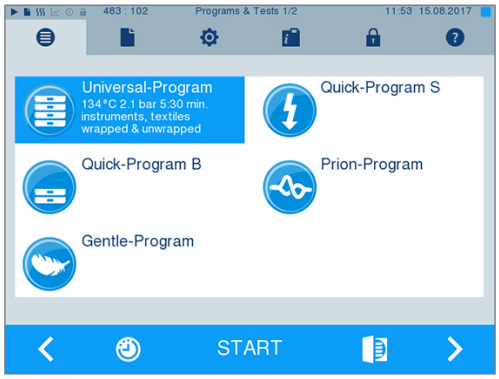


4. To activate automatic shutdown, set a checkmark and confirm with SAVE.



Starting the program

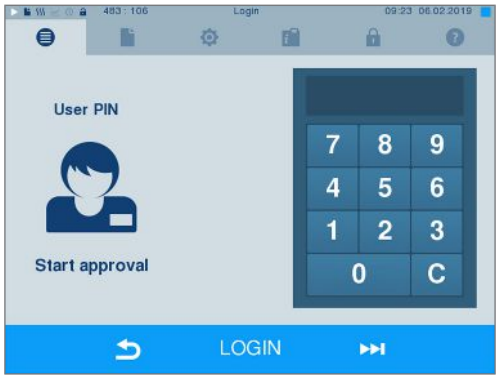
1. To start a program, press the START button.



   ↪ The door closes pressure-tight and the device controls the amount of ▸feed water and its ▸conductivity.

2. With activated user authentication: Enter the user PIN or, if possible, press the button ▶▶| to skip, see User administration [▸ page 50].

   PLEASE NOTE: Use the function “Skip user authentication” only in an emergency.



PLEASE NOTE When starting Quick-Program S, a warning and an acoustic signal indicates that this program is suitable only for the sterilization of unwrapped instruments. If the load contains unwrapped instruments only, confirm with YES to start the program.

Program in progress

A program runs in three main phases: the de-aeration 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 sterilization / drying.

Air removal and heating phase

During this phase, the steam will be injected and removed from the sterilization chamber (conditioning) to generate over-pressure and remove residual air. Then, during fractionation, the mixture of air and steam is evacuated from the sterilization chamber and steam is injected. This reduces the level of residual air in the sterilization chamber to a minimum. At the same time, the requirements for pressure and temperature are created for sterilization.

Sterilization phase

In the sterilization phase, pressure and temperature are held in the area required for sterilization.

The display indicates whether the sterilization phase has been completed successfully. The coloured ring and the LED status bar switches from blue to green as soon as the drying phase has been introduced.

The sterilization phase is unsuccessful if the user or the system (responding to an malfunction) aborts the program run. A system abort returns the steam sterilizer to a pressureless state. This explains why a system abort takes longer than an abort by the user.

Drying phase

The steam sterilizer provides excellent drying of the ▸load. Depending on the setting, drying is performed either via the time-controlled drying or the pre-set intelligent drying, see Intelligent drying (DRYtelligence) [▸ page 55]. If difficult-to-dry items require better drying, you can undertake the following steps to improve drying:

- Load the steam sterilizer properly. Stand e.g. the transparent and paper sterilization packaging upright, see Loading the steam sterilizer [▸ page 21]. Use the optional package holder if necessary.
- Time-controlled drying: Activate function **`Additional drying`** in order to extend the drying time by 50%.
- Intelligent drying: Activate function **`Additional drying`** in order to restrict the criteria for ending the drying phase.

Monitoring the program run on the computer

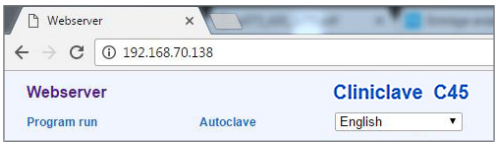
You can follow the current progress of a reprocessing program on every computer in the practice network.

The following must be fulfilled or present:

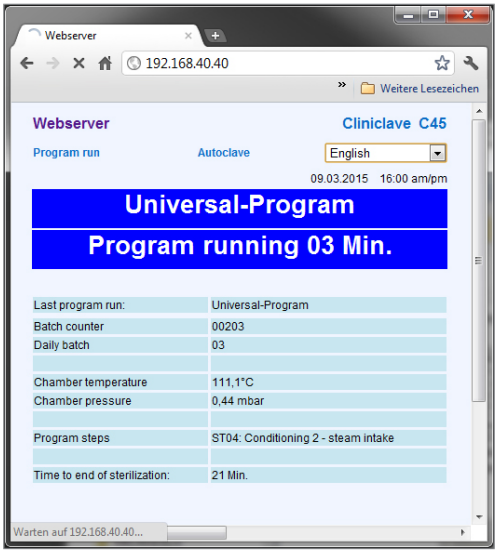
✓ An IP address is assigned for the steam sterilizer.

✓ The steam sterilizer is integrated into the practice network.

1. Open a web browser (we recommend Mozilla Firefox or Internet Explorer/Microsoft Edge) and enter the IP address of the steam sterilizer in the address bar of the web browser e.g. 192.168.57.41.



2. Confirm with [ENTER]. Now you can display the program run or information about your steam sterilizer, e.g. serial number, device software version and selected values.



Manual program abort

You can abort a current program in all phases. If you abort the program before the end of the sterilization phase, the load is **not** sterile.

⚠ WARNING

Warning of burns

Hot steam can be released from the emergency release valve under the rear of the steam sterilizer following a program abort effected with the power switch. This can result in scalding.

- Never cancel a program by switching off at the mains.

Comply with the following for safe handling:

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

Program abort before the start of drying

⚠ WARNING

Warning of contamination

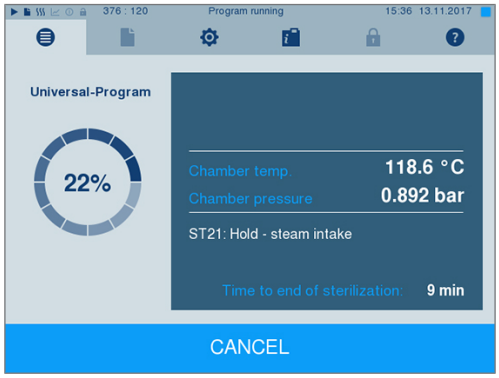
If a program is terminated before drying starts, the load is **not** sterile.

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

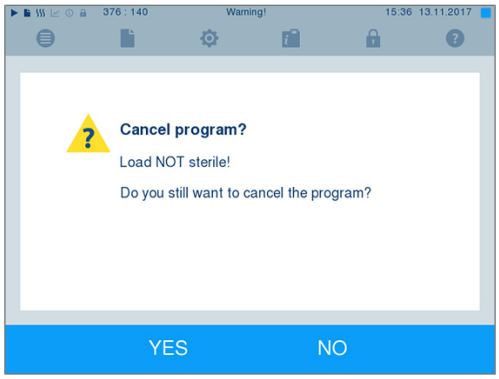
Upon ending a program before the start of drying, the display indicates that the program was NOT completed successfully; this is also recorded on the log.

Should you still wish to do so, proceed as follows to abort the program before drying:

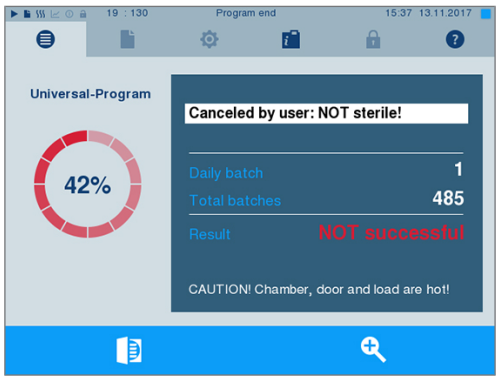
1. Press CANCEL on the action bar.



2. Confirm the security query with YES.



3. After a short time, you can open the door by pressing .



➥ The display shows a warning.

➥ Sterilization is marked on the log as **`NOT successful`**.

Program abort after the start of drying

⚠ CAUTION

Warning of recontamination

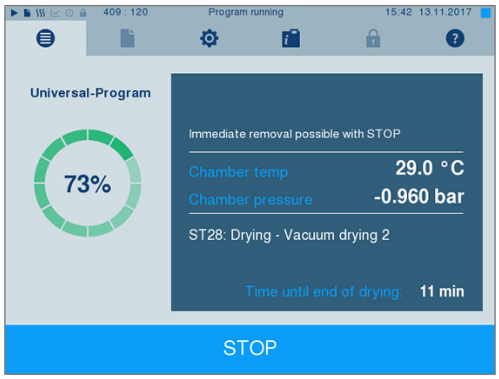
If the drying phase is terminated prematurely, it is possible that the maximum residual moisture (textiles < 1 %, metal < 0.2 %) required by the ▸EN 285 standard cannot be met. This impairs the storage stability of the sterile material.

- Only ever perform a premature drying abort in exceptional cases to effect immediate renewed availability of the device.
- Check the sterile material after a program abort for residual moisture. Never store sterile material when it is still damp, as the residual moisture can result in recontamination of the sterilized material.

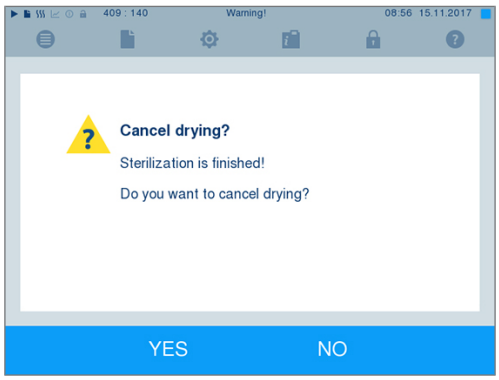
Should you abort a program after drying has started, the sterilization is having been completed successfully. The steam sterilizer will not issue a malfunction message. You should expect insufficient drying, especially in the case of wrapped ▸sterile material and a full load. Sterile storage requires sufficient drying. To ensure this, allow programs with wrapped sterile material to continue to the end of the drying phase as far as possible. Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

Proceed as follows to abort the program during drying:

1. Press STOP on the action bar.



2. Confirm the security query with YES.

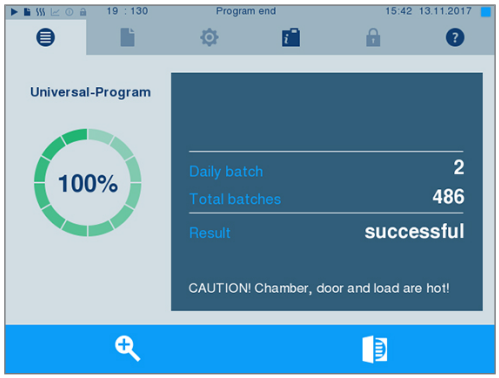


3. After a short time, you can open the door by pressing .

Program end

When the program has ended successfully, the corresponding message will be issued on the display. Before opening the door, you can view further values on the display from the program which has just completed, e.g. the plateau time or ▸conductivity etc. by pressing the zoom symbol .

▶ Press the door symbol  to unlock the door.



If automatic logging after program end is activated (= Immediate output) in the **`Settings`** > **`Logging`** menu, the log of the completed program will be outputted to the activated output medium after opening the door.

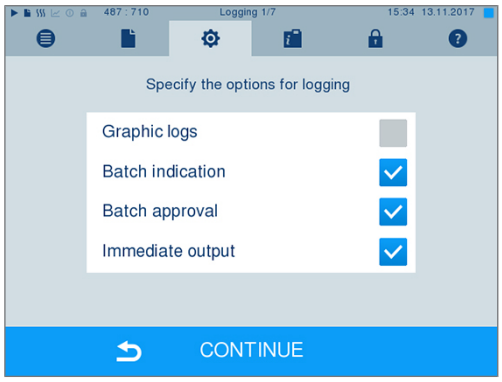
The approval process

In accordance with ▸RKI “Hygiene requirements for the reprocessing of medical devices”, instrument preparation ends with the documented approval 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. This is ensured by the activated user authentication. To do this, enter the user PIN, see Settings [▸ page 44].

PLEASE NOTE

Skipping user authentication means that the batch is not approved.

- Use the function “Skip user authentication” only in an emergency.



Batch indication includes checking the indicators carried in the reprocessing program (e.g. MELAcontrol Helix/SteriHero Helix or MELAcontrol Pro). Approval of the indicator strip is possible only if it changes colour entirely.

Batch approval comprises the checking of the process parameters using the sterilization results on the steam sterilizer and the sterilization log as well as checking of the individual packaging for damage and residual moisture. The sterilization log records the approval of the ▸batch and any indicators. Depending on the setting in the user administration, approval for the ▸sterile material requires the user PIN of the person who provides approval for the batch and the indicators.

Removing the sterile material

⚠ WARNING

Warning of contamination

If packaging is damaged or has burst after sterilization, the instruments are unsterile.

- Re-wrap the load.
- Carry out the sterilization again.

⚠ CAUTION

Warning of burns

Touching hot metal surfaces can cause burns.

- Allow the device to cool sufficiently before opening.
- Never touch the load, the sterilization chamber or the door with unprotected hands.

⚠ CAUTION

Warning of burns

If the mount slips out, it can cause burns.

- Only remove the trays and instrument baskets one at a time from the device.
- Do not remove the mount with trays or instrument baskets on 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 red brochure of 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.
- Use suitable protective gloves to remove the trays.

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:

- 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.

8 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.

Capacity of the internal log memory

The device is equipped with an internal log memory where all data from completed reprocessing programs are stored. The capacity is sufficient for approx. 100 logs. If the internal log memory becomes almost full and at least one log has not been output via an activated output medium, the following warning **`Internal log memory is almost full`** will appear. Prepare the output media specified in menu **`Settings`** > **`Logging`**. Print the relevant logs (menu **`Log output`**).

Print any unprinted logs if message **`Internal log memory full`** appears. By pressing **`YES`**, the data in the device's log memory will be automatically deleted, except for the last 40 logs.

Output media

You are able to output and archive the logs of the completed programs on the following output media:

- ▸CF card
- MELAprint 60 label printer
- MELAprint 42/44 log printer
- A computer (via the practice network)

Any combination of the output media is possible. Log output on multiply activated media is performed successively. In its delivery state, the ▸CF card is activated as the output medium for text and graphic logs from the steam sterilizer. Automatic logging (=Immediate output) is thus activated.

Detailed information regarding the activation and setting of log output is to be found in the chapter Settings, Logging [▸ page 44].

Using the CF card as an output medium

NOTICE

Warning of material damage and data loss

When the CF card is pulled from the card slot prematurely or if it is treated improperly, data loss, damage to the CF card, the device and/or its software may occur.

- Never push the CF card in the slot with force.
- Never remove the CF card from the slot whilst it is being written or read. The square in the upper right-hand corner of the display lights up during reading and writing access.

The card slot for the CF card is located on the right-hand side of the display housing.

Proceed as follows in order to insert the CF card in the slot.

✓ The CF card is set as the output medium in the **Settings** > **Logging** menu.

1. Insert the CF card in the card slot fully with the raised finger edge pointing rightwards and to the rear.
   If the CF card is inserted correctly, a blue square will illuminate in the right upper corner of the display.



2. Check whether the CF card has been selected as the output medium.

Using the computer as an output medium

You can connect the steam sterilizer directly to a computer or integrate it in an existing (practice) network via FTP or TCP. The computer must be fitted with a RJ45 socket (LAN).

