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MELAG
competence in hygiene

User manual

Cliniclave®45
Cliniclave®45 M

Large steam sterilizer

v3.097



Dear doctor,

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 treatment 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 systems is subject to close monitoring: Our certified quality management systems is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485 and ISO 9001 conducted by the certification agency BSI. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE 0535

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General notes

Please read this user manual before you start operation of the device. The manual includes important safety information. The functionality and value-retention of this device depend on the care accorded to it.

Please store the user manual carefully and in close proximity to the device, e.g. in the bracket on the inside of the floor unit door. It represents a component of the product.

Validity

This manual is valid for the autoclave Cliniclave 45 and Cliniclave 45 M.

About this manual

Symbols used

Symbol	Explanation
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Indicates a dangerous situation which if not avoided could entail damage to the instruments, the practice equipment or the device.
	Draws your attention to important information.

Formatting rules

Symbol	Explanation
Fig. 1/(12)	Reference to a detail in a figure – in the example, to part no. 12 in figure 1.
`Settings`	Words or phrases appearing on the display of the device are marked as display text.
see Chapter 2	Reference to another text section or a figure within this manual.

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Symbols on the device

Symbol	Explanation
CE 0535	In affixing the CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the medical products directive. The four-digit number confirms that this is monitored by an approved certification agency.
CE 0035	In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the pressure device directive. The four-digit number confirms that this is monitored by an approved certification agency.
	This symbol indicates areas 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 a raised danger of crushing resulting from the improper closure of the autoclave door. Please comply with the instructions outlined in the corresponding chapter.
	The symbol of the crossed out waste bin identifies a device that must not be disposed in domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of. By the designation of an apparatus with this symbol, the manufacturer furthermore declares that he satisfies all requirements of the law concerning the release, redemption and environmentally sound disposal of electric and electronic appliances.

Scope of delivery

Standard scope of delivery

- Cliniclave 45 (without floor unit) or Cliniclave 45 M (with floor unit)
- User manual
- Technical manual
- Record of installation and set-up
- Declaration of conformity Medical Device Directive
- Declaration of conformity Pressure vessel Directive
- Warrenty
- Slide rail "Standard"
- Protective gloves
- Carrying handles
- Waste water hose (flexible hose)
- Open-ended wrench for the validation fitting connection/floor unit rollers
- Ring spanner for the validation fitting fastening nuts
- Allen key to open the door in an emergency
- Grease for door locking mechanism
- Filter insert for housing fan
- 3M Bowie&Dick-Test
- Installation package (sent in advance) consisting of
  - ¾" Rubber seal
  - surface-mounted siphon
  - ¾" water tap with safety combination

As option

- Floor unit (for Cliniclave 45)
- Reverse osmosis unit MELA*dem* 56 (for Cliniclave 45) or MELA*dem* 56 M (for Cliniclave 45 M)
- Leak detector (water stop)
- Loading system for effortless loading and unloading

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⚠Safety Instructions

When operating the autoclave, please observe the following safety instructions as well as those contained in subsequent chapters.

Intended use

- The autoclave is suited to highly-demanding sterilization tasks. It can be used to sterilized instruments with a low inner diameter and transfer instruments - both wrapped or unwrapped - and large quantities of textiles.
- Do not sterilize any thermo-unstable products.
- Do not sterilize any fluids in this autoclave.

Power cable and mains socket

- Never damage or alter the plug or power cable.
- Never operate the autoclave if the plug or power cable are damaged.
- Never unplug by pulling on the power cable. Always grip the plug itself.

Double-jacket steam generator

- The autoclave remains pressurized for a long time after being switched-off. Check the pressure display of the manometer below on the front of the autoclave.

Setup, installation and commissioning

- The autoclave should only be set-up, installed and commissioned by MELAG authorized persons.
- Never operate the autoclave in areas exposed to the danger of explosion.
- The connections for electrical provision and water supply and waste water must be set-up by trained personnel.

Autoclave with floor unit

- Move the autoclave with floor unit in the installation location solely for maintenance purposes.
- Do not roll the autoclave over any uneven surfaces or thresholds.

Treating and sterilizing textiles and instruments

- Follow the manufacturer instructions of your textile articles and instruments regarding their treatment and sterilization.
- Observe the relevant standards and directives applicable to the treatment and sterilization of textiles and instruments.
- Only ever use packaging material and systems which have been cleared by their manufacturer for steam sterilization.

Program termination

- 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 chamber.
- Depending on the time of the program abort, it is possible that the load is unsterile. Observe the clear instructions on the autoclave display. It may be necessary to re-pack and re-sterilize the sterilization material.

Removing the sterilized equipment

- Never use force to open the door.
- Use protective gloves to remove the tray. Never touch the sterilized equipment, the chamber or the inside of the door with bare hands. The components are hot.
- Check the packaging on the sterilized equipment for damage when removing it from the autoclave. Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

Maintenance

- Maintenance should only be performed by authorized personnel.
- Maintain the specified servicing intervals.

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Carrying the autoclave

- The autoclave should only ever be carried by four people. In exceptional cases, the Cliniclave 45 can be carried by two persons. In such cases, observe and comply with the corresponding specifications issued by your respective professional association.
- Transport the autoclave with the carrying handles included in the scope of delivery and screw these on only for transport purposes.
- The carrying handles can be stored in the bracket in the floor unit intended for this purpose.

Malfunctions

- Upon the incidence of repeated fault messages in the autoclave during operation, turn off the autoclave.
- The autoclave may only be serviced by authorized personnel.

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Chapter 1 – Device description

Intended Use

The steam sterilizer is designed for application in a medical context, e.g. general medical and dental practices, day hospitals, outpatient centres, medical centres, group practices and hospitals.

According to DIN EN 285, this steam sterilizer is a large steam sterilizer. As a universal autoclave, it is suited to highly-demanding sterilization tasks. It can be used to sterilize large quantities of instruments with a low inner diameter and transfer instruments – both wrapped or unwrapped – and textiles.

DANGER!

The sterilization of liquids can result in a delay in boiling, which could result in damage to the autoclave and burns.

- Never use this autoclave to sterilize any liquids. It is not licensed for the sterilization of liquids.

WARNING

Failure to observe these provisions can result in damage or can compromise safety.

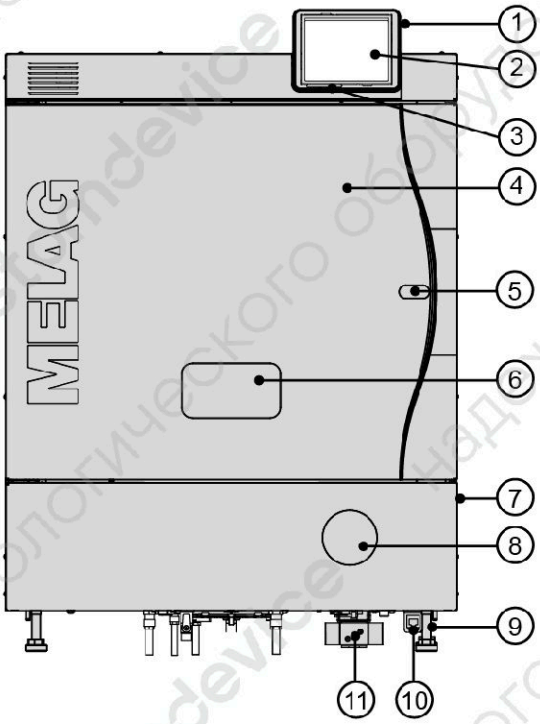
- Only ever use the autoclave for the applications as foreseen in the technical documentation and only in connection with the devices and components as recommended by MELAG.
- As with the preceding instrument treatment and in accordance with §2 MPBetreibV, the sterilization of instruments and textiles using this steam sterilizer may only be carried out by competent personnel.
- When conducting sterilization procedures, only use instruments, packaging and textiles which the manufacturer has cleared for steam sterilization.