For more information on the requirements and setting the computer as the output medium, see Settings, Logging [▸ page 44].

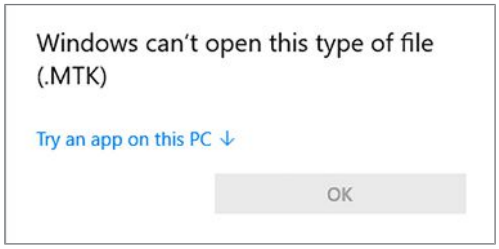
Reading out a text log on the computer

All text logs can be opened and printed using a text editor, a word processing program or a spreadsheet program. Graphic logs can only be displayed with the MELAtrace documentation software.

Each text log (e.g. .PRO, .STR, .STB) must be linked with the text editor to enable the computer to open them automatically with a text editor. For the meaning of the endings, see Subsequent log output [▸ page 38]. The following examples show how you can link the Windows 10 editor with a specific text log.

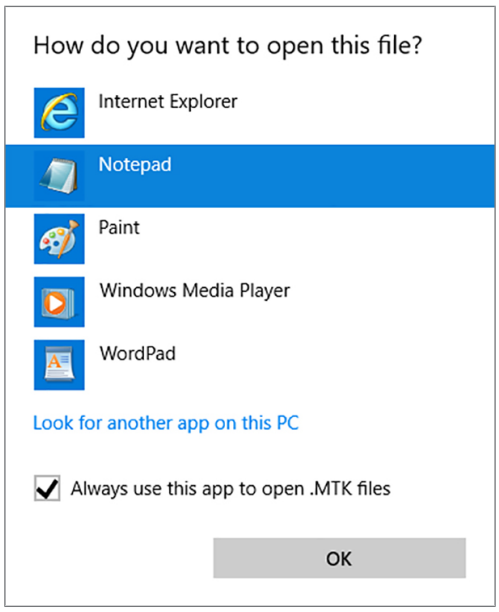
1. In Windows Explorer double click on the log file.

2. If the file ending is unfamiliar, Windows 10 will display the following message:



3. Select “Try an app on this PC”.

4. Mark the editor and confirm with “OK”.



➥ You can then open files with this ending via a double-click in Windows Editor.

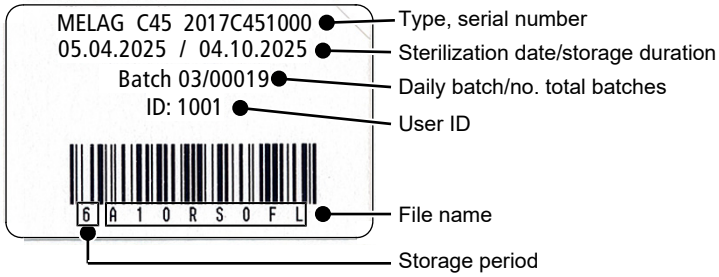
Label printer as output medium

The use of a label printer facilitates batch traceability. By entering the following data, the sterile material can be assigned to the patient and the sterilization batch:

- Sterilization date
- Storage duration
- Batch number (daily / total batches)
- User ID (person who has authorised the sterile material for use)
- Device (type, serial number, program used)
- File name

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

PLEASE NOTE To facilitate easy assignation of a package marked with a label to a specific batch, the sterilization log file name must not be changed.



Outputting text logs automatically after program end (immediate output)

If you would like to output the associated text and graphic logs (optional) on an output medium immediately after the end of a program, use the **`Immediate output`** option. In its delivery state, the immediate output of the text and graphic logs via the CF card after program end is activated.

If the output medium selected for this purpose has not been connected, the logs are saved in the internal memory and a warning is issued. The steam sterilizer provides the option of outputting this log at the next possible opportunity. Graphic logs cannot be saved in the internal log memory; they are lost. For more information about the output of graphic logs, see Outputting graphic logs (optional) [▸ page 45].

The following points must be fulfilled for immediate output:

- The date and time have been set correctly.
- An output medium is selected and connected.
- Instant output is activated in the **Settings** > **Logging** menu.

For more information on setting the instant output with the desired output media, see Settings, Logging [▸ page 44].

Subsequent log output

The **Log output** menu provides the option of outputting text logs subsequently and independently of the point of the program end. You can set the output media yourself. By default, the output media that are also selected under **Settings** > **Logging** are preselected provided that automatic instant output is activated.

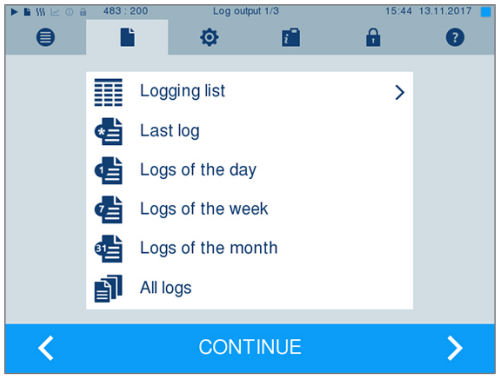
The **Log output** menu offers various opportunities for log output. All program logs present in the memory are displayed in the **Logging list**. You can sort the list according to number, date, time, program, and outcome by pressing on the column headings. Here is an overview of all possible output media.

Name	File ending	Description
Last log	.PRO	The log of the last successful completed program is output.
Logs of the day	.PRO	The log of the last successful program of the current day is output.
Logs of the week	.PRO	Logs of all successfully completed programs of the week – Monday to Sunday – will be output.
Logs of the month	.PRO	Logs of all successfully completed programs performed in the current month will be output.
All logs	.PRO	The logs of all successfully completed programs will be output.
Last fault log	.STR	The last malfunction log is output.
Fault logs of the day	.STR	The malfunction logs of the current day are output.
etc.	...	
Legend log file	.LEG	Contains an explanation of all abbreviations contained in the log.
Status log	.STA	A summary of all important settings and system states (e.g. counter, measured values).
Fault in standby	.STB	This log type is generated following malfunctions during a time at which no program was active.
System log	.LOG	A sort of logbook listing all malfunctions and changes to the system in order of their incidence.
Delete all logs	--	Deletes all logs stored in the internal log memory. **Notice:** All logs that were not previously output to another output medium will be deleted.

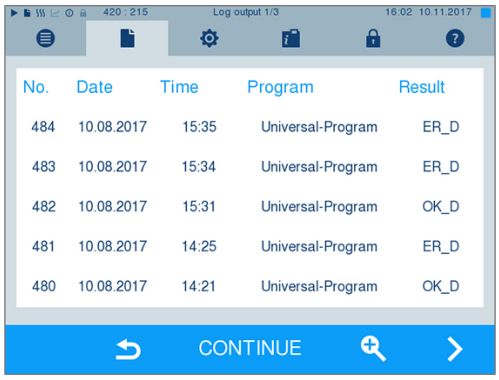
Output a log from the log list

Proceed as follows to output a specific log from the internal memory:

1. Navigate to the **`Log output`** menu, and select **`Logging list`**.

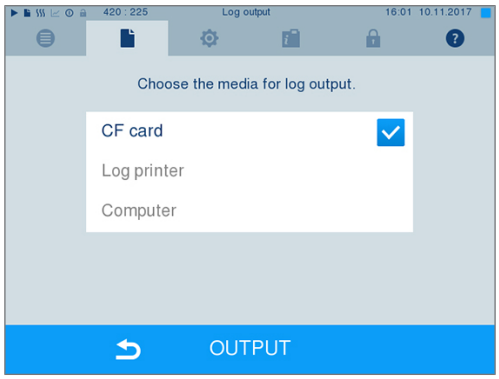


2. A list is displayed with all text logs that have been saved in the internal memory. To facilitate the search, you can filter the log sorting sequence by date, program or outcome by selecting the top line.



3. Select a log and press CONTINUE.

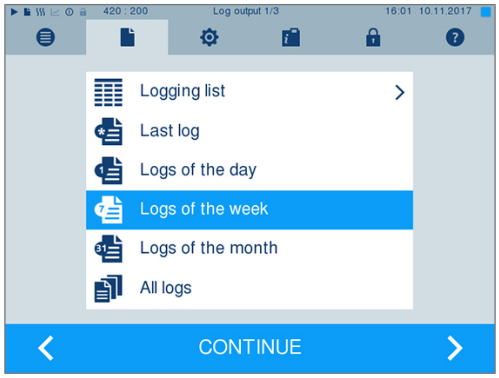
4. Select an output medium and press OUTPUT.



Output the daily, weekly logs, etc.

Proceed as follows e.g. to output all the logs of a week:

1. Navigate to the **`Log output`** menu, and select the **`Logs of the week`** option.



2. Press CONTINUE.

3. Select an output medium and press OUTPUT.

Proceed in a similar fashion to output the last log or all the logs of that day or month or all logs.

Finding logs

PLEASE NOTE If possible, do not rename the directories because otherwise, logs will be stored both in the renamed directory and in the device directory automatically regenerated by the steam sterilizer.

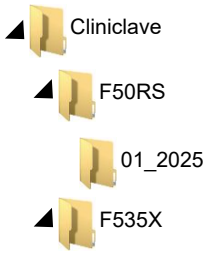
Storage location for logs

When transferring the logs to a CF card, they will be stored in a separate folder in the main directory.

Transfer of the logs to a computer via the network and using the MELAG ▸FTP server allows you to work directly in the FTP server program to determine directly where on your computer the device directory with the log files is to be saved. With output via ▸TCP and MELAtrace, you can work directly in the program to determine the folder in which they are to be saved.

Log directory

A folder is created on all memory media (CF card or computer) after log output containing the encoded serial number of the steam sterilizer concerned. The folder name consists of five characters identical with the first five characters of every log (e.g. B5002). This folder contains sub-folders with the month of log generation, e.g. 01_2025 for January 2025. This contains all logs generated by the steam sterilizer this month. The device directory is entered in the main directory on the ▸CF card.



The steam sterilizer checks the storage medium for every type of log output (immediate output after completed program run or transfer of several logs at once). If a directory does not exist, it automatically creates a directory for the device and the month. If the logs are output repeatedly to the same storage medium, a directory named “duplicate” is created there under the device directory.

For further information on meaning of the log file extensions, see Subsequent log output [▸ page 38].

Example log of a successfully completed program

```
----------------------------------------
!0 01100DDUSN01
!1 F50P100B.PRO
----------------------------------------
10 MELAG Cliniclave 45
----------------------------------------
15 Program:    Universal-Program
20 Program type: 134 °C wrapped
25 Date:       07.12.2025
30 Daily batch: 11 Total: 00011
34 ID load: 1001
35 ID approval: 1001
36 Indicators changed: deactivated
37 Batch released: deactivated
======
40 Universal-Program ended successfully
42 = =
======
45 Temperature:  135.4  +0.18/-0.19 °C
50 Pressure:     2.18   +0.01/-0.01 bar
55 Plateau time: 05 min 30 s
60 Conductivity: 6 µS/cm (1293:72.9)
65 Start time:   20:19:28
70 End time:     21:07:47 (48:19 min)
======
80 SN:2025C450901
======
81 MR   V3.240 12.10.2025
82 Para V3.222 13.10.2025
83 BO   V3.319 12.10.2025
----------------------------------------
Step  Time t[m:s] P[mbar] T[°C]
SP-S  0:00   0:00   1014  115.6
SK11  0:37   0:37   1768  112.6
...
SF12  4:11   0:29    509  112.3
SF13  4:35   0:24   1646  118.7
SF21  4:48   0:13   1306  118.3
SF22  5:38   0:50    191  113.8
SF23  6:13   0:35   1833  121.6
SF31  6:34   0:21   1311  119.4
SF32  7:23   0:49    208  111.4
SF33  8:01   0:38   1923  121.2
SF41  8:24   0:23   1309  119.0
SF42  8:58   0:34    411  103.9
SF43  9:28   0:30   1733  117.8
SH01 10:17   0:49   2873  131.9
SH02 10:37   0:20   2881  132.0
SS01 11:27   0:50   3068  134.1
SS02 16:57   5:30   3182  135.5
SA00 17:42   0:45   1302  112.1
SI01 22:44   5:02    111  116.7
...
SB10 48:12   0:27    812  115.4
SB20 48:18   0:06    923  115.7
SP-E 48:19   0:01    926  115.6
>> Never change code on follow. line<<
01004162271431B28355772AE6B57ADBCB7E4E33
BAD9726B2FA0F21C35C1163FB01A3212051D7144
1CDB905EF84F796276A30186C03200D841E7074F
1D95EB05506D7D2F570B782541402C7750428EBA
A6B2F2193974164CADC55654107BAE108F7C6E46
168873EE811EF43E0822632831E3F25F6E806F37
5F5A38CED888615F1618F38F370C4C27205C836B
>> Authentication of batch log <<
----------------------------------------
0.00   0.0   0.0   0.0 ---.-   0.0
-edk----etm---etd---etp---etv--ett-END-
```

!0 Ident number
!1 File name
---
10 Steam sterilizer type
---
15 Program name
20 Program sterilization parameters
25 Date
30 Daily and total batch number
34 User ID program start
35 User ID program end
36 Batch indication
37 Batch approval
=====
40 Control message
42 Warning or malfunction message upon program abort
=====
45 Sterilization temperature with max. deviations
50 Sterilization pressure with max. deviations
55 Plateau time
60 Conductivity of the feed water
65 Time at program start
70 Time at program end
==========
80 Device serial number
==========
81 Current version of the device firmware
82 Current version of the device parameters
83 Current version of the user interface

Step – Program step

Time – Time (min:s) which has elapsed since the program start

t [m:s] – Duration (min:s) which a program step requires

P [mbar] – Chamber pressure

T [°C] – Chamber temperature

Legend for the program steps:
SK – Conditioning
SF – Fractionation
SH – Holding
SS – Sterilization
SA – Pressure release
ST – Drying
SI – Intelligent drying
SB – Ventilation
SP-E – End

Proof of authenticity (electronic signature)
Should never be altered; decoding the code (by MELAG) indicates whether the data was generated on a MELAG steam sterilizer and has been changed.

Sensor measurement values are displayed here in the case of a malfunction. The values are helpful for a service technician.

9 Function checks

Service programs

Additional programs		Use/function
Vacuum test		For measuring the leakage rate, test with a dry and cold device (test without load)
Bowie & Dick test		Steam penetration test with special test package (available from specialist stockists)
Conductivity meas.		For manual measurement of the ▸feed water quality (conductivity)
Drain		For draining and pressure release of the ▸steam generator, e.g. for service, maintenance or before transport

Vacuum test

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

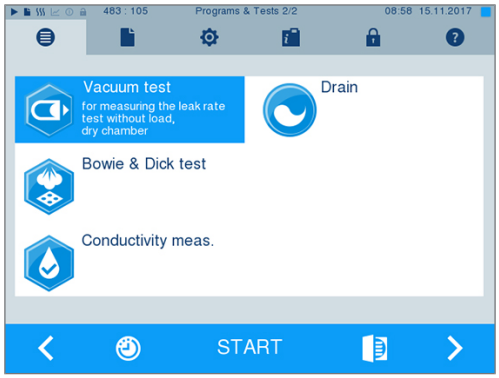
Perform a vacuum test in the following circumstances:

- Once a month in routine operation
- During commissioning
- Following longer operating pauses
- Following a malfunction (e.g. in the vacuum system)

Perform the Vacuum test with the steam sterilizer in a cold and dry state as follows:

1. Switch on the steam sterilizer at the power switch.

2. Working in the **`Programs & Tests`** menu, select Vacuum test and press START.



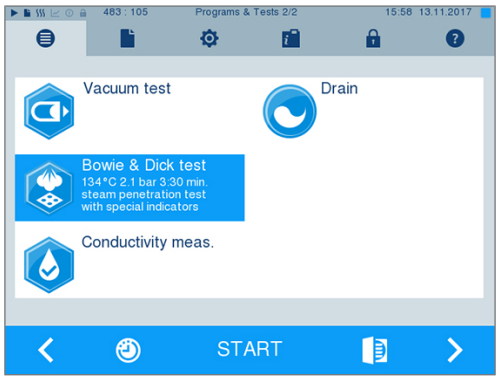
➥ The leakage rate is shown on the display after the vacuum test has been completed. If the leakage rate is higher than 1.3 mbar, a corresponding message will appear.

Bowie & Dick test

The ▸Bowie & Dick test serves as evidence of steam penetration of ▸porous materials such as e.g. textiles. You can perform a routine function check for evidence of steam penetration. To do so, use the **`Bowie & Dick test`** test program with a suitable test system, e.g. MELAcontrol Bowie & Dick Test. Depending on the application, use either a test system for hollow-body instruments or for porous loads (laundry, etc.). Combination test systems can also be used. Perform the Bowie & Dick test in accordance with the test system manufacturer's specifications.

Perform the Bowie & Dick test as follows:

1. Switch on the steam sterilizer at the power switch.
2. Place the test system in the sterilization chamber of the steam sterilizer and close the door.
3. In the **Programs & Tests** menu, select **Bowie & Dick test** and press START.



Evaluation of the indicator following the colour change

Depending on the manufacturer batch, indicators often exhibit differing intensities in the colour change resulting from different lengths of storage or other influences. Of crucial importance for evaluating the Bowie & Dick test is not the strength of contrast in the colour change on the test sheet, but the uniformity of the colour change on the indicator. If the indicator indicates an equal distribution of colour change, the de-aeration of the sterilization chamber is without fault. If the indicators are uncoloured or exhibit less colour in the centre in comparison to the end, de-aeration was insufficient. In this case, contact the authorised technician.

Test body systems

The MELAcontrol Pro, MELAcontrol Helix and SteriHero Helix test body systems comply with the requirements of the ▸EN ISO 11140-6 standard and consist of a test body and an indicator strip. According to the EN ISO 11140-1 standard, MELAcontrol Pro, MELAcontrol Helix and SteriHero Helix are to be classified as type 2 indicators. The test body systems can be used in large steam sterilizers for hollow-body loads in accordance with ▸EN 285. When sterilizing category “critical B” instruments, you should add the test body system to every sterilization cycle as a batch control. Regardless of this, you can perform a steam penetration test in the Universal-Program at any time using a test body system. Intended use of the test body system can result in discolouration of the plastic surface. This discolouration does not have any effect on the functionality of the test body system.

Feed water quality

The conductivity of the feed water is subject to automatic monitoring. Nevertheless, the conductivity should be checked every day before beginning routine operation. If a conductivity of 15 µS/cm or higher is registered, the mixed-bed resin cartridge in the water treatment unit must be changed. A warning message is issued automatically on the display above a conductivity of 20 µS/cm.

PLEASE NOTE

If, despite all warnings, the steam sterilizer continues to be operated with a conductivity of 20 µS/cm or higher, a test body should be added to each batch to check the steam for non-condensing gases. A malfunction message is shown on the display at 35 µS/cm. Further operation is then no longer possible.

Validation

According to ▸EN ISO 17665 and ▸DIN 58946-7, validation of the steam sterilizer should be carried out as part of the sterilization processes before starting routine operation.

Renewed performance qualification (requalification)

▸EN ISO 17665 and ▸DIN 58946-7 recommend renewed performance qualification (requalification) at regular intervals after 12-24 months.

10 Settings

Setting the display position

The display can be set at various positions to permit ergonomic working on the steam sterilizer.

For more information on setting the display position, see Technical manual.

Logging

All settings pertaining to the output of text and graphic logs i.e. output medium, log format, immediate output etc. are performed in menu **`Settings`** > **`Logging`**.

To this end, you are led through a settings wizard.

Immediate log output

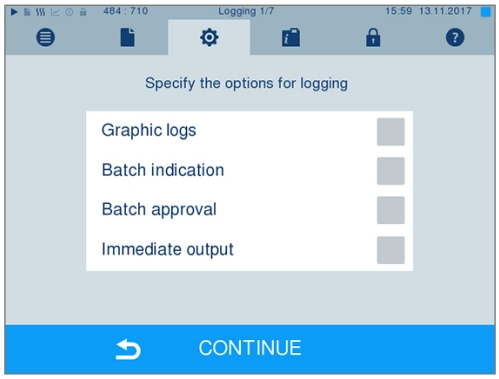
In its delivery state, the immediate output of the text and graphic logs via the CF card is activated.

Deactivating immediate output

If you do not want the log to be output directly after the end of the program but rather once a week, you can deactivate the immediate output as follows:

✓ You are in the **`Settings`** > **`Logging`** menu.

1. Remove the check mark in front of the **`Immediate output`** option.



2. Press repeatedly on CONTINUE until you reach the summary window.
3. Press SAVE to accept all settings and leave the menu.

Outputting graphic logs (optional)

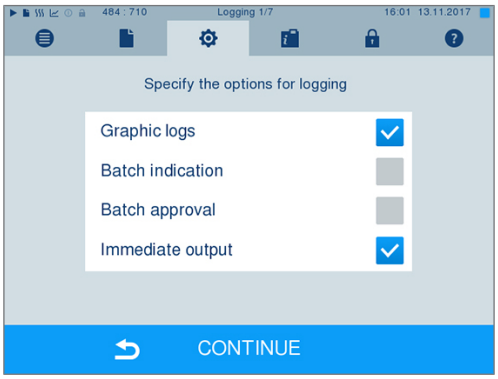
PLEASE NOTE Graphic logs cannot be saved in the internal log memory. A subsequent output of graphic logs is thus not possible.

If you wish to output a graphic log (optional) in addition to a text log, proceed as follows:

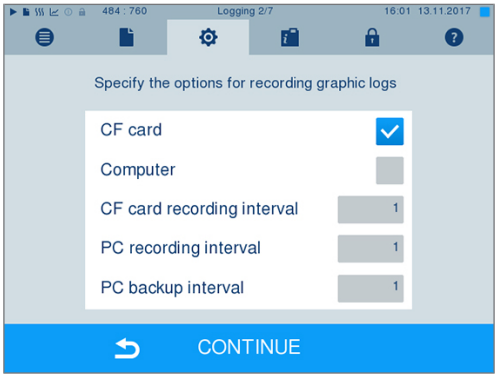
✓ You are in the **Settings** > **Logging** menu.

✓ Immediate output is activated.

1. Set a check mark next to the **Graphic logs** option and check whether the check mark is also set next to the **Immediate output** option.

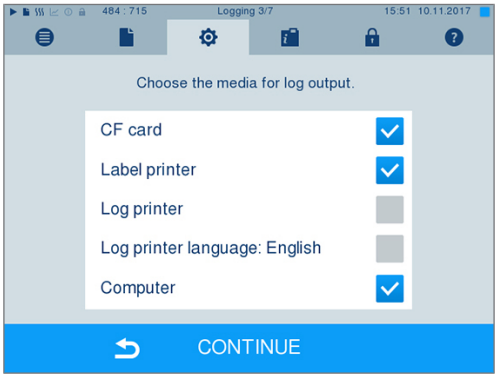


2. Press CONTINUE and select the CF card and/or computer as an output medium.



3. If necessary, change the intervals and press CONTINUE.

4. Working in this window, check whether at least one of the two output media have been selected for text logs.



5. Check whether the activated output medium is connected (computer) or has been inserted (CF card).

6. Press repeatedly on CONTINUE until you reach the summary window.

7. Press SAVE to save the setting.

Explanation of the possible settings for graphic recording:

Interval	Description
CF card recording interval	in seconds – Indicates the time intervals in which the program curve is recorded on the ▸CF card. The smaller the time interval, the more exact the curve. In the example, the time interval is set at one second.
PC recording interval	in seconds – Indicates the time intervals in which the program curve is recorded if the computer is selected as output medium. The smaller the time interval, the more exact the curve. In the example, the time interval is set at one second.
PC backup interval	in seconds – Indicates the time interval in which the graphic data from the steam sterilizer is saved on the computer. In the example, the backup interval is set to one second.

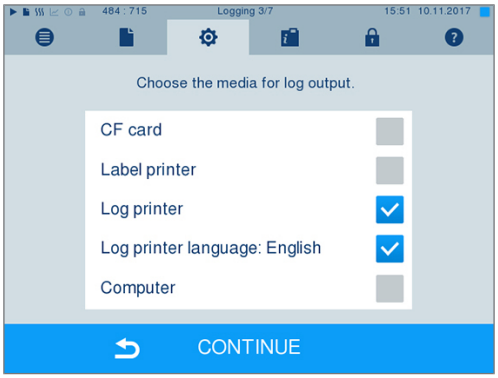
Log output in English

If you want to print all text logs on the MELAprint log printer in English, proceed as follows:

✓ The text log should be printed in English, regardless of the language of the graphical user interface.

✓ You are in the **`Settings`** > **`Logging`** menu.

1. Press CONTINUE repeatedly until you reach the window for selecting the output medium.
2. Select **`Log printer`** as the output medium.
3. Additionally, select **`Log printer language: English`**.



4. Press repeatedly on CONTINUE until you reach the summary window.
5. Press SAVE to accept all settings and leave the menu.

➥ The text logs will be printed in English on the MELAprint log printer.

Using the computer as an output medium

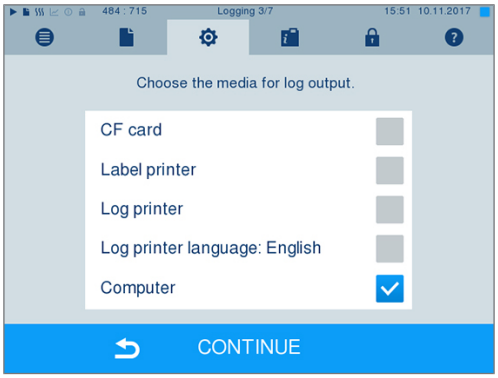
Log transmission can be performed via an FTP server / service or TCP. The following section shows how to set the desired connection:

✓ You are in the **Settings** > **Logging** menu.

✓ The steam sterilizer is connected to a computer via a network cable (RJ45).

✓ Depending on the output type, an FTP server / service or a suitable program (e.g. MELAtrace) is installed.

1. Press on CONTINUE until you reach the window for selecting the output medium.



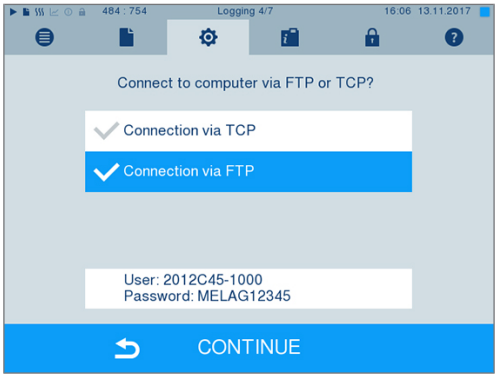
2. Select the computer as an output medium and press CONTINUE.

➥ The selection window opens and asks whether the connection to the computer should be effected via FTP or TCP.

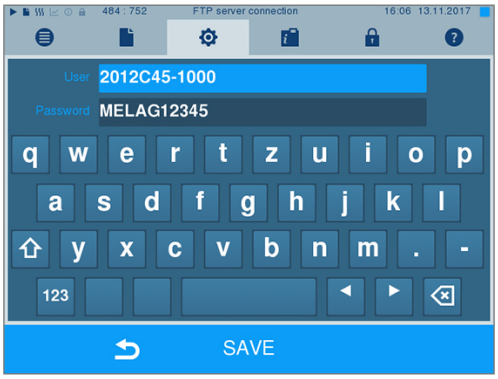
Connection via FTP

✓ An FTP server or an FTP service is installed on the computer.

1. Select **Connection via FTP**. The lower pushbutton displays the current user data settings (standard user name: Year of construction + manufacture number; Password MELAG12345).



2. Press the lower pushbutton to change the pre-set TCP user data. The display switches to the settings window.

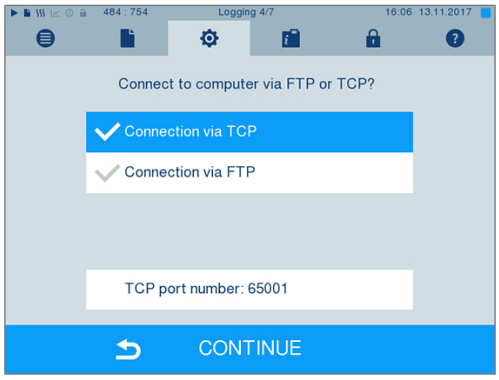


3. Enter the user name and password and confirm with SAVE.

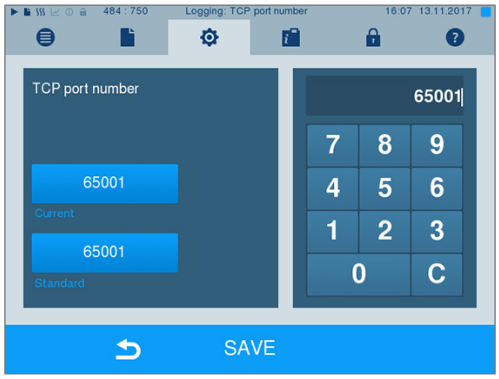
Connection via TCP

✓ A suitable documentation software e.g. MELAtrace is installed.

1. Select **`Connection via TCP`**. The TCP port currently set is displayed on the lower pushbutton (Standard TCP port: 65001).



2. Press on the lower pushbutton to change the pre-set TCP port.



3. Delete the most up-to-date TCP port using button 'C'; enter another TCP port.
4. Confirm with SAVE.

IP addresses

PLEASE NOTE

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

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

As a standard, the device is assigned IP addresses in the factory, which all belong to a common network with the subnet mask stated in the following.

Device	IP address	Remarks
Steam sterilizer	192.168.40.40	Pre-set ex works
Computer	192.168.40.140	Pre-set ex works
MELAprint 42/44 log printer	192.168.40.240	Pre-set ex works
MELAprint 60 label printer	192.168.40.160	Pre-set ex works
Gateway	192.168.40.244	Not relevant within a network
Subnet mask	255.255.255.0	Possibly to be adopted by customer network

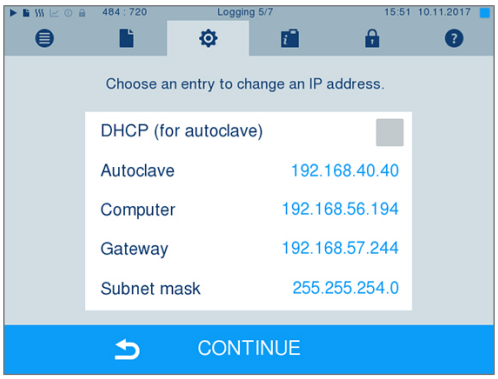
When integrating the device into an existing (practice) network, the following requirements must be met:

✓ The IP addresses listed in the table have not yet been assigned in the (practice) network.