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Views of the device

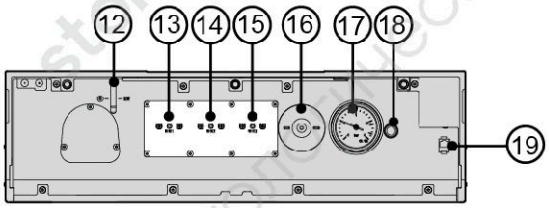
Front side



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. Manometer for pressure display*
9. Device foot
10. Ethernet connection
11. Bracket and clamp for waste water hose

*behind cover

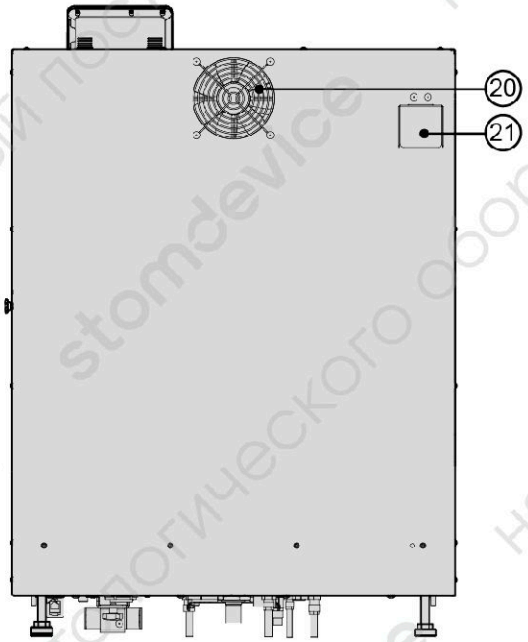
Detailed fore view with an opened service hatch



12. Steam generator level gauge
13. Reset button overheat control RHK1 (safety temperature limiter)
14. Reset button overheat control RHK2 (safety temperature limiter)
15. Reset button overheat control RHK3 (safety temperature limiter)
16. Sterile filter
17. Manometer for pressure display
18. Opening for emergency activation of the vacuum pump
19. Ethernet connection for service

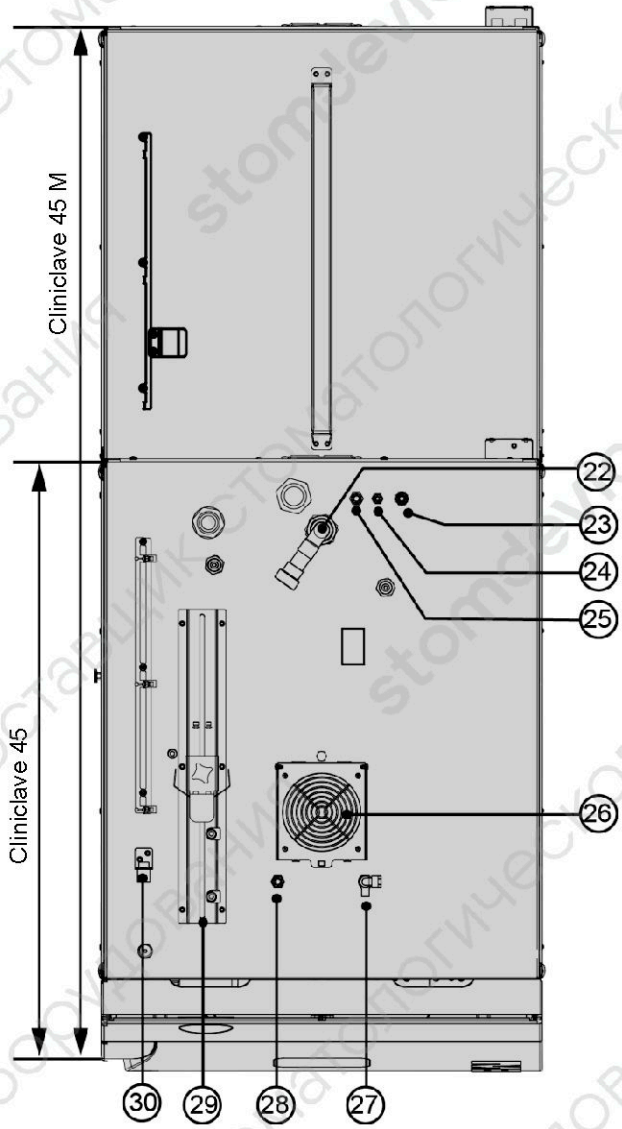
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Back side



20. Fan
21. Pressure and emergency release behind cover plate

Lower side



22. Waste water connection
23. Feed water inflow (from water treatment unit)
24. Connection of the concentrate duct from the water treatment unit
25. Cold water inflow to the water treatment unit
26. Fan
27. Connection for emptying the air gap
28. Connection for cleaning/decalcifying the vacuum pump (only for service technicians)
29. Bracket and clamp for waste water hose
30. Ethernet connection

Fig. 1: Views of the device

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Colour-Touch Display



1. Status bar
2. Menu bar
3. Main area
4. Action bar

Fig. 2: Fore view with Colour-touch display

Symbols in the status bar	Meaning
Programs/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 recording of graphic logs is activated/deactivated
Energy-saving mode	Indicates whether the autoclave is currently in energy-saving mode
Service area	Indicates whether a service technician is logged-in to the service area
Status CF card	Indicates whether a CF card has been inserted and whether a reading or writing action is in process.

Symbols in the menu bar	Meaning
Programs/Tests	Lists all sterilization programs and tests e.g. vacuum test, Bowie & Dick-Test etc.
Log output	Here you can display the entire log list or the list of logs from a restricted time e.g. the day, month etc. You can also delete specific log types and logs.
Settings	Here you can perform various settings such as date and time, light intensity etc. 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 technicians
Help menu	Depending on the window and the operating situation, gives information regarding operation or the function of the window currently selected.

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Symbols in the action bar	Meaning
 **Door open**	Opens the steam sterilizer door
 **Back**	Returns 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 "Start time pre-selection" menu
 **Delete**	Deletes the log permanently
 **Search**	Searches for label printer(s)/log printer(s)

LED status bar

The colour of the status bar on the edge of the display indicates a variety of situations e.g. in standby, during a program run or during warning or malfunction messages.

LED colour	Meaning
blue	Standby, program running, drying has not yet begun
green	Drying running, program completed successfully
yellow	Upon warnings, during a software update
red	Upon a malfunction message, program not completed successfully

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Load mount

Mount for 2 instrument baskets or 4 large instrument trays

The mount can accommodate two instrument baskets or four large instrument trays.

The sterilization chamber of Cliniclave 45 holds a single mount of this type, the chamber of Cliniclave 45 M holds two mounts.

*Mount for 6 standard tray cassettes**

The mount can accommodate six standard tray cassettes.
The sterilization chamber of Cliniclave 45 accommodates up to three mounts of this type and the chamber Cliniclave 45 M up to six mounts.

*Mount for 8 dental trays**

The mount can accommodate eight dental trays. The sterilization chamber of Cliniclave 45 accommodates up to three mounts of this type and the chamber of Cliniclave 45 M up to six mounts.

*Mount for 5 dental containers**

The mount can accommodate five dental containers, five standard tray cassettes or five instrument trays. Up to three mounts of this type can be used per sterilization unit.

* We do not recommend using this mount in the rear half of the Cliniclave 45 M with the loading system "Standard". In such a case, please use the loading system "Comfort".

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Chapter 2 – First steps

Preconditions for commissioning

All preconditions for commissioning are listed in the Technical manual under "Setup and Installation".

Record of installation and set-up

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

Providing feed water

Always use high-quality feed water

Steam sterilization requires distilled or demineralized/de-ionized water. DIN EN 285:2009 recommends observance of the guide values in accordance with Appendix B, table B.1 when using feed water (see Technical Manual).

The special construction of the steam generator and the procedure employed to generate the steam (integrated gas venting) makes higher conductivity values permissible. As a result, the value of 5 µS/cm recommenced in accordance with DIN EN 285:2009 in table 1 can be exceeded.

At 15 µS/cm, the water treatment unit mixed-bed resin cartridge should be replaced.

Once conductivity has reached 20 µS/cm the display issues a warning message. At this point at the latest, the mixed-bed resin cartridge should be replaced/the unit should be checked.

> ***Feed water generated in the osmosis procedure using the MELAdem 56/56 M complies with the requirements placed on feed water.***

Feed water supply of the steam sterilizer

Feed water supply is best performed via the water treatment units MELA*dem* 56 or MELA*dem* 56 M. These water treatment units produce optimal feed water for the steam sterilizer.

The vacuum pump and the water treatment units are supplied via the type AB free discharge installed in the autoclave.
This prevents the water from flowing back into the drinking water supply and corresponds to the full requirements of DIN EN 1717 (fluid category 5).

> ***Should you wish to use a water treatment unit from another manufacturer, please first consult with MELAG and observe the installation hints.***

Tap water supply

The autoclave vacuum pump and the water treatment unit require tap water for operation.

The vacuum pump and the water treatment unit are supplied via the type AB free discharge installed in the autoclave. This prevention of water flowing back into the drinking water supply complies with the full requirements of DIN EN 1717 (fluid category 5).

The used water is disposed via an on-site effluent system.