✓ The device cannot be automatically administered in a dynamic (practice) network (i.e. a DHCP network).

1. Select the **Settings** > **Logging** menu.

2. Working in the logging assistant, navigate to the window in which the IP addresses of the individual device are listed.



3. Select the steam sterilizer [Autoclave], for example.

4. Press the number block that you wish to change.



5. Press the button 'C' to delete the digits. Enter a new number block.

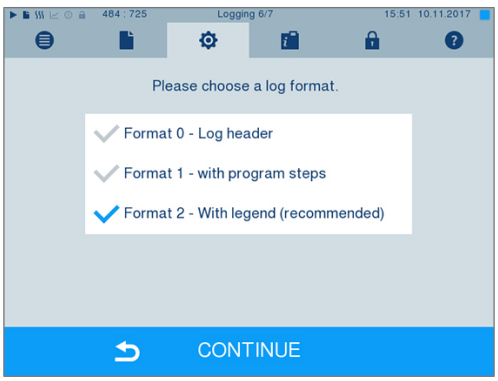
6. Press SAVE to accept all settings and leave the menu.

7. Proceed in a similar fashion with the other device that are to be integrated in the network.

Log formats

Different data are issued depending on the nature of the log format.

▶ The log format is determined under **Settings** > **Logging**.



You can choose between the following formats:

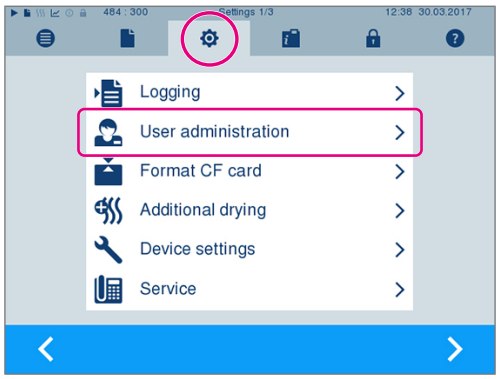
Format	Description
Format 0	Short form – only the log header is output.
Format 1	The log header and the program steps are output.
Format 2	Standard format – in addition to the log header and the program steps, a key is displayed explaining the individual program steps. In logs output via the log printer MELAprint, the corresponding legend row is always located under the row to which it refers.

User administration

An ID and individual user PIN can be issued to every user with which to authenticate him/herself, so as to enable reliable traceability via the clearance process. You can determine the necessity of user authentication via a PIN in the **`User administration`** menu. Activation of this option documents the user ID and the outcome of the approval procedure in the log header.

Adding a user

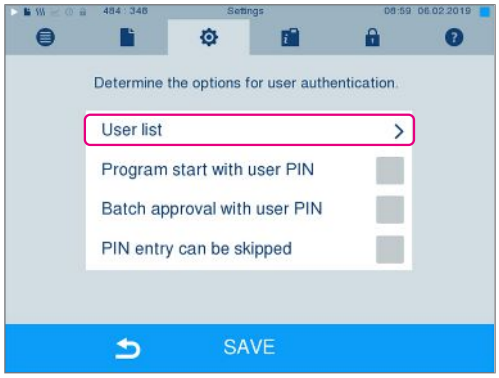
1. Select the **`Settings`** > **`User administration`** menu.



2. Entry of the Admin PIN is necessary to reach the **`User administration`** menu and undertake settings. Enter the Admin PIN (standard 1000) and confirm with LOGIN.

   ➥ The display switches to **`User administration`** window.

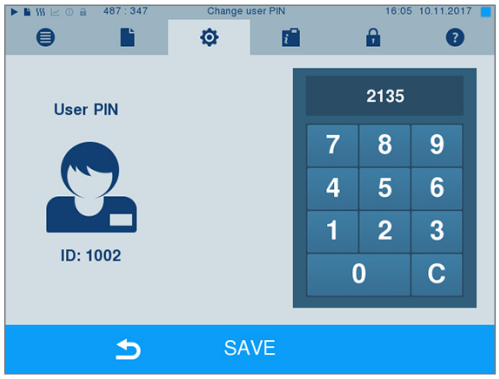
3. Select menu **`User list`** to display the user list.



4. Select a free ID and select EDIT. in order to create a new user. The first ID is reserved for the Admin PIN.



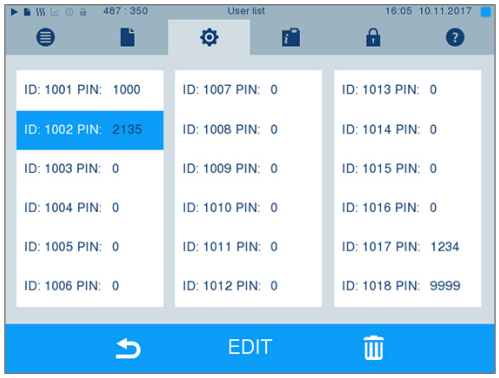
5. Enter a 4-digit PIN in the right-hand key pad for the selected user ID.



6. Press SAVE to accept all settings and leave the menu.

Deleting a user

1. Select the **`User administration`** option as described above and open the user list.



2. Select the user ID that you wish to delete.

3. Press  to delete this user.

   ➥ A warning is issued.

4. Confirm the warning with YES.

   ➥ The PIN number of this ID is set to “0”.

➥ A new PIN can be issued for this user ID at any time.

Changing the Admin PIN

PLEASE NOTE If you forget the Admin PIN, consult your stockist/MELAG customer services provider.

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

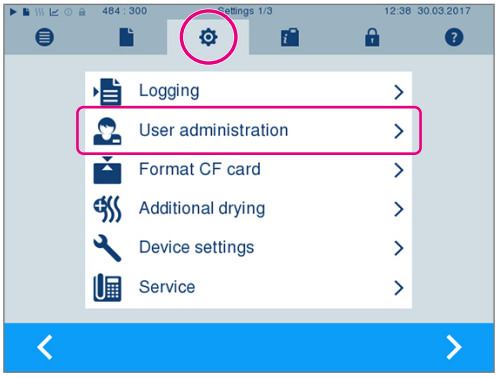
User authentication for sterilization

The user authentication can be set to ensure exact logging and verification. User authentication is performed by entry of the user PIN. The following settings are possible:

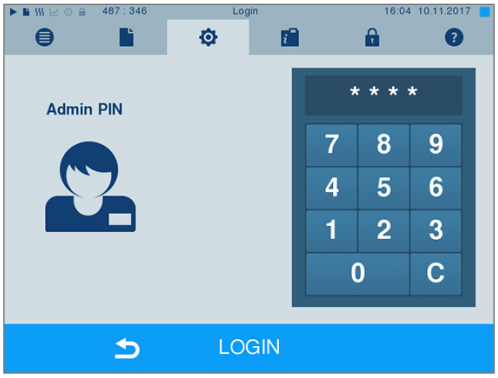
- Query user authentication upon program start
- Query user authentication upon program end
- Query user authentication upon program start and end
- You can skip the query user authentication

Determining options for the user authentication

1. Select the **`Settings`** > **`User administration`** menu.

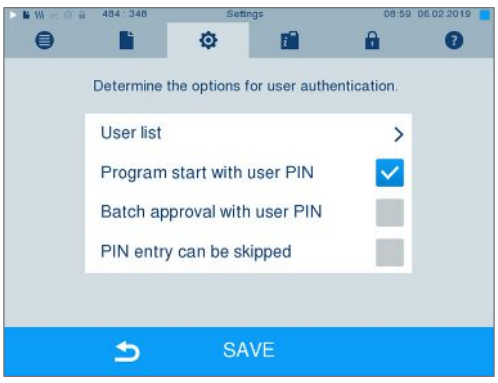


2. Entry of the Admin PIN is necessary to reach the **`User administration`** menu and undertake settings. Enter the Admin PIN (standard 1000) and confirm with LOGIN.

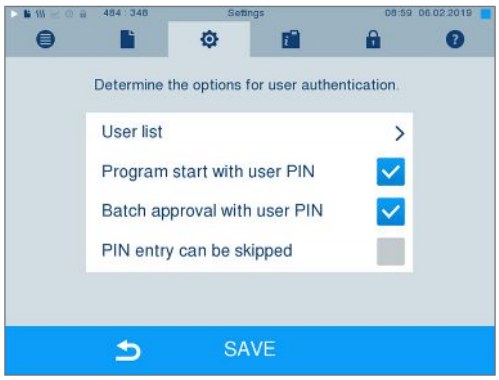


➥ The display switches to **`User administration`** window.

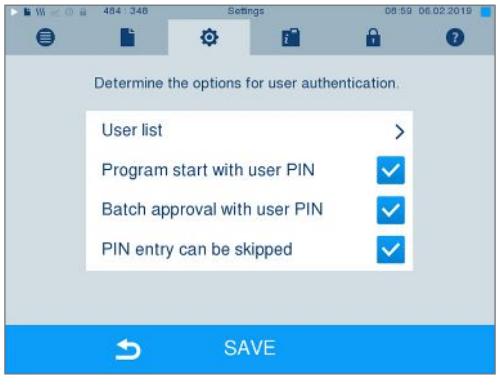
3. Set a checkmark next to **`Program start with user PIN`** to perform user authentication upon every program start. The program will start only after entry of the user PIN.



4. Set a checkmark next to **`Batch approval with user PIN`** to perform user authentication upon every program end. The device door will open following program end only after the user PIN has been entered.



5. Set a checkmark next to **`PIN entry can be skipped`** to enable the user PIN query to be skipped.



   ➥ The user PIN query continues to be displayed before program start or after program end. Press ⏭ to skip user authentication.

6. Press SAVE to accept all settings and leave the menu.

Formatting the CF card

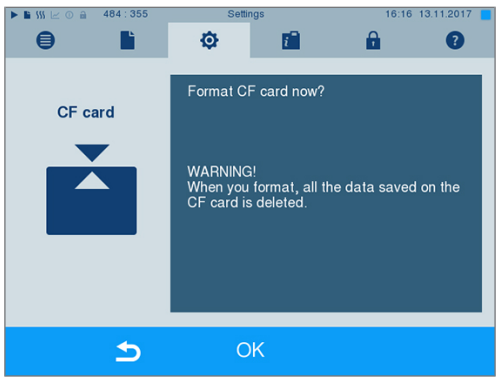
NOTICE

Warning of data loss

All data stored on the CF card is deleted during formatting.

- Check whether important data is stored on the CF card.
- Save any logs or other data on the computer or another memory medium.

1. Insert the CF card in the steam sterilizer card slot correctly (tangible raised bar on the edge pointing back right). Do not use force.
2. Select the **`Settings`** > **`Format CF card`** menu.
3. To start formatting, press the OK button.



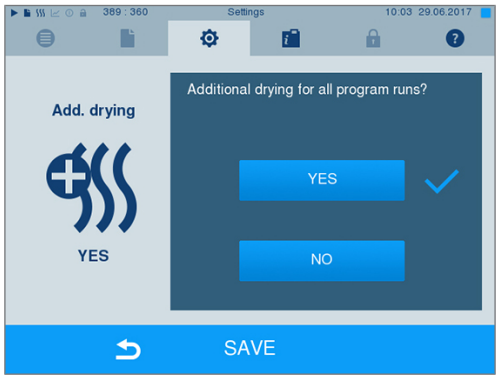
4. Confirm the security query with YES. You can remove the CF card as soon as formatting has been completed.

Additional drying

Selecting additional drying extends the drying time of conventional drying by 50 %. Activating intelligent drying restricts the criteria for ending the drying phase.

Activating/deactivating additional drying for all program runs

1. Select the **`Settings`** > **`Additional drying`** menu.

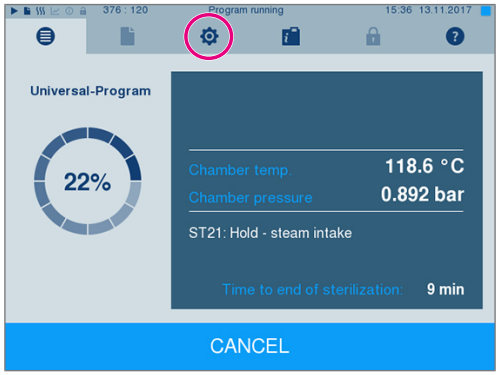


2. Press YES or NO to set whether additional drying should be performed during all subsequent program runs.
3. Confirm with SAVE.

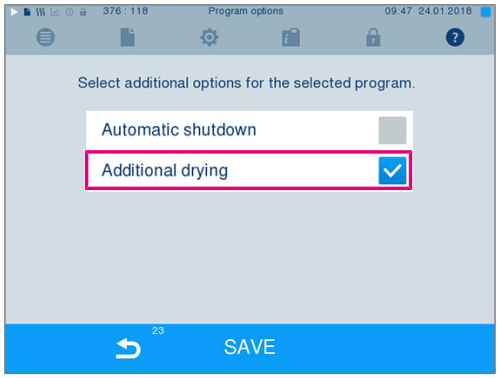
Activating/deactivating additional drying for the current program run

You can activate or deactivate additional drying exclusively for the current program during the program run and into the sterilization phase. The settings during the program run are not carried over for the subsequent program runs.

1. Select the desired program.
2. Press START.
3. Select the **`Settings`** menu.



4. Check or uncheck the option **`Additional drying`**.



5. Press SAVE to accept all settings and leave the menu.

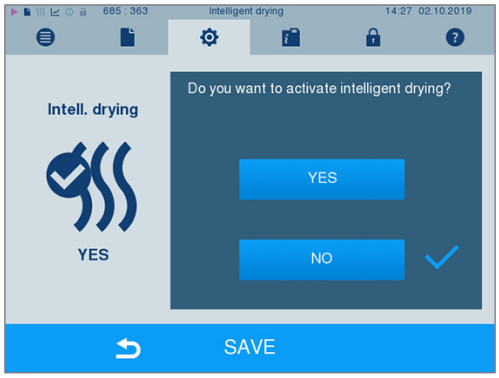
Intelligent drying (DRYtelligence)

In contrast to a conventional time-controlled drying procedure, in which the duration of the drying phase is determined by the program, the duration of the intelligent drying is automatically calculated using the residual moisture in the sterilization chamber. A number of factors play a role in this process including the type of load, whether it is wrapped or unwrapped, the load quantity, and the distribution of the load in the sterilization chamber, see Loading the steam sterilizer [▸ page 21].

Intelligent drying is activated in the delivery state. Should you wish to deactivate intelligent drying, proceed as follows:

1. Select the **`Settings`** > **`Device settings`** > **`Intelligent drying`** menu. The display switches to the corresponding window.

2. If you wish to deactivate intelligent drying, select NO.



3. Press SAVE to accept all settings and leave the menu.

Date and time

Correct ▸batch documentation requires the correct date and time setting on the device. Ensure that you take into account the clock change in autumn and summer, as this is not adjusted automatically. Set the date and time as follows:

1. Select the **`Settings`** > **`Date & time`** menu.

2. Select the parameters which you wish to change (day, month, year / hour, minute).

   ↪ The marked parameter is depicted light blue, here e.g. the day.

3. Change the respective value using  and . Repeat this step for all the parameters which you wish to change.

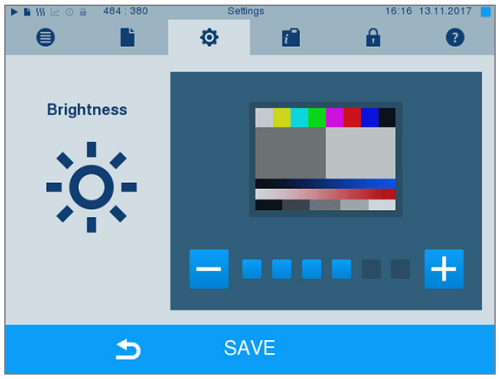
4. Press SAVE to accept all settings and leave the menu.

↪ The display is restarted.

Brightness

1. Select the **Settings** > **Brightness** menu.

2. Press − or + to adjust the brightness and contrast on the display.

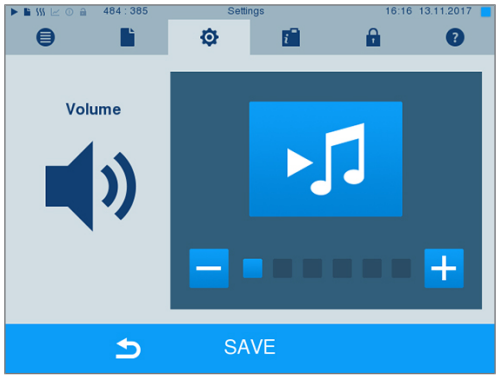


3. Press SAVE to accept all settings and leave the menu.

Volume

1. Select the **Settings** > **Volume** menu.

2. Press − or + to adjust the volume.



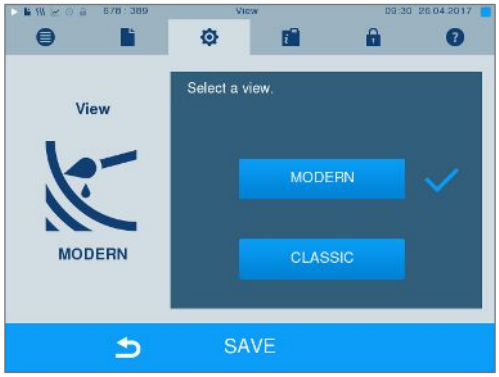
3. Press SAVE to accept all settings and leave the menu.

View

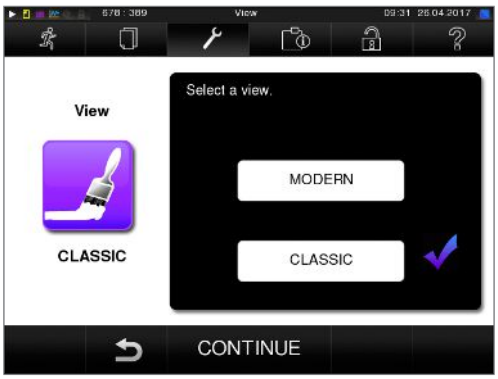
You can choose between classic and modern view.

Switching from MODERN to CLASSIC

1. Select the **Settings** > **View** menu. The display switches to the settings window.



2. Press the CLASSIC button. The design changes immediately.

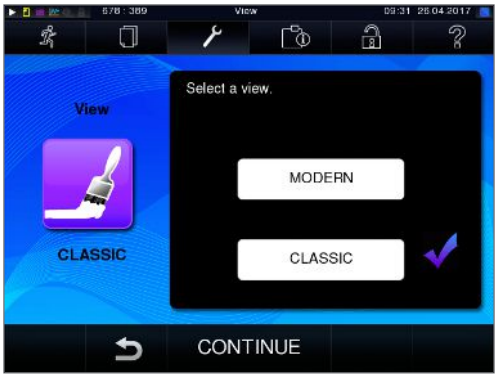


3. Press CONTINUE.
4. Tap on a colour box to change the background colour. The white frame around the colour box indicates which colour is currently selected.

   ↪ The background colour changes immediately.
5. Press SAVE to accept all settings and leave the menu.

Switching from CLASSIC to MODERN

1. Select the **`Settings`** > **`View`** menu.

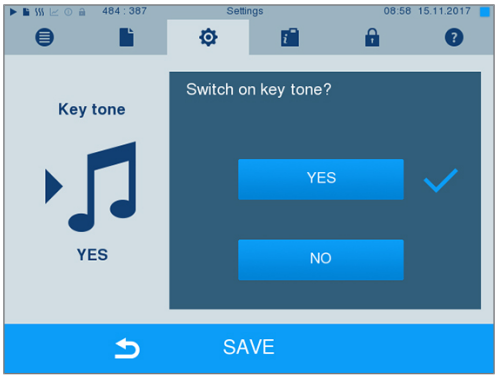


2. Press the MODERN button.

   ↪ The design changes immediately.
3. Press SAVE to accept all settings and leave the menu.

Key tone

1. Select the **`Settings`** > **`Key tone`** menu.
2. Press YES or NO to set whether a tone should be emitted every time a pushbutton is pressed. This can be deactivated at any time.



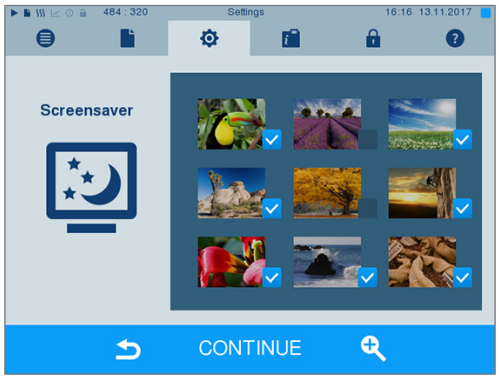
3. Press SAVE to accept all settings and leave the menu.

Screensaver

A screensaver can be activated to protect the display in standby operation. This displays a continuous slide show of any pictures.

Select images for the slide show

1. Select the **`Settings`** > **`Screensaver`** menu.



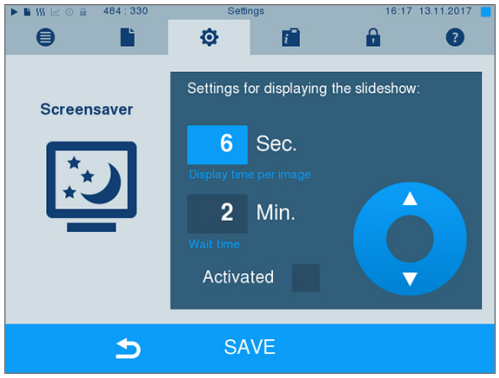
2. Tap on a picture to select it. The white frame around the picture indicates which picture is currently selected.
3. Repeated tapping on the picture selects/deselects it for the slide show.

   ➥ The checkmark on the lower right-hand corner ☑ indicates whether the picture has been selected for the slide show.
4. Press CONTINUE to make further settings.

Setting the display duration of the pictures and the waiting time of the slide show

Proceed as follows to alter one of the named options:

1. Select the parameter directly that you wish to change. The marked parameters are displayed light blue.



2. Change the respective parameter value via the ▼ and ▲ pushbuttons.
3. Press SAVE to accept all settings and leave the menu.

Explanation of the slide show options

Display duration per picture	Indicates the time in seconds between the display of two separate pictures.
Waiting time	Indicates how long the display remains in normal mode before the slide show starts.
Activated	Setting/unsetting the checkmark activates/deactivates the screensaver.

Log printer MELAprint 42/44

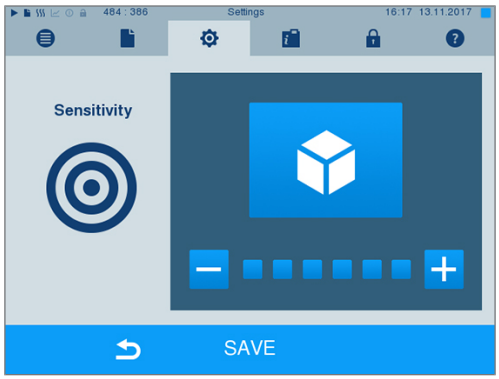
If you wish to output the sterilization log via the log printer MELAprint 42/44, you need to set this on the steam sterilizer once. The user manual of the log printer indicates how to set it up.

MELAprint 60 label printer

If you wish to output the sterilization log via the MELAprint 60 label printer, you need to set this on the steam sterilizer once. The user manual of the label printer indicates how to set it up.

Sensitivity

1. Select the **`Settings`** > **`Touchscreen sensitivity`** menu.
2. Press − or + to adjust how much pressure must be applied when touching a button to trigger an event.



3. Press SAVE to accept all settings and leave the menu.

Energy-saving mode

If the steam sterilizer is not to be switched off during longer operating pauses, it can be operated in energy-saving mode. This reduces the time that is required in order to pre-heat the ▸double jacket steam generator to the necessary start temperature after deactivation. Two waiting times can be set in energy-saving mode:

Waiting time 1 (W1): After a pre-set waiting time of 3 min, the temperature of the ▸double jacket steam generator falls to 103 °C. The program run time increases by approx. 2 min upon the next start.

Waiting time 2 (W2): After a pre-set waiting time of 25 min (Cliniclave 45) or 40 min (Cliniclave 45 M) the ▸double jacket steam generator is no longer heated. Accordingly, the length of the program run time increases by approx. 5 min upon the next start, depending on the length of the operating pause, as the double jacket steam generator must first be pre-heated to the necessary start temperature.

In order to set up the energy saving mode, proceed as follows:

1. Select the **`Settings`** > **`Energy saving mode`** menu.
2. Select waiting time 1 directly by touching.

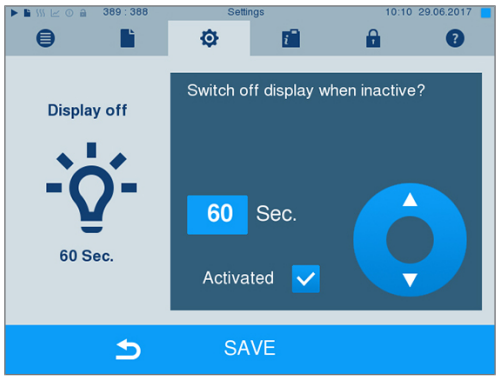
   ➥ The area is displayed light blue.

3. Press ▼ or ▲ to adjust the minutes.
4. Repeat the step for waiting time 2.
5. Press CONTINUE.

Switching off the display

You can choose whether the display is to be switched off when the steam sterilizer is in energy-saving mode (waiting time 2).

1. Set the check-mark next to **`Activated`**, and set the number of seconds after which the display is to be deactivated.



2. Press SAVE to accept all settings and leave the menu.
3. Switch the display back on by touching the screen.

11 Maintenance

PLEASE NOTE

The user can do the maintenance work described below as part of in-house maintenance.

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

Servicing intervals

Interval	Measure	Device component
Weekly	Check for soiling, deposits or damage	sterilization chamber including door gasket and chamber sealing surface, mount for load
Every 2 months	Clean, check and oil the locking spindle and nut	Door mechanism
After 4000 cycles but no later than 12 months	Maintenance	by the authorised customer services working in accordance with the maintenance instructions
As required	Clean the surfaces	Housing parts

Cleaning

NOTICE

Warning of material damage from incorrect cleaning

Inappropriately performed cleaning can lead to the scratching of and damage to surfaces as well as the development of leaks in sealing faces. This also favours the development of soiling deposits and corrosion in the sterilization chamber.

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

Sterilization chamber, door gasket, mount, trays

To maintain the value of your device and to avoid persistent contamination and deposits, MELAG recommends weekly cleaning of the surfaces. Use the Chamber Protect chamber cleaning set or, if not available, a neutral liquid cleaner or spirit.

PLEASE NOTE: Note the instructions for use of the cleaning agent.

The following must be fulfilled or present:

✓ The door is open.

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

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

1. Apply the cleaning agent on a lint-free cloth.
2. Use a lint-free cloth to uniformly spread the cleaning agent on the surfaces to be cleaned.

   PLEASE NOTE: Do not allow cleaning agents to get into the pipes coming from the sterilization chamber.
3. Allow the cleaning fluid to act and evaporate for a sufficient time. This may take a few minutes.
4. Wet a new lint-free cloth with plenty of demineralised water.
5. **NOTICE! Warning of material damage.** Residues of cleaning fluids can ignite or cause deposits on the instruments. Wipe the cleaned surfaces thoroughly.
   If necessary, wring out the cloth and repeat the process.
6. Allow the cleaned surfaces to dry completely. This may take a few minutes.
7. Wipe the cleaned surfaces with a dry, lint-free microfibre cloth.

Housing parts

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

Comply with the following specifications when disinfecting the housing parts:

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

Avoiding staining

Only proper cleaning of the instruments prior to sterilization enables you to avoid residue from being released from the load under steam pressure during sterilization. Loosened dirt residue can clog the filter, fittings and valves of the device and deposit themselves on the instruments and in the sterilization chamber as deposits and stains.

All steam-conducting parts of the device consist of non-rusting material. This rules out the development of rust caused by the device. Any rust which develops is always extraneous rust.

Incorrect instrument reprocessing can result in the accretion of rust even on stainless steel instruments of leading manufacturers. Often, a single instrument which drops rust can suffice to cause the development of rust on other instruments or in the device. Remove foreign rust from the instruments using chlorine-free stainless steel cleaning fluid (see Cleaning [▸ page 61]) or send the damaged instruments to the manufacturer.

The extent of stain accretion on the instruments is also dependant on the ▸feed water used for steam generation.

Replacing of the door gasket

Replace a worn, porous or cracked door gasket immediately:

1. Remove the door gasket from the groove in the round door.
2. Insert the new door gasket into the groove at four points that are evenly distributed over the door rim.
3. Press the gasket into the groove in each of the four quadrants. Ensure even distribution.

Checking and oiling the door lock

NOTICE

Warning of material damage from wear

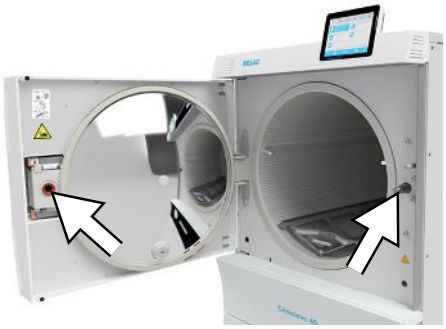
If the door lock is not oiled regularly it can become worn. Pressure-tight closing of the door can no longer be ensured.

- Check and oil the door lock every two months.
- Use MELAG oil (included in the scope of delivery) to oil the door lock.

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.



Replacing the sterile filter

Comply with the following for safe handling:

- 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.

1. Unscrew the sterile filter counter-clockwise from the holding socket.
2. Replace the sterile filter with a new sterile filter.
3. Turn the new sterile filter clockwise straight into the holding socket.

Maintenance

Comply with the following for safe handling:

- Maintain the specified maintenance intervals. Continuing operation beyond the maintenance interval can result in malfunctions in the device.
- Have maintenance performed only by trained and authorised technicians using the original MELAG maintenance set.
- If components that are not included in the maintenance set have to be replaced during maintenance, only original spare parts from MELAG may be used for the replacement.

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 carried out regularly after 4000 cycles, however, after 12 months at the latest. The steam sterilizer will issue a maintenance message at the relevant time.