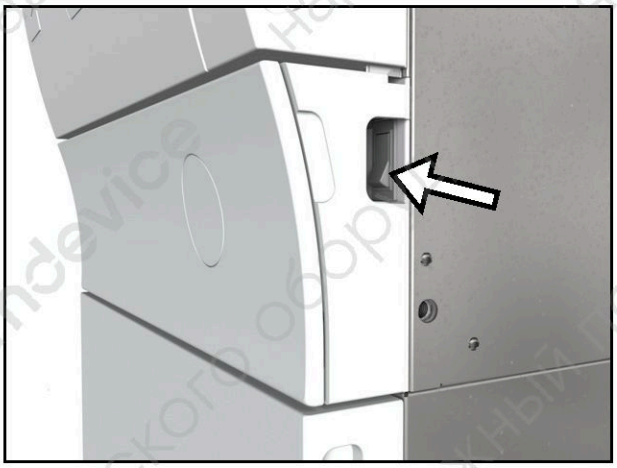
The intelligent water management system inbuilt in the autoclave control reduces water consumption to a minimum.

Switch on the autoclave

The autoclave is switched-on via the power switch on the right-hand side of the autoclave.

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Opening and closing the door

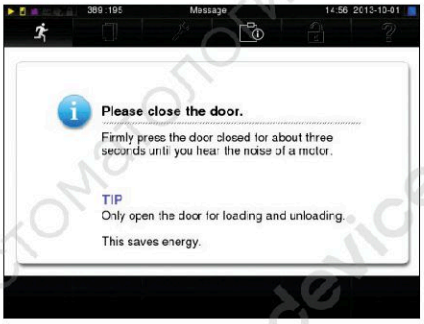
PLEASE NOTE
Entry on the display is only possible when the door is closed.

The autoclave is fitted with a motor-driven automatic door locking mechanism with a thread spindle.

Press the door symbol  in the action bar to open the door.

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

If the door is open, the following message will be displayed:



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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.

Please observe the following when closing the autoclave door:

- Do not exert too little pressure when pushing the door closed.
- Hold the door closed for at least three seconds.
- Never slam the door.
- If your autoclave has a floor unit, ensue that the breaks on the casters are engaged.

DANGER OF CRUSHING

Grasping the door between the inside of the door panel and the door beam brings the risk of crushed hands should the door swing round.

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

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Chapter 3 – Loading the steam sterilizer

Preparing the sterilization material

The most important precondition for the safe disinfection and sterilization of sterilization material is the correct cleaning and care of the sterilization material in accordance with the manufacturer's specifications. The choice of materials, cleaning fluid and treatment procedures used are also of great significance.

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

Treating textiles

Please observe the following points when treating textiles and putting the textiles in sterilization containers:

- Observe both the textile manufacturer's instructions regarding treatment and sterilization as well as the relevant standards and directives.
- Arrange the folds in the textiles parallel to each other.
- Stack textiles vertically wherever possible and not too closely together in the sterilization chamber. This enables the development of flow channels.
- Retain the vertical stacking system when packing textiles in the sterilization container.
- If textile packages do not remain together, wrap the textiles in sterilization paper.
- Only ever sterilize dry textiles.
- The textiles must not be permitted to come into direct contact with the sterilization chamber; otherwise they will become saturated with condensate.

DANGER OF INFECTION!

Steam penetration of the textile package can be restricted and/or will produce poor drying results. The textiles could not be sterilized.
This could endanger the health of patient and practice team.

- Comply with the treatment instructions contained in these instructions.

Treating instruments

Please ensure the following when treating used and brand-new instruments:

- Follow both the instrument manufacturer's instructions regarding treatment and sterilization and comply with the relevant standards and directives.
- Clean the instruments thoroughly e.g. using a Washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with de-mineralized or distilled water and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
- Use only those care products suitable for steam sterilization. Consult the manufacturer of the care agents.

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DANGER!

The incorrect treatment of instruments could result in any dirt residue being loosened by the steam pressure during sterilization. The presence of residual disinfection and cleaning fluids results in corrosion.

The use of unsuitable care agents e.g. water repellent agents or oils impermeable to steam could result in unsterile instruments. This represents a danger to the health of both patients and yourself.

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

- Comply with the treatment instructions contained in these instructions.

When using ultra-sound devices, care equipment for hand pieces and washing and disinfection devices, please observe the manufacturer's treatment instructions.

Loading the autoclave

Only when correctly loaded is effective sterilization and good drying possible.

Ensure the following during loading:

- Insert trays or cassettes in the chamber only with their appropriate mount.
- Use perforated trays such as those from MELAG. Only in this way can the condensate drain off. The use of a non-perforated base or half-shell to accept the sterilization material can result in poor drying results.
- Under certain circumstances, the use of paper tray inserts can result in poor drying results.

Packaging

Only ever use packaging materials and systems (sterilization barrier systems) corresponding to the standard DIN EN IS0 11607-1.

The correct use of suitable packaging is important in achieving successful sterilization results.

You can use re-usable rigid packaging systems such as e.g. standard tray cassettes or soft packaging such as transparent sterilization packaging, paper bags, sterilization paper, textiles or fleece.

Closed sterilization containers

Please observe the following when using closed sterilization containers for sterilization material:

- Use aluminium sterilization containers. Aluminium retains and conducts heat and thus improves drying.
- To guarantee steam penetration and vacuum drying, closed sterilization containers must be fitted with filters or valves on at least one side (preferably above).

  With heavy loads (e.g. orthopaedic instruments) on which a great deal of condensate can develop, we recommend the use of containers with condensate drains (e.g. from Wagner).
- Wherever possible, please ensure that sterilization containers are stacked on top of those of identical size, so that the condensate can run down their sides.

  MELAG sterilization containers fulfil the requirements for successful sterilization and drying. They have a perforated lid and are fitted with single-use paper filters.
- Ensure that the perforations are not covered when stacking the containers.

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WARNING

The use of unsuitable sterilization containers results in insufficient steam penetration and even failure of the sterilization. This can also prevent condensate drain-off.

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

WARNING

Incorrect stacking of the sterilization containers can result in the dripping condensate being unable to drain off to the chamber floor. This would then saturate the sterilization material directly underneath it.

This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

- Do not cover the perforations when stacking the sterilization containers.

Soft sterilization packaging

Soft sterilization packaging can be used in both sterilization containers and on trays. Please observe the following when using soft sterilization packaging e.g. MELA*fol*®:

- Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- If the seal seam tears during sterilization, this could be caused by the choice of undersized packaging. Should this not be the case, re-pack the instruments and sterilize them again.
- Should the seam seal rip during sterilization, extend the sealing pulse on the sealing device or make a double seam.

Multiple wrapping

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

Mixed loads

Please observe the following when using mixed loads:

- Always place textiles at the top.
- Place the sterilization containers at the bottom.
- Place transparent sterilization packaging and paper bags at the top - except in combination with textiles. In this case, place them at the bottom.
- As far as possible, arrange transparent sterilization packaging on their edge. If this is not possible, place them with the paper side facing downwards.

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Loading volumes

Table 1: Maximum permissible load quantity.

Loading variation	Load	
	Instruments	Textiles
max. weight per piece	2 kg	2 kg
Cliniclave 45		
max. total weight[1] Unwrapped, wrapped[3] load	40 kg	7 kg
max. total weight Unwrapped load	35 kg	--
Cliniclave 45 M		
max. total weight[1] Unwrapped, wrapped[3] load	80 kg	14 kg
max. total weight Unwrapped load	70 kg	--
Loading variations per sterilization unit[2]		
Mount for 2 instrument baskets or 4 large instrument trays	max. 4 large instrument trays, depth 59 cm max. 2x ½ StU sterilization containers max. 2x ½-StU instrument baskets	
Mount for 6 standard tray cassettes[4]	max.18 standard tray cassettes (6 per mount)	
Mount for 8 small instrument trays[4]	max. 24 dental trays, depth 29 cm (8 per mount)	
Mount for dental containers[4]	max. 15 dental containers (5 per mount)	
Without mount	max. sterilization containers (1 StU)	

1 The total weight is the sum of the mass of the sterilized equipment, the packaging materials, the containers and the mount
2 Mounts, trays, standard tray cassettes etc. from MELAG see appendix A
3 The autoclave can sterilize up to 40 kg/80 kg total load weight. The drying was checked for the 35 kg/70 kg load with dental containers The drying of other large weights of other loads (20-40 kg/40-80 kg wrapped) or other load configurations must be checked individually and locally; otherwise use additional drying.
4 We do not recommend using this mount in the rear half of the Cliniclave 45 M with the loading system "standard". In such a case, please use the loading system "comfort".

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Loading system

MELAG provides a loading system, enabling the effortless and ergonomic loading and unloading of the autoclave. This consists of a transport trolley, slide rail, batch slider and loading hook. The applicable operating manual provides information regarding the set-up and use of the transport trolley.



PLEASE NOTE

Please consult the operating manual of the sterilization container. Never exceed the maximum permissible load size and weight.

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Chapter 4 – Sterilizing

Important information regarding routine operation

Daily routine controls

- Check the sterilization chamber and seal for its correct condition, see **Chapter 8 – Maintenance, Cleaning**.
- Check the operation readiness of the recording equipment, see **Chapter 5 – Logging**.
- Perform a Bowie & Dick test (steam penetration test), see **Chapter 7 – Functional Checks, Bowie & Dick test**.
- Please perform regular checks of the pressure on the pressure tank manometer of the water treatment unit before first program start.

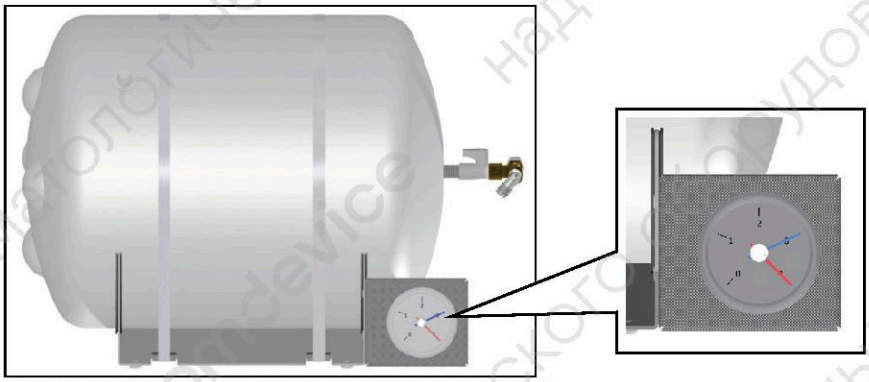


Fig. 3: Lateral view of the MELA*dem* 56 pressure tank

With daily operation, the pressure tank is still sufficiently full from the previous day. The blue indicator must display 3-4 bar to guarantee fault-free feed water supply.

If a pressure of less than 3 bars is measured, leave the autoclave switched on. Do not switch it off, so that the water treatment unit is able to produce sufficient feed water.

If the pressure in the pressure tank lies below 2.5 bar (red marking) before the program start, this means that there is insufficient feed water in the pressure tank and that a warning or malfunction message can be displayed.

Further routine controls

The former DIN 58946-6 and DIN 58946-7 both 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
Annually or following 4000 cycles	Maintenance
After changes to the autoclave and its maintenance	Operational qualification (OQ)
After changes to the configuration	Renewed performance qualification (PQ) for a particular reason
In regular intervals after 1-2 years (in accordance with DIN EN 17665, section 12.4 and DIN 58946-7) and after assessment of the validator.	Renewed performance qualification (PQ)

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Selecting the program

Select the sterilization program according to how and whether the sterilization material is packed. It is also necessary to take into account the temperature resistance of the sterilization material.
All sterilization and additional programs are displayed in the `Programs & Tests` menu.

The following table shows which program fits which load plus an overview of the supplementary programs.

Used with the types of load specified in this chapter, the program-specific drying times guarantee very good drying of the sterilized equipment.

For difficult drying tasks, navigate to the `Settings` menu and chose the option `Additional drying` to extend the drying time by 50%, see Chapter 6 – Settings.

Table 2: Overview of sterilization programs

	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Sterilization temperature	134 °C	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2.1 bars	2.1 bars	2.1 bars	1.1 bars	2.1 bars
Sterilization time	5.5 min.	3.5 min.	3.5 min.	20.5 min.	20.5 min.

Table 3: Overview of the use of the respective sterilization programs

Program	Operating time[1]		Drying[2]	Wrapping
	Cliniclave 45	Cliniclave 45 M		
Universal-Program				
Partial load[3]	~23 min.	~27 min.	20 min.	multiple wrapped
Full load[4]	~35 min.	~48 min.	20 min.	
Textiles[5]	~26 min.	~35 min.	20 min.	
Quick-Program B				
Partial load[3]	~20 min.	~25 min.	~10 min.	single wrapped
Quick-Program S				
Partial load[3]	~17 min.	~22 min.	~6 min.	unwrapped
Gentle-Program				
Partial load[3]	~36 min.	~45 min.	20 min.	multiple wrapped
Textiles[5]	~42 min.	~53 min.	20 min.	
Prion-Program				
Partial load[3]	~38 min.	~42 min.	20 min.	multiple wrapped
Full load[4]	~50 min.	~63 min.	20 min.	
Textiles[5]	~41 min.	~50 min.	20 min.	

1) Without drying and dependent on the load and the set-up conditions e.g. mains voltage and air-pressure. The steam sterilizer requires additional one-off heating-up period to heat the double-jacket steam generator after activation. Given normal operation of a Cliniclave 45, this requires c. 13 minutes and 20 minutes for a Cliniclave 45 M.

2) By taking into account the specified load quantities, the program-specific drying times guarantee excellent drying of the sterilized equipment. The drying time can be extended by 50% for especially difficult drying tasks by activating the additional drying.

3) This corresponds to 15 kg for a Cliniclave 45 and 30 kg for the Cliniclave 45 M.

4) This corresponds to 35 kg for a Cliniclave 45 and 70 kg for the Cliniclave 45 M.

5) This corresponds to 7 kg for a Cliniclave 45 and 14 kg for the Cliniclave 45 M.

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Additional program	Use/function
Vacuum test	For measurement of the leakage rate, text with dry and cold devices (test without load)
Bowie & Dick test	Steam penetration test with special test package (available from specialist stockists)
Conductivity measurement	For manual measurement of the feed water quality
Emptying	For emptying and pressure relief of the double-jacket steam generator e.g. for service, maintenance or before transport

Selecting the start time pre-selection

The function start time pre-selection enables you to select any program and start it at a time of your choice.

1. After selecting the program, press the  symbol in the action bar. The display switches to the "Start time pre-selection" window.
2. For example, to change the time, tap directly on the parameters "hour" or "minute". The selected field is highlighted light blue.



3. Change the time by pressing on the pushbuttons  and .
4. Then press START. The display remains in the "start time pre-selection" screen.

PLEASE NOTE

The safety question function means that start time pre-selection function is not possible for Quick-Program S.

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

The start time pre-selection is only active for the unique time and program selection. That means that after completion of the program, the pre-selected start time expires.

You can switch-off the autoclave during the start time pre-selection. However, the autoclave must be switched on before the timer runs out.

Selecting automatic shutdown

The automatic shutdown function enables the automatic deactivation of the autoclave at the end of a program, e.g. after the last batch at the end of the day. Batch clearance can be performed by reactivating the autoclave as usual.

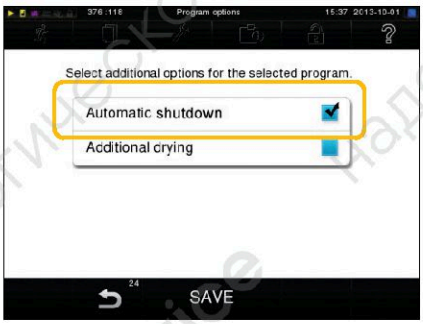
Proceed as follows to activate automatic shutdown for the next program run:

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

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The display switches to the following window.



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

WARNING

Unsupervised operation of the device can result in damage to the device or your facility. In such a case, MELAG does not accept any liability.

- Never operate the device unattended. Unsupervised operation of electrical devices, including this autoclave at the operator's risk.

Starting the program

A program is displayed as marked after it has been selected. You can now start via pressing START.



The door locks pressure-tight upon program start. The autoclave checks the quantity of feed water and its conductivity.

A visual warning and an acoustic signal are issued upon start of the Quick-Program S. Quick-Program S is intended exclusively for the sterilization of unwrapped instruments. If the load contains unwrapped instruments only, confirm with YES and the program will start.