Maintenance of the reverse osmosis unit

The conductivity of the feed water is measured automatically before every program run. If the water quality falls further, the display of the steam sterilizer will show the message **`Poor feed water quality`** a program start is however still possible.
If the water quality falls further, the display of the steam sterilizer will show the message **`Feed water quality insufficient`**. A program start is no longer possible. Perform punctual maintenance on your reverse osmosis unit to avoid device downtime.
Further information and detailed maintenance instructions are listed in the user manual of the reverse osmosis unit.

When in standby mode, the conductivity can also be measured manually in menu **`Programs & Tests`** (see Feed water quality [▸ page 43]).

12 Pause times

Frequency of sterilization

Pause times between the individual programs are not necessary, as the sterilization chamber is maintained permanently at the same temperature. After the end/abort of the drying time and removal of the ▸sterile material, you can load the steam sterilizer again and start a new program.

Duration of the operating pause

Duration of the operating pause	Measure
Short pauses between two sterilization processes	• Keep the door closed to save energy • Set the energy-saving mode correspondingly
Pauses which last longer than an hour	• Switch off the steam sterilizer
Longer pauses e.g. over night or the weekend	• Open the door and switch off the steam sterilizer • Leave the door ajar to prevent premature wear and the sticking of the door gasket • Shut off the cold water inflow and if present, the water inflow of the water treatment unit
Longer than two weeks	**Before starting the operating pause:** • Open the door and switch off the steam sterilizer • Leave the door ajar to prevent premature wear and the sticking of the door gasket • Shut off the cold water inflow and if present, the water inflow of the water treatment unit **Following the operating pause:** • Perform a vacuum test • After a successful vacuum test, perform an empty sterilization run in Quick-Program S

After pauses, perform the checks described in chapter Function checks [▸ page 42] depending on the length of pause.

Decommissioning

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

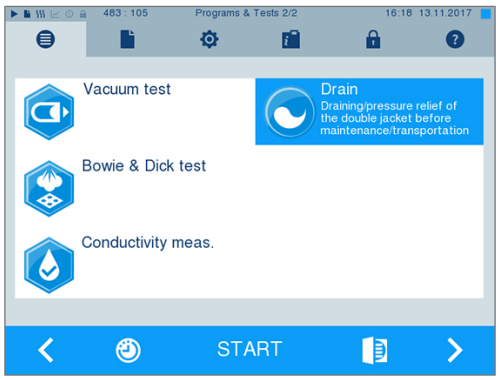
1. Empty the double jacket steam generator, see Emptying the double jacket [▸ page 64].
2. Switch off the device at the power switch.
3. Disconnect the power plug from the socket and if necessary, allow the device to cool.
4. Should the steam sterilizer need to be transported, wait until the container on the air gap has emptied automatically (approx. 10 min).
5. Close the water feed.
6. Shut off if present, the water inflow of the water treatment unit.

Emptying the double jacket

You have the option of draining the water in the double jacket steam generator easily via program Drain. In order to do so, the steam sterilizer is heated once, building up pressure in the double jacket so that the water can be drained fully from the double jacket steam generator.

1. Switch on the steam sterilizer at the power switch.

2. Working in menu **`Programs & Tests`** select program Drain and press START.



3. Following notification **`Draining successful`** switch off the steam sterilizer, so that water is not fed into the double jacket.

Transport

⚠ CAUTION

Warning of injury

Lifting and carrying the device incorrectly can cause spinal damage, crushing injuries and bruising.

- MELAG recommends carrying the device with at least six people.
- Transport the steam sterilizer using the carrying handles or transport bars included in the scope of delivery.
- Wear protective gloves and safety shoes when moving the steam sterilizer.
- Comply with the safety regulations that apply to you.

Comply with the following for safe handling:

- Store and transport the device frost-free.
- Avoid strong shocks/vibrations.
- Store the device in a fashion protected against moisture.

Preparing the steam sterilizer for transport

1. Decommission the device, see Decommissioning [▸ page 64].
   PLEASE NOTE: It is not necessary to empty the steam generator when transporting the steam sterilizer within the practice (level ground).
2. Disconnect the outlet hose and inflow hose from the connections on the walls. Guide both hoses and the power cable into the floor unit.
3. Remove the plastic caps on the side walls at the front and back.
4. Screw in the four carrying handles.
5. Should you wish to leave the mounts and trays or cassettes in the sterilization chamber during transport, protect the surface of the round blank. To do so, place e.g. some foam or bubble wrap between the round blank and mount.
6. Close the steam sterilizer door before moving it.
7. Release the holding brake on the casters.

Transport within the practice

Comply with the following provisions during transport within a room or the practice:

- Prepare the steam sterilizer for transport, see Transport [▸ page 65].
- Use the casters to transport the device. It is not necessary to carry the device.
- Protect the practice floor from any damage from the weight of the device.
- Do not roll the steam sterilizer over any uneven surfaces or thresholds. Lift the device over uneven floors or doorsteps using the carrying handles.

Transport over long-distance / dispatch

When transporting the steam sterilizer over long distances, between different floor levels or dispatching it, comply with the following:

- For transport over longer distances, during the danger of frost and/or for dispatch, an authorised technician must prepare the steam sterilizer in accordance with the instructions and empty the steam generator and the container of the air gap entirely, see Decommissioning [▸ page 64].
- Use the casters to transport the device.
- Carry the device only in exceptional circumstances (e.g. between different floor levels without an elevator or for loading purposes within the scope of relocations). MELAG recommends carrying the device with at least six people.
- Only ever carry the steam sterilizer over short distances.
- Take appropriate measures to secure the steam sterilizer for dispatch. Consult your stockist or an authorised MELAG customer service provider.

Proceed as follows:

1. Prepare the steam sterilizer for transport, see Transport [▸ page 65].
2. Empty the sterilization chamber.
3. Remove the carrying handles from both sides of the device. The carrying handles can be stored in the bracket in the floor unit.
4. If required, fit the transport bars instead. The spacer must sit between the side wall of the device and the transport bar.
5. Fix the transport bars by screwing the four screws tight using a spanner (AF 19).



Ordering further transport bars

If the device and floor unit are delivered separately, the transport bars are included in the scope of delivery. If you need transport bars for transport but don't have any (e.g. due to loss or delivery of your device as a complete dispatch), you can reorder the transport bars, see Accessories and spare parts [▸ page 81]. Consult your stockist or an authorised MELAG customer service provider.

Recommissioning after relocation

When recommissioning after changing the location of the device, proceed as for initial commissioning, see Technical manual.

13 Malfunctions

Comply with the following for safe handling:

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

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.

	Type of message	Description
	Notification	A number of notifications are messages providing information. They support the operation of the steam sterilizer.
	Warning message	Warnings are displayed when necessary. These contain instructions that apply to you, the operator. Warning messages are not malfunction messages. They help to ensure malfunction-free operation and to recognise undesirable situations. Comply with these warnings early in order to prevent malfunctions.
	Malfunction message	Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after activating the steam sterilizer or during a program run. If a malfunction occurs during a program run, the program will be aborted.

Troubleshooting online

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



Before contacting the technical service

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

Messages

Event	Possible causes	What you can do
248	Vacuum test was carried out despite residual moisture in the sterilization chamber or with a load.	Repeat vacuum test if steam sterilizer is cold and empty.

Warning and malfunction messages

Event	Possible causes	What you can do
61	When using a MELAG water treatment unit: a) Residual air is in the feed system of the water treatment unit after initial commissioning or after replacing the mixed-bed resin cartridge. b) The pressure tank of MELAdem 56/56 M has not been filled sufficiently and/or the tap on the pressure tank has not been opened completely.	a) Acknowledge the malfunction message and start the program repeatedly until the malfunction message is no longer displayed. b) Please note that after initial commissioning of a MELAdem 56/56 M it takes approx. 1 h until the pressure tank is sufficiently full with water. Check whether the tap on the pressure tank has been opened completely.
	When using a central water treatment unit: c) The central water supply has been interrupted or the flow pressure is insufficient.	c) Check that all inlet valves from the central system to the steam sterilizer are open. If necessary, arrange for an inspection of the flow pressure of the central water treatment unit using a flow pressure gauge (min. 0.5 bar at 5 l/min).
	If using an external storage container: d) There is air in the intake line from the storage container to the steam sterilizer. e) The suction filter of the external storage container is blocked.	d) Check whether sufficient feed water is in the storage container; the end of the intake hose is submerged in water and that no air is being drawn in. Note that the container may be max. 1.5 m lower than the steam sterilizer because otherwise water cannot be drawn in. e) Check whether the filter in the external storage container is soiled or blocked and clean if necessary.
63	Very poor feed water quality (conductivity ≥ 35 µS/cm). a) The mixed-bed resin cartridge, pre-filter or the activated carbon filter of MELAdem 56/56 M is exhausted. b) Poor quality of the feed water in the external water storage container.	a) Replace the mixed-bed resin cartridge and, if necessary, the prefilter and activated carbon filter of the MELAdem 56/56 M as described with the corresponding user manual. **PLEASE NOTE:** The message may also continue to be shown after the filter has been replaced until the water remaining in the pressure tank has been consumed. Start the draining program once or twice to flush the poor feed water from the pressure tank. The flushing of the pressure tank means that it can take up to 2.5 h for the tank to be filled and become ready. b) Drain and replace the feed water in the external water storage container.
64	see event 63	
65	see event 63	
66	The feed water hose between the water treatment unit and the steam sterilizer is leaking. Air is drawn in with the feed water.	Check that the feed water hose to the steam sterilizer is not leaking and has been connected correctly.
67	The wastewater cannot drain. a) The outlet hose is kinked or laid with large sags. b) The U-trap or building's wastewater pipe is blocked. c) The Quick-Program B and Quick-Program S programs are mainly used. These programs do not perform automatic flushing.	a) Check the installation of the outlet hose. It must be installed without kinking or sagging and at a constant decline. If necessary, use the tensioning device on the underside of the steam sterilizer to tighten the outlet hose. b) Check whether the building's U-trap is blocked. **PLEASE NOTE:** If you operate multiple devices at the same time, MELAG recommends installing an additional U-trap. c) Start another program, e.g. Universal-Program, Gentle-Program or Prion-Program to carry out the necessary rinsing.

Event	Possible causes	What you can do
72	Poor feed water quality (conductivity ≥ 20 µS/cm). The mixed-bed resin cartridge, pre-filter or the activated carbon filter of MELAdem 56/56 M is exhausted.	Replace the mixed-bed resin cartridge and, if necessary, the prefilter and activated carbon filter of the MELAdem 56/56 M as described in the corresponding user manual. **PLEASE NOTE:** The message may also continue to be shown after the filter has been replaced until the water remaining in the pressure tank has been consumed. Start the draining program once or twice to flush the poor feed water from the pressure tank. The flushing of the pressure tank means that it can take up to 2.5 h for the tank can to be filled and ready.
73	see event 72	
74	see event 72	
75	see event 72	
76	see event 67	
81	a) The door was not pushed shut for long enough with sufficient force; as a result, the thread has become caught. b) The door lock nut has not been greased regularly and is therefore dry.	a) Push the door with force for approx. 3 s until the spindle engages in the door lock nut and the door is closed automatically. A motor sound is audible. b) Check the door spindle and the door lock nut for damage. Clean both and oil the door lock nut with the MELAG oil provided, see Maintenance [▸ page 61]. Use the test gauge to check the door lock nut for wear.
82	a) There are objects in the door area. The door was blocked from outside during the opening process. b) There is still a residual vacuum in the sterilization chamber. Pressure equalisation is not yet completed. c) The door gasket sticks to the seal face of the sterilization chamber.	a) Always keep the area in front of the door free so that it can open unhindered. b) 1. Wait 2 min, and then acknowledge the message with OK. 2. If the door does not open by itself, switch off the steam sterilizer, wait for 5 min and then switch it back on. Try again to open the door. If the door still doesn't open, please contact the technical service. c) If it was possible to open the door (e.g. using the manual door emergency opening, see Manual door emergency-opening [▸ page 18]), then clean the door gasket and the face seal on the sterilization chamber, see Cleaning [▸ page 61].
83	The door does not reach a pressure-tight state after the program start. a) The door gasket and/or the seal face is soiled and or damaged. b) The load blocks the closing sequence. c) The closing mechanism is stiff.	a) Check the door gasket and seal face on the sterilization chamber for soiling, foreign bodies and damage. b) Check whether the load is blocking the door. c) Check the door spindle and the door lock nut for damage. Clean both and oil the door lock nut with the MELAG oil provided, see Maintenance [▸ page 61]. Use the test gauge to check the door lock nut for wear.
84	see event 82	
86	The door has not been closed correctly upon program start.	Push the door with force for approx. 3 s until the spindle engages in the door lock nut and the door is closed automatically. A motor sound is audible.
89	see event 86	

Event	Possible causes	What you can do
102	The wastewater cannot flow away. a) The outlet hose is kinked or sags. b) The U-trap or the building-side outlet line is blocked, or multiple devices have been connected to a single U-trap. c) The chamber filters are blocked.	a) Check the installation of the outlet hose. This must be laid free of kinks or sags and with a constant gradient. b) Check whether the building's U-trap is blocked. **PLEASE NOTE:** If you operate multiple devices at the same time, MELAG recommends installing an additional U-trap. c) Check whether the chamber filters are soiled/clogged (at the fixing points under the front and rear of the slide rail), e.g. by packaging residues. If necessary, clean the chamber filters.
103	The sterile filter is soiled/blocked.	1. Check whether the sterile filter suction aperture (centre aperture) behind the service hatch of the steam sterilizer is blocked. If yes, replace it with a new sterile filter, see Replacing the sterile filter [▸ page 63]. 2. If nothing can be recognised, remove the sterile filter and perform a program run without a load. If the program has been ended successfully, the sterile filter is blocked. In this case, replace the sterile filter with a new one, see Replacing the sterile filter [▸ page 63].
104	see event 103	
110	a) The steam sterilizer is overloaded or the load has been arranged badly. b) The mains voltage is too low, poor building voltage supply (e.g. undersized installation, defective socket, multiple devices on a single socket/fuse).	a) Comply with the maximum permissible load quantities, see Loading the steam sterilizer [▸ page 20]. Ensure that the load does not come into direct contact with the steam injection nozzles or cover them. b) Check the on-site installation (e.g. automatic circuit breaker) or test the steam sterilizer at another socket or in another circuit.
111	see event 110	
113	a) The steam sterilizer was switched off at the power switch during a program run. b) The power plug has been disconnected or has not been connected correctly in the socket. c) Power outage in the building supply or the building-side RCD switch has tripped.	a) Never switch off the steam sterilizer at the power switch during a program run. b) Check whether the power plug is connected, the power cable has suffered damage or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket. c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.
114	see event 102	