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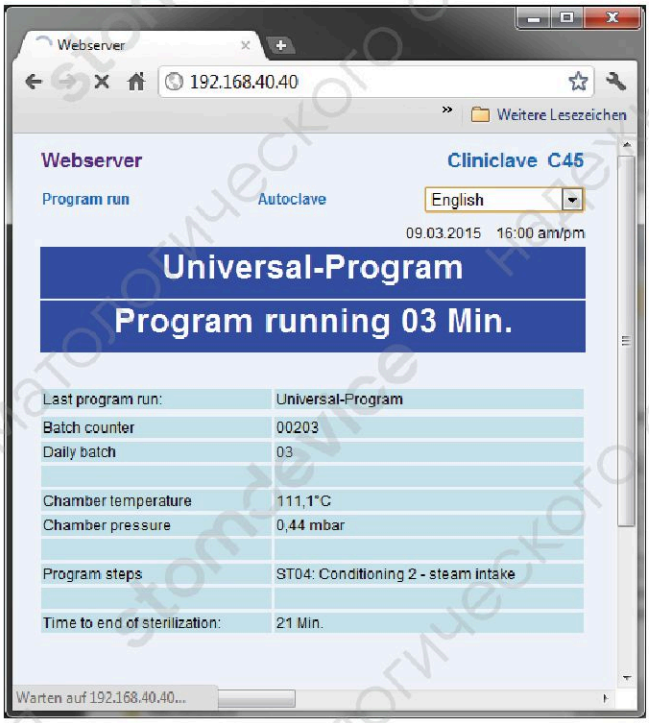
Following the program run on the computer

You can follow the progress of a current program on every computer of the user network via the website integrated in the autoclave.

The autoclave must be assigned an IP address and be connected to the user network.

1. Open a web browser window (we recommend Mozilla Firefox or Internet Explorer).
2. Enter the autoclave IP address on the user P.C. in the address bar of the web browser, e.g. 192.168.40.40 and confirm with ENTER.

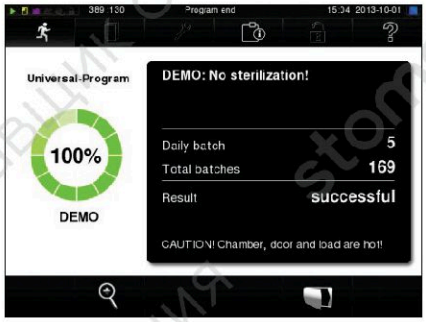
   You can now view the program run or information regarding your autoclave such as the serial number or device software version.



Sterilization phase is ended

The display enables you to see whether the sterilization phase has already 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 operator or the system (responding to a fault) aborts the program run.

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Drying phase

The autoclave provides excellent drying of the sterilization material. If difficult-to-dry items require better drying, you can undertake the following steps to improve drying:

- e.g. stand the transparent and paper sterilization packaging upright, see section Loading the autoclave on page 17.
- Use the optional package holder if necessary.
- Activate additional drying, see Chapter 6 – Settings.

Program is ended

When the program has ended successfully, the corresponding message will be issued on the display. You can view further values generated by the program just ended on the display before opening the door.

Press the magnifying glass symbol .

Working in the "Settings" menu under "Logging", if immediate output after program end is activated, the log of the completed program will be outputted to the activated output medium after opening the door (see Chapter 5 – Logging, page 30).

Manual program abort

You can abort a current program in all phases. If you end the program before drying begins, the sterilization material remains **unsterile**.

WARNING

Aborting a current program by switching off the power switch can result in the egress of hot steam from the emergency release valve behind the cover plate (Fig. 1/(22)). This will result in damage to the autoclave.

- Never abort a program by switching off at the power switch.

DANGER!

The sterilization chamber, door and the sterilized equipment are hot. Moreover, depending on the time of the program abort, opening the door following a program abort can lead to the egress of hot steam.

This could result in burns.

- Use suitable protective gloves to remove the trays.
- Never touch the sterilized equipment, the sterilization chamber or the door inside with bare hands.

Manual abort during drying

You can abort the program during the drying phase via the STOP pushbutton without the autoclave registering a fault.
You then need to expect insufficient drying, especially in the case of wrapped sterilized equipment (e.g. full load).
Sterile storage requires sufficient drying.
As a result, a drying abort is only permissible if the instruments are to be used directly afterwards or dried off within a prescribed time.

According to the Arbeitskreis für Instrumentenaufbereitung (AKI; Red Broschure; 10 Edition; S.57): "In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable."

Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

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WARNING

The standard DIN EN 285 prescribes very good drying (residual moisture < 1% for textiles/0.2 % for metal). This is not guaranteed if a program is aborted prematurely.

In such a case, following the requirements placed on sterilization by DIN EN 285 and DIN 58946-7, sterilization is classified as not completed successfully.

- Only ever perform a premature drying abort to effect immediate renewed availability of the instruments in an emergency.

Press the STOP pushbutton to abort the program. Confirm the abort with YES.

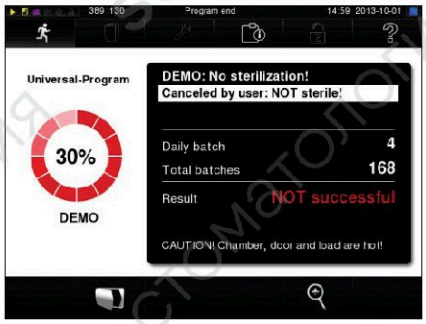
After a short time, you can open the door by pressing the door symbol .



Manual abort before drying

If you end the program before drying begins, the sterilization material remains **unsterile**.

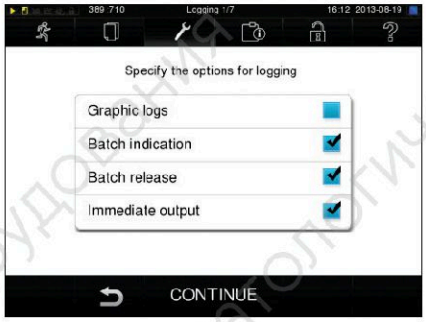
A warning appears on the display. Sterilization is marked on the log as NOT successful.



The clearance process

Instrument treatment ends with the documented clearance for storage and application of the sterilized equipment.

The clearance process consists of batch indication and batch clearance. Both must be performed by an authorized expert.



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Batch indication comprises the checking of the indicators used in the sterilization program e.g. MELA*control*/MELA*control* PRO.

Clearance of the indicator strip is possible only if it changes colour entirely.

Batch clearance comprises the checking of the process parameters using the sterilization results on the autoclave and the sterilization log as well as checking of the individual packaging for damage and residual moisture. Batch clearance and any indicators used is documented on the sterilization log.

Depending on the setting in user administration, clearance of the sterilized equipment requires the user PIN of the person clearing the batch and the indicators.

Removing the sterilized equipment

DANGER!

Metal parts and load are hot after the program end. Hot steam egress is possible. This can result in burns

- Comply with the instructions regarding removal of the sterilized equipment.

DANGER!

If packaging is damaged or split during a program run, the instruments may not be sterile. This can endanger the health of your patients and practice team.

- Damaged or split packaging must be repackaged and re-sterilized.

You must observe the following specifications whilst removing the sterilized equipment upon a program end:

- Never use force to open the door. This could damage the autoclave and/or result in the emission of hot steam.
- Use suitable protective gloves to remove the trays.
- Never touch the sterilized equipment, the chamber or the inside of the door with bare hands. The components are hot.
- Check the packaging on the sterilized equipment for damage when removing it from the autoclave.
- Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

PLEASE NOTE

When using a mount for 2 instrument baskets and 4 large instrument trays, for safety reasons, please ensure that the instrument trays/baskets are removed individually. Never remove the entire mount with load on it.

If you remove the sterilized equipment from the autoclave directly after the end of the program, it is possible that the instruments can be partially damp.

According to the Arbeitskreis für Instrumentenaufbereitung (AKI; Red Broschure; 10 Edition; S.57): "In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable."

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Storing sterile instruments

Use only standard-conform packaging for the sterilized equipment. Do not store the sterilized instruments in the treatment room. Observe the provisions of DIN 58953, part 8 and the following criteria when storing sterilized equipment:

Observe the following criteria when selecting the storage location and duration of the sterilized equipment:

- Protected against dust e.g. in a closed instrument cupboard
- Protected from damage to their shiny surfaces
- Protected from significant temperature differences
- Protected from moisture (e.g. from alcohol, disinfection fluids)
- The possible length of storage depends on the type of packaging
- The maximum storage time is dependent on the packaging and the storage conditions. For standard-conform packaged sterilized equipment (protected from dust) it can amount up to six months.

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Chapter 5 – Logging

Batch documentation

The batch documentation acts as proof of the successful conclusion of the sterilization process and represents an obligatory part of quality control (MPBetreibV).

The steam sterilizer 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 read out the internal log memory and transfer the log 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 capacity of the internal log memory is sufficient for c. 100 logs. If the internal log memory becomes almost full and at least one log has not been outputted via an activated output medium, the following warning will appear on the display: `Internal log memory almost full`. If this warning appears, working in the `Settings` menu → `Logging`, provide the pre-determined output media and output the logs affected (in the `Log output` menu).

Shortly afterwards, the following message is displayed: `Internal Memory full`. You now have the last chance to archive logs which have not been outputted (confirm query with YES) before the data in the autoclave log memory (up to the last 40 logs) are deleted.

Output media

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

- MELA*flash* CF card
- A computer via the user network (LAN)
- MELA*print* 42 log printer with network adaptor

Any combination of the output media is possible. For example, it is possible both to save logs on the MELA*flash* CF card and print them. Log output on multiply activated media is performed successively. Selecting the desired output medium (once only): working in the `Settings` menu → `Logging` or working in the `Log outout` menu, select subsequent log output.

Detailed information regarding the activation and setting of log output is listed in **Chapter 5 – Logging**.

In its delivery state, the MELA*flash* CF card is activated as the output medium for text and graphic logs. Automatic logging is thus activated.

Using the CF card as an output medium

WARNING

Premature removal of the CF card from the card slot or its inappropriate handling can result in data loss, damage to the CF card, the steam sterilizer or its software.

- 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 red LED next to the card slot on the right will illuminate red in short irregular intervals during reading and writing access.

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Inserting the CF card

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.

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



Using the computer as an output medium

You can either connect the autoclave directly to a computer or via a network if the following conditions are fulfilled:

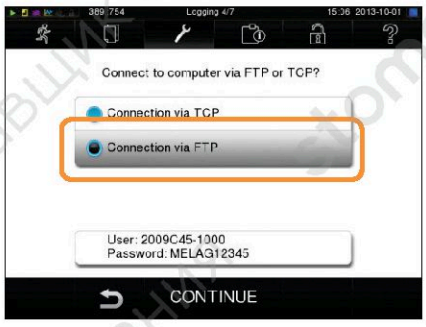
- ✓ *The computer is fitted with a network card with a RJ45 socket (LAN).*
- ✓ *An FTP server or an FTP service is installed on the computer (only for log output via FTP).*
- ✓ *A suitable program e.g. MELAtrace is installed (only for log output via TCP).*

Connection via FTP/TCP

If you have selected the computer as the output medium in the logging assistant (`Settings` menu → `Logging`) decide in the next window whether the connection should be established via FTP or TCP.

Connection via FTP

1. Set a user name with password in the FTP program.
2. Enter the user name and password in the autoclave in the `Settings` menu →`Logging`.
3. Select `Connection via FTP`.

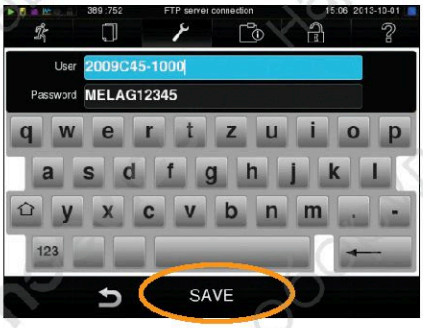




The lower pushbutton displays the current user data settings (**Standard user name:** Year of construction + manufacture number; **Password** MELAG12345).

4. Press this pushbutton to alter the pre-set FTP user data. The display switches to the settings window.

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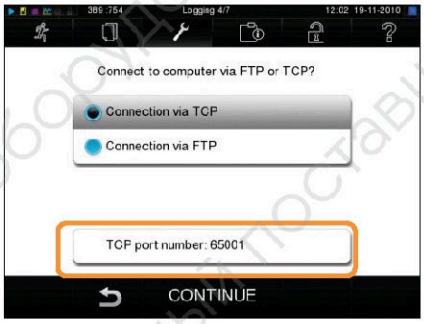
5. Enter the user name and password and confirm with SAVE.

Connection via TCP

With a TCP connection, enter the TCP port number in the autoclave as follows:

1. Select a connection via TCP.





2. The TCP port currently set is displayed on the lower pushbutton (**Standard TCP port:** 65001)
3. Press this pushbutton to alter the pre-set TCP port. The display switches to the settings window.



4. Enter the corresponding TCP port via the key pad. First delete the current TCP port with the C key.
5. Confirm with SAVE.
6. Log output via TCP requires an additional suitable program e.g. MELA*trace*.

Opening text logs with a computer

You can open and print all text logs using a text editor of every operating system or with a word processing or table calculation program.

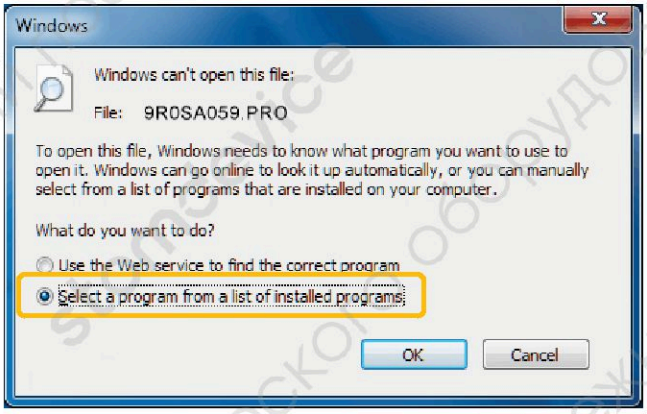
PLEASE NOTE
Graphic logs can only be displayed with the documentation software MELA*view*/MELA*trace*.

To ensure that the operating system at your computer will automatically open the text logs with a text editor, you need to connect each text log (e. g. PRO, .STR, .STB usw.) to the text editor.
For the meanings of the log endings please see page 38, **Reading logs correctly**.

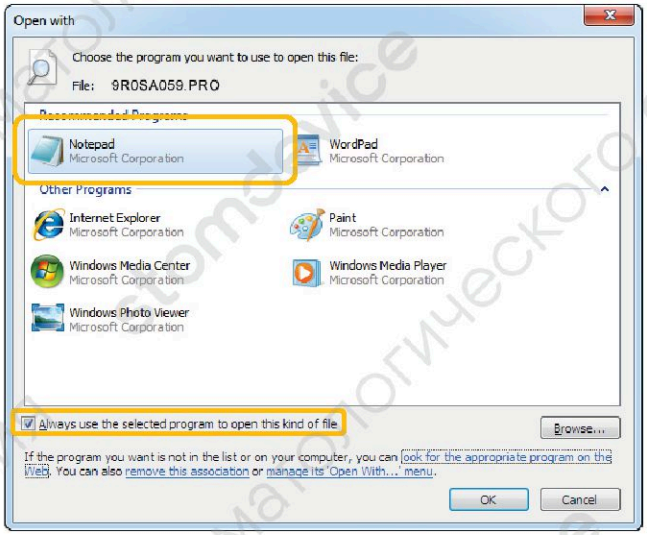
The following example of the Windows editor shows how you can link other Windows programs with a particular ending.

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1. Double click in Windows Explorer on the log file.
2. When the ending is unfamiliar, Windows 7 displays the adjacent message.



3. Select ***Select a program from a list of installed programs*** and confirm with ***OK***.
4. Select the editor from a list of programs in the opening window. Ensure to tick the option ***Always use the selected program to open this kind of file*** so that the operating system recognizes this ending the next time.



5. Confirm with ***OK***. You can then open files with this ending via a double-click in Windows Editor.

Alternatively, all text logs can be opened with the documentation software MELA*trace*/MELA*view*.

Using the label printer as an output medium

The use of a label printer, e.g. MELA*print* 60 facilitates batch traceability. Using the sterilization date, the storage duration, batch number, user ID of the person clearing the application for use, the autoclave used and the file name it is possible to assign the sterilized instruments to the patient and sterilization batch.

Faultless packages containing sterilized equipment are marked with labels after sterilization.

As such, the preconditions for correct "clearance" by the person conferred with the task of treatment are given.

All information regarding the correct sterilization procedure can be attributed to the instruments used in patient records.

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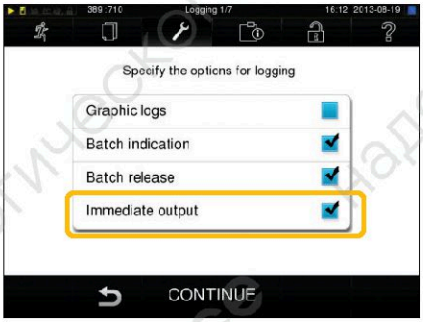
Outputting logs immediately and automatically

Outputting text logs automatically after program end (immediate output)

If you want to output the associated text log automatically after the end of a program, use the `Immediate output` option. As delivered, the autoclave is set to automatic log output via the CF card.