Event	Possible causes	What you can do
124	a) The steam sterilizer is overloaded. b) The steam sterilizer was operated without a mount and the load (especially the textiles) come into direct contact with the chamber wall. c) The chamber filters in the floor of the sterilization chamber are blocked. d) The cooling water in the steam sterilizer is too warm.	a) Comply with the maximum permissible load quantities, see Loading the steam sterilizer [▸ page 20]. If necessary, perform a vacuum test, see Vacuum test [▸ page 42]. b) Always operate the steam sterilizer with a mount and follow the loading instructions, see Loading the steam sterilizer [▸ page 20]. c) Check whether the chamber filters (at the fixing points under the front and back of the slide rail) are soiled/blocked, e.g. by packaging residue. Clean the chamber filter if necessary. d) Check whether the inlet hose heats up during operation. If yes, check whether the hose has been connected to the hot water connection by mistake. **PLEASE NOTE:** In the summer, heat accumulation in the supply line can lead the water to warm up. Restart the program so that new, cold water is flushed.
125	see event 124	
126	see event 124	
127	see event 124	
131	see event 102	
132	The steam sterilizer is overloaded or the load has been arranged badly.	Comply with the maximum permissible load quantities, see Loading the steam sterilizer [▸ page 20]. Ensure that the load does not come into direct contact with or covers the steam injection nozzles.
133	see event 124	
135	a) The cooling water hose is kinked. b) The inflow filter in the aqua stop of the inflow hose is blocked by soiling in the building supply. If a leakage water detector (water stop) is installed: c) The leakage water detector is without function. d) The inflow filter in the leakage water detector is blocked by soiling in the building supply.	a) Check the installation of the inflow hose. It must be installed without kinking and may not be crushed. b) Unscrew the inflow hose on the water inflow tap and check the inflow filter; clean it if necessary. c) Unplug the leakage water detector control device from the socket, wait approx. 30 s and plug it back in again. A switching noise on the leakage water valve (black box on the water inflow tap) must be audible. d) Clean the inflow filter in the leakage water detector valve as follows: 1. Close the water inflow tap and start a vacuum test. 2. Wait until the device displays a malfunction message and then switch it off. 3. Unscrew the leakage water detector valve on the water inflow tap and check the inflow filter; clean it if necessary.
136	a) The ambient temperature of the steam sterilizer is too hot. The steam sterilizer is installed. The minimum clearances to the surrounding surfaces has not been maintained. c) The door was left open after loading or unloading and hot steam has escaped from the sterilization chamber. d) The filter in the base plate fan is soiled.	Switch off the steam sterilizer and allow it to cool for approx. 1 h. a) The ambient temperature must be below 40 °C. MELAG recommends a maximum temperature of 26 °C. b) Maintain a minimum clearance to the surrounding surfaces, see Technical manual. c) Always close the door after loading or unloading. d) Check whether the fan filter in the base plate of the steam sterilizer is clogged, and replace it if necessary.

Event	Possible causes	What you can do
175	The overheat control of the control heater on L1 (RHK1) has tripped. This notification may be issued in alternation with “E176: ACOUT 02 open”.	1. Switch off the steam sterilizer and push in fully the reset button RHK1 behind the service hatch of the steam sterilizer until a switching noise is audible. 2. Acknowledge the malfunction message. 3. Switch off the steam sterilizer and back on again and then perform an empty sterilization run if necessary. The steam sterilizer is now ready for operation.
176	The overheat control of the control heater on L1 (RHK1) has tripped. This message may be issued in alternation with “E175: ACOUT 01 open”.	1. Switch off the steam sterilizer and push in fully the reset button RHK1 behind the service hatch of the steam sterilizer until a switching noise is audible. 2. Acknowledge the malfunction message. 3. Switch off the steam sterilizer and back on again and then perform an empty sterilization run if necessary. The steam sterilizer is now ready for operation.
179	a) The motor protection switch of the vacuum pump has tripped. b) The vacuum pump is blocked, e.g. after lengthy operating pauses.	a) Switch the steam sterilizer off and then on again. b) A stuck vacuum pump can be released as follows: 1. Acknowledge the malfunction message. 2. Switch off the steam sterilizer, disconnect the power plug and open the service hatch. 3. Insert an Allen key (6 mm) into the opening for emergency starting of the vacuum pump as far as it will go until the Allen key engages. Turn the Allen key alternately in both directions to free the blockage of the vacuum pump. Repeat the process until the Allen key can be turned easily. 4. Remove the Allen key. 5. Close the service hatch. Connect the power plug and activate the device.
182	The mains voltage is too low, poor building voltage supply (e.g. under-dimensioned building installation, defective socket, multiple devices connected to a single socket or fuse).	Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.
183	see event 124	
185	see event 110	
186	see event 132	
187	see event 102	
203	No options have been set for the output of logs.	Check the configuration in the **Settings** > **Logging** menu.
204	The internal log memory is full.	Output the log saved in the steam sterilizer on any output medium or adapt the general output options in the **Settings** > **Logging** menu.
207	see event 203	
208	see event 204	
211	see event 204	

Event	Possible causes	What you can do
214	The steam sterilizer has not recognised the CF card; it cannot be read, or it is damaged.	1. Check whether the CF card has been inserted correctly (do not insert under voltage). 2. Make sure that the CF card is not larger than 4 GB. 3. Check whether the write-protection has been set on the CF card by mistake. 4. Test the CF card on a computer. 5. Check whether the memory on the CF is full. If the memory is full, transfer the log files on the CF card to a computer and delete the files on the CF card. 6. Transfer the log files on the CF card to a computer and re-format the CF card in the steam sterilizer. 7. The CF card is defective or incompatible. A non-MELAG CF card has possibly been used. **PLEASE NOTE:** MELAG recommends only using original MELAG CF cards.
215	see event 214	
218	The attempt was made to overwrite a write-protected log with a log of the same name.	1. Transfer the log file the CF card to another computer and delete the file from the CF card. 2. Insert the empty CF card in the card slot and enter the log again.
221	The CF card or a subdirectory of the CF card is full.	1. Transfer the present log files from the CF card to a computer. 2. Format the CF card in the steam sterilizer. 3. Try again.
223	The CF card has not been recognized.	1. Transfer the present log files from the CF card to a computer. 2. Format the CF card in the steam sterilizer. 3. Try again.
224	see event 223	
228	see event 223	
229	The CF card was removed from the slot during a writing/reading action.	Never remove the CF card from the slot whilst it is being written or read. Insert the CF card in the card slot and repeat the procedure.
231	The CF card cannot be located/has not been inserted.	Check whether the CF card has been inserted correctly or insert it in the slot again. Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again.
232	see event 229	
236	File malfunction on the CF card.	1. Transfer the present log files from the CF card to a computer. 2. Format the CF card in the steam sterilizer. 3. Try again.
237	The CF card has not been recognised.	Check whether the CF card is write protected. Disable the write protection. Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again.
238	a) It is not possible to format the CF card because it is larger than 4 GB. b) The CF card is defective or incompatible. c) The CF card is write-protected.	a) Use only CF cards with a maximum storage capacity of 4 GB. b) 1. Try formatting the CF card on a computer. 2. The CF card is defective or incompatible. It is possible that a non-MELAG CF card has been used. **PLEASE NOTE:** MELAG recommends using only original MELAG CF cards. c) Disable the write-protection on the CF card.

Event	Possible causes	What you can do
240	The CF card has not been recognized.	Make sure that the CF card has been inserted in the slot correctly. Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again.
249	The door does not close. The door gasket and/or the seal face is soiled.	Check and clean the door gasket and seal face on the sterilization chamber for soiling, foreign bodies or damage, see Cleaning [▸ page 61].
305	a) The connection cable behind the display is loose or has a loose contact. b) The CF card is slow or defective.	a) Remove the display from the mount and check that the connection cable is correctly connected to the display and is undamaged. b) Use a different CF card.
351	The maximum operating interval or the number of batches since initial commissioning or the last maintenance have been reached. Maintenance is necessary.	Schedule a maintenance appointment with an authorised technician. You can continue to operate the steam sterilizer until the maintenance.
353	The steam sterilizer was switched off too early after alteration of the settings.	Always wait until the alterations in the steam sterilizer have been fully accepted before switching off the steam sterilizer. This is indicated in the display by changing into the previous menu or through the start screen.
360	--	Please contact the technical service.
367	The internal malfunction log memory is full.	Ensure that the selected output media are suitable for your instruments and are ready. Working in the **Log output** menu, output the non-outputted logs.
372	The device's internal memory for program logs is full.	Make sure that the selected output media are connected and ready. Output all logs that have not yet been output in the **Log output** menu.
377	An attempt was made to output logs via the log printer but a log printer is not connected.	Check whether the log printer has been connected correctly. If you do not wish to output any logs in the log printer, deactivate the log printer as an output medium, see Logging [▸ page 44].
380	see event 377	
386	The internal program log memory is almost full.	Ensure that the selected output media are suitable for your instruments and are ready. Working in the **Log output** menu, output the non-outputted logs at the next opportunity.
397	a) The network cable has been disconnected or is damaged. b) The network cable is not compatible. c) The computer is not switched on. d) The network connection was not configured correctly. e) The documentation software on the computer was not started.	a) Check whether the network cable has been connected correctly or is damaged. b) Check whether a 1:1 network cable has been connected. A 1:1 network cable must be used for the direct connection between steam sterilizer and computer. c) Switch on the computer. d) Check the network settings, see Logging [▸ page 44]. e) Start the documentation software.
402	The door is blocked and cannot be closed. a) The door gasket and/or the seal face is soiled and or damaged. b) The load blocks the door area. c) The closing mechanism is stiff.	a) Check the door gasket and seal face on the sterilization chamber for soiling, foreign bodies and damage. b) Check whether the load is blocking the door. c) Check the door spindle and the door lock nut for damage. Clean both and oil the door lock nut with the MELAG oil provided. Use the test gauge to check the door lock nut for wear.
407	see event 83	

Event	Possible causes	What you can do
408	a) The water inflow tap has not been opened or has been opened only insufficiently. b) The building water pressure is too low or fluctuates. c) The inflow filter is kinked. d) The inflow filter in the Aqua-Stop of the inflow hose or the leakage water detector (if present) is blocked by soiling in the building supply. If a leakage water detector (water stop) is installed: e) The leakage water detector is without function.	a) Open the water inflow tap completely and check whether the central water inflow tap is open. b) Check the pressure of the building water supply. The minimum flow pressure should amount to 1.5 bar at 8 l/min. c) Check the installation of the inflow hose. It must be installed without kinking and may not be crushed. d) Clean the inflow filter in the Aqua Stop of the inflow hose or the leakage water detector valve as follows: 1. Turn off the water inflow tap. 2. Switch off the steam sterilizer. 3. Unscrew the inflow hose or the leakage water detector valve on the water inflow tap and check the inflow filter; clean it if necessary. e) Unplug the leakage water detector control device from the socket, wait approx. 30 s and then plug it back in again. A switching noise on the leakage water valve (black box on the water inflow tap) must be audible.
414	The wastewater cannot flow away. a) The outlet hose is kinked or sags. b) The U-trap or the building-side outlet line is blocked, or multiple devices have been connected to a single U-trap. c) The chamber filters are blocked.	a) Check the installation of the outlet hose. This must be laid free of kinks or sags and with a constant gradient. b) Check whether the building's U-trap is blocked. **PLEASE NOTE:** If you operate multiple devices at the same time, MELAG recommends installing an additional U-trap. c) Check whether the chamber filters are soiled/clogged (at the fixing points under the front and rear of the slide rail), e.g. by packaging residues. If necessary, clean the chamber filters.
416	see event 214	
417	see event 397	
428	see event 102	
434	Overheat on temperature sensor 2	1. Switch off the steam sterilizer and allow it to cool for 15 min. 2. Switch on the steam sterilizer. Steam sterilizer is ready to operate again. If this occurs repeatedly, please contact the technical service.
438	The steam sterilizer must be validated.	Arrange for validation of the steam sterilizer.
439	see event 102	
452	An attempt was made to execute actions on the display although the label printer is still printing labels.	Please wait until the label printer has printed all labels. The desired action can then be executed.
457	The date or time was set incorrectly.	Check the date and time settings and correct if necessary, see Date and time [▸ page 55].
458	a) The date or time was set incorrectly. b) The start time pre-selection timer has run down but the steam sterilizer was switched off at the time for which the start time was selected.	a) Check the date and time settings and correct if necessary, see Date and time [▸ page 55]. b) The steam sterilizer must be switched on at time for which the start time is selected.
464	An attempt was made to execute actions on the display although the log printer is still printing.	Please wait until the log printer has printed the log(s) completely. The desired action can then be executed.
465	a) The connection to the label printer has been interrupted. b) The label printer has not been switched on.	a) Check whether the power cable is connected to the socket and the Ethernet cable of the label printer is correctly connected with the steam sterilizer. b) Switch on the label printer. The power LED must illuminate green.

Event	Possible causes	What you can do
479	see event 397	
486	see event 82	
488	see event 457	
489	see event 136	
490	see event 136	
491	see event 136	
492	see event 136	
493	see event 136	
495	see event 408	
496	see event 408	
499	a) The shut-off valve of the MELAdem 56/56 M pressure tank is closed. b) Insufficient pressure in the pressure tank of the MELAdem 56/56 M (< 1 bar). c) Leak or kinked hoses in the feed water supply. d) The supply from an external feed water supply has been interrupted / the flow pressure is too low (e.g. central water treatment). e) Insufficient flow pressure on the cold water inflow of the MELAdem 56/56M. f) The water supply on the steam sterilizer is set to a pressureless water treatment unit, but a pressurized unit e.g. MELAdem 56/56 M, has been connected.	a) Connect the shut-off valve of the MELAdem 56/56 M pressure tank. b) Check the pressure on the manometer of the MELAdem 56/56 M. If the pressure is under 1 bar, leave the steam sterilizer activated until the pressure in the pressure tank has risen over 1 bar. The pressure pump of the MELAdem 56/56 M must function audibly. Do not switch off the steam sterilizer immediately after sterilization; leave it switched on for approx. 30 min. c) Check all the hoses of the feed water supply from the MELAdem 56/56 M to the steam sterilizer for leaks and kinks. d) 1. Check whether all the taps of the house water supply in the feed water line are open. 2. Check the flow pressure (min. 1 bar). e) Check the flow pressure of the house water supply using a flow pressure gauge (min. 0.5 bar at 5 l/min). f) If a MELAdem 56/56 M or another pressurized device is connected, check whether in the menu **`Settings`** > **`Device settings`** > **`Water supply`** the option **`YES`** has been selected.
500	see event 499	
543	a) The outlet hose is kinked, blocked or has insufficient tension. b) The outlet line is blocked. c) Multiple devices have been connected to a single siphon.	a) Check the installation of the outlet hose. It must be installed without kinking and may not be crushed. Depending on the device type and its position, the outlet hose must be stretched taught below the floor trough using a tensioning carriage. b) Check whether the building siphon is blocked. c) If multiple devices are operated simultaneously, we recommend the installation of an additional siphon.
545	a) The building fuse via residual current device has tripped. b) The power plug has been disconnected or has not been connected correctly in the socket. c) Malfunction in the electrical installation.	a) Switch the residual current device back on or replace it if necessary. b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket. c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.