Activating the `Immediate output` option:

1. Select the `Settings` menu .
2. Select the `Logging` option. The display switches to the settings wizard.
3. Activate the `Immediate output` option by setting a check mark.



4. Press CONTINUE until you come to the summary window.
5. Press SAVE to save the setting.

The following requirements must be satisfied in order permit immediate output after program end:

- ✓ *Logging is selected for a minimum of one output medium in the settings menu → logging.*
- ✓ *The output medium selected is connected e.g. computer or CF card.*

If automatic log output is not possible e.g. because the selected output medium is not connected, the text log is saved in the internal memory. It will not be lost.

The autoclave registers logs not issued for every selected output medium. The option of output will be provided at the next available opportunity.

> ***We recommend retaining immediate output.***

Deactivating the immediate output function

If text logs are not to be ouptutted immediately following the end of a program, but saved in the internal memory, (e.g. to be collected and outputted together within a single week), you can deactivate the immediate output option. Proceed in the following fashion:

1. Select the `Settings` menu.
2. Select the `Logging` option. The display switches to the settings wizard.
3. Remove the check mark in front of the `Immediate issue` option.
4. Press CONTINUE until you come to the summary window.
5. Press SAVE to save the setting.

Section **Subsequent log output** describes how to output logs subsequently from the internal memory.

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Recording graphic logs (optional)

If you wish to output a graphic log in addition to a text log, activate the `Graphic logs` option.

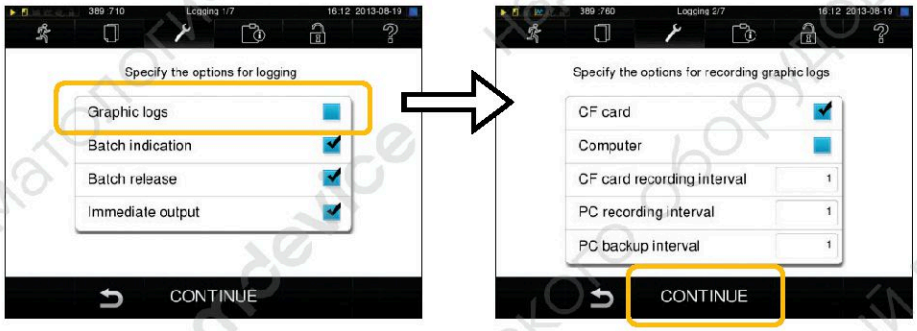
The following additional requirements must be fulfilled in order to record graphic logs:

- ✓ *In the Setting menu → logging → Graphic log, a minimum of one output medium is selected.*
- ✓ *At least one of the output media selected corresponds to an output medium for the text log.*
- ✓ *The output medium selected is connected e.g. computer or CF card.*

This function is already activated in the delivery state from the device software version 3.094.

Proceed in the following fashion to activate the option:

1. Select the `Settings` menu .
2. Select the `Logging` option. The display switches to the settings wizard.
3. Activate the `Graphic log` option by setting a check mark. Then press CONTINUE



4. Select at least one output medium on which the graphic log is to be saved.
5. Press CONTINUE until you come to the summary window.
6. Press SAVE to save the setting.

Explanation of the possible settings for graphic recording:

CFC recording interval in sec. – 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 1 second.

PC recording interval in sec. – 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 1 second.

PC backup interval in sec. – indicates the time interval in which the graphic data is saved from the autoclave on the computer. In example 1, the backup interval is set to 1 seconds.

PLEASE NOTE
Graphic logs cannot be saved in the internal log memory.

Subsequent log output

The `Settings` menu → `Logging` provides the option of outputting text logs subsequently and independently of the point of the program end.

You can set the output media yourself. The output medium is selected as standard, which are selected under `Settings` → `Logging`, as far as automatic immediate output has been activated.

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Outputting a log from the log list

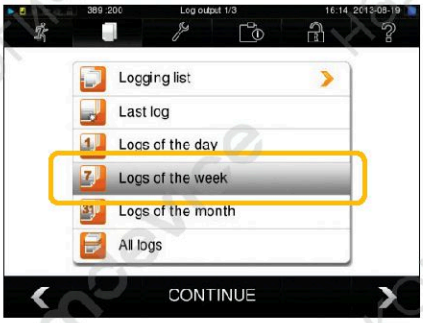
Proceed as follows to output a specific log from the internal memory:

1. Select the `Log output` menu.
2. Select `Log list` and press CONTINUE. A list with all text logs is displayed which have been saved in the internal memory.
3. To ease the search, you can filter the log sort sequence by date, program or event by selecting the top line.
4. Select a log and press CONTINUE.
5. Select an output medium and press OUTPUT.

Outputting the daily/weekly log etc.

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

1. Select the `Log output` menu.
2. Select the `Logs of the week` option and 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.

Determining the log format

Format	
Format 0	Short form - only the log header is outputted.
Format 1	The log header and the program steps are outputted.
Format 2	Standard format - in addition to the log header and the program steps, a key is displayed explaining the individual program steps.

The output format is set under `Settings` → `Logging`.

PLEASE NOTE
In logs outputted via the log printer MELA*print*®42, the corresponding legend row is always located under the row to which it refers.

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```
----------------------------------------
!0 01100EDUSN02
!1 C50P37VI.PRO
----------------------------------------
10 MELAG Cliniclave 45
----------------------------------------
15 Program:       Universal-Program
20 Program type: 134 °C wrapped
25 Date:          28.01.2015
30 Daily batch:   01 Total: 10206
35 User:          deactivated
36 Indicators changed: deactivated
37 Batch released:     deactivated
======
40 Universal-Program Ended successfully
42 = =
======
45 Temperature:  135.5  +0.10/-0.09 °C
50 Pressure:     2.16  +0.01/-0.01 bar
55 Plateau time: 05 min 30 s
60 Conductivity: 15 µS/cm (6683:70.3)
65 Start time:   08:23:39
70 End time:     09:04:23 (40:44 min)
======
80 SN:2012C450903
======
81 MR   V3.097 18.12.2014
82 Para V3.116 18.12.2014
83 BO   V3.203 18.12.2014
----------------------------------------

Step  Time t[m:s] P[mbar] T[°C]

SP-S  0:00   0:00   1001   50.6
SK11  0:40   0:40   1719   80.5
SK12  0:57   0:17   1262   89.0
SK11  1:22   0:25   1719   97.9
SK12  1:41   0:19   1266  100.3
SK21  2:05   0:24   1730  106.9
SK22  2:26   0:21   1271  105.2
SK21  2:48   0:22   1683  111.1
SK22  3:07   0:19   1273  106.9
SK21  3:30   0:23   1703  113.1
SK22  3:49   0:19   1269  108.6
SF12  4:20   0:31    485   86.0
.
.
SF32  8:00   1:00    194   75.5
SF33  8:39   0:39   1939  118.4
SF41  9:04   0:25   1262  110.1
SF42  9:42   0:38    388   86.2
SF43 10:11   0:29   1723  114.5
SH01 11:08   0:57   2863  132.0
SH02 11:28   0:20   2869  132.3
SS01 11:59   0:31   3068  134.3
SS02 17:29   5:30   3164  135.5
SA00 18:15   0:46   1267  109.1
ST01 22:01   3:46    140   69.5
ST02 22:02   0:01    172   69.3
ST03 23:31   1:29    132   81.2
ST02 23:33   0:02    158   81.6
ST03 25:02   1:29    133   93.2
ST02 25:03   0:01    160   93.3
.
.
ST02 38:37   0:02    154   97.8
ST03 40:06   1:29    129   97.9
SB10 40:34   0:28    807  101.1
SB20 40:38   0:04    873  101.4
SP-E 40:39   0:01    876  101.4

>> Never change code on follow. line <<
01004170D314F2F18B55772ABC9972B8E37E8430
3637720D1E3866C3BC15143F50193212631C7144
1CCC0F85B6FB796276DC018603F3AC3BC0C1064F
FD1AEDC25052452FBED17825410C2CC75B42CAD3
965A291942E3164CBC4D5654E37B5D27BF7C6E46
165A8860811E3DB084CC636C59590D5F9F976F37
015A14F9F687615F1618173DFB0C82D5205C833D
>> Authentication of batch log <<