Event	Possible causes	What you can do
546	a) The building fuse L1 has tripped. b) The power plug has been disconnected or has not been connected correctly in the socket. c) Malfunction in the electrical installation.	a) Switch the fuse L1 back on or replace it if necessary. b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket. c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.
547	a) The building fuse L2 has tripped. b) The power plug has been disconnected or has not been connected correctly in the socket. c) Malfunction in the electrical installation.	a) Switch the fuse L2 back on or replace it if necessary. b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket. c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.
548	a) The building fuse L3 has tripped. b) The power plug has been disconnected or has not been connected correctly in the socket. c) Malfunction in the electrical installation.	a) Switch the fuse L3 back on or replace it if necessary. b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket. c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit.
549	a) The vacuum pump motor protection switch has tripped. b) The vacuum pump has suffered a blockage e.g. following long shutdown periods.	a) Switch off steam sterilizer and switch on again. Then the steam sterilizer is ready for operation. b) A vacuum pump can be unblocked in the following fashion: 1. Acknowledge the malfunction message. 2. Switch off the steam sterilizer, disconnect the power plug and open the service hatch. 3. Insert a 6 mm Allen key into the opening to its fullest extent to effect an emergency turning of the vacuum pump. Insert until the key takes a grip and then turn it in both directions to free the blockage of the vacuum pump. Repeat until the screw driver can be turned easily. 4. Then remove the key again. 5. Close the service hatch, connect the power plug and switch on the device. Then the steam sterilizer is ready for operation.
553	The vacuum pump has suffered a blockage e.g. following long shutdown periods.	A vacuum pump can be unblocked in the following fashion: 1. Acknowledge the malfunction message. 2. Switch off the steam sterilizer, disconnect the power plug and open the service hatch. 3. Insert a 6 mm Allen key into the opening to its fullest extent to effect an emergency turning of the vacuum pump. Insert until the key takes a grip and then turn it in both directions to free the blockage of the vacuum pump. Repeat until the Allen key can be turned easily. 4 Then remove the key again. 5. Close the service hatch, connect the power plug and switch on the device. The steam sterilizer is now ready for operation. Should this repeat, please contact the service technician.

Event	Possible causes	What you can do
576	see event 546	
577	see event 547	
578	see event 548	
579	see event 546	
580	see event 547	
581	see event 548	
589	see event 136	
590	see event 136	
591	see event 136	
593	see event 136	
594	a) The chamber fittings (pressure plate) in the sterilization chamber are soiled or covered. b) The condensate guard is slipped.	a) Check the sterilization chamber interior for packaging or soiling. The load should have no contact with the sterilization chamber. b) Check the position of the condensate guard in the sterilization chamber and correct the alignment. The condensate guard must sit directly below the temperature sensors.
595	see event 594	
596	see event 594	
597	see event 594	
598	see event 594	
599	see event 594	
629	An unpermitted feed water flow was detected.	Switch off the device and switch on again.
635	The label printer was selected as an output medium, but a label printer could not be located.	Check the configuration in the menu **`Settings`** > **`Label printer`**.
637	Label printer label roll exhausted.	Insert a new label roll in the label printer.
638	Label printer cover is open.	Close the label printer cover.
645	The log printer was selected as an output medium, but a label printer could not be located.	Check the configuration of the log printer in the menu **`Settings`** > **`Log printer`**.
646	a) The user name or password for log-in to the FTP server is incorrect. b) The user name or password for log-in to the FTP server has not been setup correctly.	a) Check whether the user name and password set on the steam sterilizer corresponds wit those set on the FTP server, see Settings [▸ page 44]. b) Check the FTP server settings and the connection to the steam sterilizer.
648	see event 646	
692	see event 132	
693	see event 132	
694	see event 132	
900	System state is incorrect.	Switch the device off and then on again.

14 Technical data

Device type	Cliniclave 45	Cliniclave 45 M
Device dimensions (H x W x D)	158 x 64 x 91 cm	158 x 64 x 153 cm
Empty weight	244 kg | 262 kg inc. MELAdem 56	315 kg | 340 kg inc. MELAdem 56 M
Operating weight	254 kg | 292 kg inc. MELAdem 56[1)]	370 kg | 423 kg inc. MELAdem 56 M[2)]
Floor loading (pressure resistance test)	400 kg | 100 kg per caster[3)]	610 kg | 152.5 kg per caster[4)]
Working pressure	max. 2.7 bar	
Permissible working pressure	2.2 bar	
Permissible working temperature	136 °C	
Sterilization chamber		
Diameter	44 cm	
Depth	72 cm	134 cm
Usable chamber space	1 StU	2 StU
Volume	105 l	200 l
Electrical connection		
Power supply (star connection)	3x380-415 V + N + PE, 16 A, 50/60 Hz	3x380-415 V + N + PE, 32 A, 50/60 Hz
Power supply (delta connection)	3x220-240 V + PE, 32 A, 50/60 Hz	3x220-240 V + PE, 63 A, 50/60 Hz
Electrical power	10.5 kW	13.5 kW
Building-side fuse protection (star connection)	3x16 A, residual current device (RCD) 30 mA	3x32 A, residual current device (RCD) 30 mA
Building fuses (delta connection)	3x32 A, residual current device (RCD) 30 mA	3x63 A, residual current device (RCD) 30 mA
Degree of contamination (in accordance with EN 61010-1)	2	
Overvoltage category (in accordance with EN 61010-1)	II	
Length of the power cable from the floor unit	1.8 m	
Ambient conditions		
Installation location	interior of a building	
Noise emission	max. 72 dB(A)	
Heat emission (at maximum solid load and with an opened door)	1.4 kW	2.0 kW
Ambient temperature	5-40 °C (ideal range 16-26 °C)	
Degree of protection (in accordance with IEC 60529)	IP20	
Relative humidity	max. 80 % at temperatures of up to 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)	
Altitude (star connection)	max. 3000 m	
Altitude (delta connection)	max. 4000 m	
Cold water connection		
Min. flow pressure	1.5 bar at 8 l/min	
Max. water consumption	8 l/min	
Max. static water pressure	10 bar	
Water quality	drinking water, water hardness 4-12° dH (in accordance with EN 285)	
Water temperature	1-20 °C (ideal 15 °C)	

[1)] This applies to an operational device filled with water and, depending on the load, can increase by up to 40 kg.

[2)] This applies to an operational device filled with water and, depending on the load, can increase by up to 80 kg.

[3)] When using MELAdem 56, an additional weight of 33 kg (8.25 kg per caster) must be taken into account.

[4)] When using a MELAdem 56 M, an additional weight of 42 kg (10.5 kg per caster) must be taken into account.

Device type	Cliniclave 45	Cliniclave 45 M
Feed water connection		
Min. flow pressure	0.5 bar at 5 l/min	
Max. water consumption	5 l/min	
Max. static water pressure	5 bar	
Water quality	EN 285, Appendix B, table B.1	
Water temperature	5-35 °C	
Wastewater connection		
Max. throughflow volume	short-term max. 9 l/min	
Water temperature	short-term max. 90 °C	

15 Accessories and spare parts

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

Category	Article	Art. no.	
		Cliniclave 45	Cliniclave 45 M
Holders	Mount for 2 instrument baskets (1/2 StM) or 4 trays (1/4 StM), 31 x 58 x 28 cm	ME04517	
Package holder	Package holder, short, 18.4 x 28 x 8.5 cm	ME22410	
	Package holder, long, 18.4 x 37 x 8.5 cm	ME22420	
Films	MELAfol+ (roll, 5 cm x 200 m)	ME00530	
	MELAfol+ (roll, 7.5 cm x 200 m)	ME00531	
	MELAfol+ (roll, 10 cm x 200 m)	ME00532	
	MELAfol+ (roll, 15 cm x 200 m)	ME00533	
	MELAfol+ (roll, 20 cm x 200 m)	ME00534	
	MELAfol+ (roll, 25 cm x 200 m)	ME00535	
	MELAfol+ (pouch, 5 cm x 25 cm, 1000 pcs.)	ME00536	
	MELAfol+ (pouch, 7.5 cm x 25 cm, 1000 pcs.)	ME00537	
	MELAfol+ (pouch, 10 cm x 25 cm, 1000 pcs.)	ME00538	
	MELAfol+ (pouches with side gusset, 20 cm x 50 cm, 100 pcs.)	ME00539	
Instrument baskets and trays	Tray large (1/4 StM), 31 x 58 x 5 cm	ME04520	
	Instrument basket (1/2 StM), 57 x 28 x 13 cm	ME00260	
MELAstore System	MELAstore Box 100, 31.2 x 19 x 4.6 cm	ME01191	
	MELAstore Box 200, 31.2 x 19 x 6.5 cm	ME01192	
Loading systems	Loading trolley	ME001146	
	Slide rail Comfort	ME80550	ME80570
	Batch slider	ME46891	
	Loading hook	ME28887	
Test body system	MELAcontrol Helix	ME01082	
	SteriHero Helix (incl. 250 indicator strips)	ME01084	
	MELAcontrol Pro (incl. 40 indicator strips)	ME01075	
	MELAcontrol Bowie & Dick test	ME01078	
Water treatment	MELAdem 56 reverse osmosis unit	ME11056	--
	MELAdem 56 M reverse osmosis unit	--	ME11057
Documentation	CF card	ME01043	
	Card reader for CF card	ME01048	
	MELAtrace documentation software	ME21138	
	MELAprint 60 label printer	ME01160	
	Network cable, 2.5 m	ME15817	
	Network cable, 5 m	ME15814	
	MELAprint 44 log printer	ME01144	
	Network adapter for MELAprint	ME40295	

Category	Article	Art. no.
Other	Water stop (leakage water detector with shut-off valve and probe)	ME01056
	Installation set	ME09027
	Carrying bar set (short) for Cliniclave 45/45 D	ME82821
	Carrying bar set (long) for Cliniclave 45 M/45 MD	ME82820
	Chamber Protect chamber cleaning set	ME01081
	MELAG Care Oil Spray	ME22935
	Heat protection gloves	ME89600
Spare parts	Door seal for Cliniclave 45/45 M/45 D/45 MD	ME60480
	MELAG oil for door lock nut	ME27515
	Test gauge TR20 for door lock nut	ME27521

Glossary

Accessory
Accessories are independent articles that are used with one or several medical devices. Accessories specifically and directly assist the intended purpose of the medical device.

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.

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

BfArM
BfArM is the abbreviation for “Bundesinstitut für Arzneimittel und Medizinprodukte” [Federal Institute for Drugs and Medical Devices] in Germany.

Bowie & Dick test
The Bowie & Dick test is a vapour penetration test with standard test package, see EN 285. This test is recognised in large-scale sterilization.

CF card
The CF card is a memory medium for digital data; Compact Flash is an official standard, i.e. these memory cards can be used in every device fitted with the corresponding slot. The CF card can be read by every device that supports the standard and where necessary, written on.

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.

Component
A component is a part of a medical device, which is delivered with it but is not permanently connected to it. A component supports or achieves the intended purpose of the medical device for at least one use case. It is not an independent accessory or medical device.

Condensate
Condensate is a liquid (e.g. water) that emerges from the vapour state when cooled and thus separates.

Conductivity
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
Corrosion is the chemical alteration or destruction of metallic materials by water and chemical substances.

Delay in boiling
Superheating is the phenomenon that it is possible under certain circumstances to heat liquids beyond their boiling point without them boiling. This condition is unstable. Low-level agitation can produce a large bubble within the shortest period; this can expand explosively.

Demineralised water
Demineralised water does not contain minerals that are found in normal spring or tap water. It is obtained from tap water by ion exchange and used as feed water.

DGSV
DGSV is the abbreviation for “Deutsche Gesellschaft für Sterilgutversorgung” [German Society for Sterile Supply]. The training guidelines of the DGSV are listed in DIN 58946, Part 6 as requirements for 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 for “Sterilization – Steam sterilizers – Part 7: Building requirements and requirements placed on the equipment and the operation of steam sterilizers in the health-care branch”

DIN 58953
Standard for “Sterilization – Sterile supply”

Distilled water
Distilled water is largely free of salts, organic substances, and micro-organisms. It is obtained by distillation (evaporation and subsequent condensation) from normal tap water or pre-purified water. Distilled water is used as feed water.

Double jacket steam generator
The double jacket steam generator is used for rapid steam generation outside the sterilization chamber and ensures uniform temperature distribution in the chamber wall.

EN 1717
Standard for “Protection against pollution of potable water installations and general requirements of devices to prevent pollution by back flow”

EN 285
Standard for “Sterilization – Steam sterilization – Large sterilizers”

EN ISO 11140-6
Standard for “sterilization of products for use in medical treatment – chemical indicators – part 6: Class 2 indicators and test bodies for the performance testing of small steam sterilizers”

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

EN ISO 17665
Standard for “Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices“

Equipment
Equipment is an article that can be used with the medical device, however, it is not necessary for assisting and/or achieving the intended purpose of the medical device. It is not an independent accessory or medical device.

Evacuation
Evacuation is the creation of a vacuum in a vessel.

Feed water
Feed water is required to generate the water vapour for the program run; guide values for water quality in accordance with EN 285 or EN 13060.

Fractionated vacuum procedure
The fractionated vacuum process is a technical process of steam sterilization. This procedure includes the repeated evacuation of the sterilization chamber in alternation with steam injection.

FTP
FTP (File Transfer Protocol) is a data transmission procedure serving to transfer data from the Internet. This data can include programs, files or even information. Special FTP programs (FTP clients) serve to load the data onto a server.

KRINKO
KRINKO is the abbreviation for “Kommission für Krankenhaushygiene und Infektionsprävention” [Commission for Hospital Hygiene and Infection Prevention] at the Robert Koch Institute in Germany.

Load
The load includes products, equipment, or materials that are reprocessed together in one operating cycle.

Medical device
Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes in accordance with Regulation (EU) 2017/745 Article 1, Paragraph 4.

Mixed loads
The load within a batch includes both packed and unpacked products.

Multiple wrapping
The load is sealed in a double layer of film, instruments wrapped in films are additionally placed in a container or containers wrapped in textiles.

Porous
Porous describes the property of materials (e.g. textiles) to allow water, air, or other liquids to pass through.

Pre-heating time
The preheating time is the time required for preheating the double-jacket steam generator after starting up the device or after starting a sterilization program before the sterilization process starts. The duration depends on the sterilization temperature.

Process evaluation system
The process evaluation system (also known as “self-monitoring system”) monitors itself and compares sensors during running programs.

Qualified electrician
The qualified electrician has the suitable technical training, knowledge, and experience to recognise and avoid hazards that can be caused by electricity, see IEC 60050 or for Germany VDE 0105-100.

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

RKI
RKI is the abbreviation for “Robert Koch-Institut” [Robert Koch Institute]. The Robert Koch Institute is the central institution for the detection, prevention, and control of diseases, especially infectious diseases.

Soft sterilization packaging
A soft sterilization wrapping is a paper bag or a transparent sterilization package.

Sterile barrier system
The sterile barrier system is a minimum level of sealed packaging that prevents the entry of micro-organisms (e.g. sealed pouches, sealed reusable containers, folded sterilization wipes) and allows for the aseptic delivery of the product at the point of use.

Sterile material
Sterile goods are successfully sterilized (i.e. sterile) goods. Sterile goods are also referred to as batches.

Sterilization chamber
The sterilization chamber is the part of the steam sterilizer where the load is sterilized.

Sterilization module

A sterilization module (StM) is a unit of volume for sterilization in steam sterilizers. It is a cuboid with dimensions 300 mm (height) × 600 mm (length) × 300 mm (width), which equals a total volume of 54 litres.

TCP

TCP (Transmission Control Protocol) designates a standard-protocol for a connection between computers and networks.

Vacuum

Colloquially, vacuum is a space free of matter. In the technical sense, it is a volume with reduced gas pressure (mostly air pressure).

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Original instructions

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