----------------------------------------
0.00   0.0   0.0   0.0 ---.-   0.0
-edk----etm---etd---etp---etv--ett-END--
```

Log head

!0	Ident number
!1	File name
10	Steam sterilizer type
15	Program name
20	Program sterilization parameters
25	Date
30	Day and total batch number
35	User ID
36	Batch indication } Clearance procedure
37	Batch clearance }
40	Control signal
42	Warning or malfunction message upon program abort
45	Sterilization temperature with max. deviations
50	Sterilization pressure with max. deviations
55	Sterilization time
60	Feed water Conductivity
65	Time of program start
70	Time of program end
80	Autoclave serial number
81	Current version of the device firmware
82	Current version of the device parameters
83	Current version of the operating interface

Program step values and legend

Time	Time (mm:ss), since program start
t [m:s]	Duration (minutes:seconds), which a program step requires
P [mbar]	Pressure in the chamber in millibars
T[°C]	Temperature of the chamber in Celsius

The individual rows begin with abbreviations which refer to the type of respective program step. Outputting a legend log provides you with a list of abbreviations referring to each step.

Program steps

SK	Conditioning
SF	Fractionating
SH	Holding
SS	Sterilization
SA	Pressure release
ST	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 autoclave and has been changed.

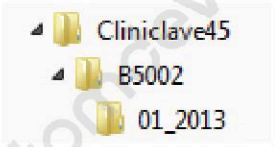
Sensor measurement values are displayed in the case of a malfunction. The values are helpful for a technician.

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Finding a log

All memory media (CF card or computer) contain a directory with the encoded serial number of the autoclave concerned. The directory name consists of five characters identical with the first five characters of every log, e.g. B5002. This directory contains a sub-directory with the month of log generation e.g. 01_2013 for January 2013. This contains all logs generated by the autoclave this month. The device directory is entered in the main directory on the CF card.



The autoclave checks the memory medium after every type of log output (immediate output after a completed cycle or the transfer of multiple logs simultaneously). Should a directory not exist, it automatically creates a directory for the device and the month.

If the logs are subject to multiple outputting on the identical memory medium, the device directory will create a "Duplicate" directory.

PLEASE NOTE

If possible, do not rename the directory, otherwise logs will be stored in both the renamed directory as well as the new device directory generated automatically by the autoclave.

Direct transfer of the log to a computer via the network and using the MELAG FTP server allows you to determine directly in the FTP server where on your computer the device directory with log files is to be saved.

With output via TCP and e.g. MELA*trace* you can determine the folder in which they are to be saved by working directly in the program.

Reading logs correctly

There now follows an overview of the logs which can be outputted:

Log type	File ending	Explanation
Log list		All program logs held in the memory are shown on the display. You can sort the list according to date, time, program and outcome by pressing on the column headings.
Last log	.PRO	The log of the last successful completed program is outputted.
Logs of the day	.PRO	The logs of all successfully completed programs of the current day are outputted.
Logs of the week	.PRO	Logs of all successfully completed programs of the week - Monday to Sunday - will be outputted.
Logs of the month	.PRO	Logs of all successfully completed programs performed in the current month will be outputted.
All logs	.PRO	Logs of all successfully completed programs will be outputted.
Last malfunction log	.STR	The last malfunction log is outputted.
Malfunction log of the day	.STR	The malfunction logs of the current day are outputted.
etc.		…
Legend log	.LEG	Contains an explanation of all abbreviations contained in the log.
Status log	.STA	A summary of all important settings and system states (counter, measured values etc.)
Malfunction in standby	.STB	This log type is generated following the malfunctions registered during a time at which no program was active.

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Log type	File ending	Explanation
System log	.LOG	A sort of log book 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. WARNING! All logs will be deleted which were not previously outputted to another output medium.

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Chapter 6 – Settings

Logging

see Chapter 5 – Logging on page 30.

User administration

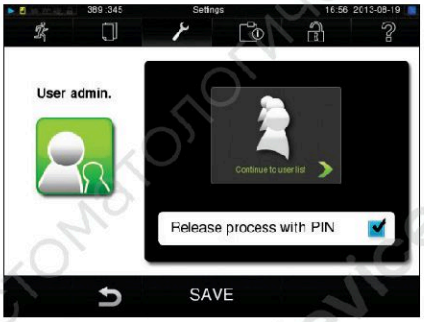
An individual ID and user PIN can be issued to every user to facilitate reliable traceability via the clearance process after the end of a sterilization program. The user is able to authenticate himself before clearing the batch.

You can determine the necessity of user authentication via a PIN via the `User administration` menu by setting a check mark next to "Release process with PIN".

Activation of this option documents the user ID and the outcome of the clearance procedure in the head of the log.

Adding a user

1. Select the `Settings` menu.
2. Navigate to the `User administration` option. To get to `User administration` and make the settings there, you must enter the Admin PIN.
3. Enter the Admin PIN (standard 1000) and confirm with LOGIN. The display switches to the "User administration" window.



4. Press the `Continue to user list` pushbutton to display the complete user list.



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

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6. Enter a 4-digit PIN for the selected User ID in the right-hand key pad and confirm with SAVE.



7. Accept all the settings with SAVE and then leave the menu.
8. Pressing the symbol enables you to leave the menu.

Deleting a user from the user list

1. Select the `User administration` menu as described above and open the user list.
2. Select the User ID which you wish to delete.



3. Press the symbol to delete this menu. A warning is issued. Confirming the warning with YES sets the PIN number of this ID to "0".

Changing the Admin PIN

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

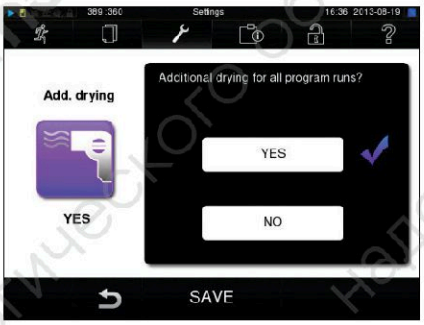
PLEASE NOTE
If you forget the Admin PIN, consult your stockist/MELAG customer services provider.

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Additional drying

Used with the types of load specified in this chapter (see the section **Loading the autoclave**), the program-specific drying times guarantee very good drying of the sterilized equipment.

For difficult drying tasks, navigate to the `Settings` menu and chose the `Additional drying` option to extend the drying time by 50%.



Date and time

Correct batch documentation requires the correct date and time setting on the autoclave. 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` menu.
2. Navigate to the `Date & Time` option. The display switches to the "Day & Time" window.



3. Select the parameters which you wish to change (day, month, year/hour, minute second). The marked parameters are displayed light blue.
4. Change the respective parameter value via the  and  pushbuttons.
5. Repeat this step for all the parameters which you wish to change.
6. Confirm the changes with SAVE.
7. The display will be restarted after saving and then changes automatically to the `Programs & Tests` menu.

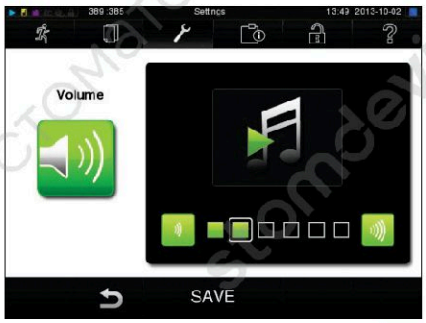
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Light intensity



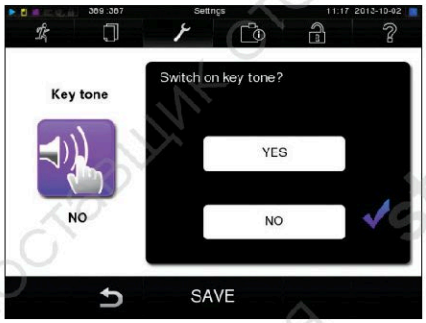
You can change the light-intensity and thus the contrast of the display via the − and + keys.

Volume



You can change the volume via the and keys.

Key tones



Select YES or NO to determine whether a tone should be emitted every time a pushbutton is pressed.
This can be deactivated at any time.

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Screensaver

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

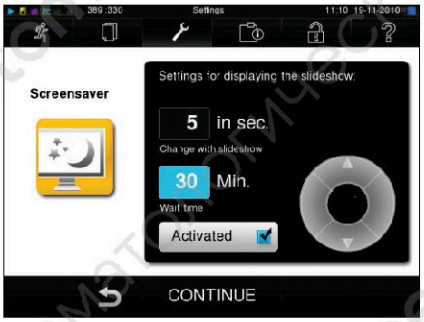
Proceed as follows to activate screensavers and pictures for the slide show.

1. Select the `Settings` menu.
2. Navigate to the `Screensaver` option. The display switches to "Screensaver" window.



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

   The check mark on the lower right-hand corner ☑ indicates whether the picture has been selected for the slide show.
4. Press CONTINUE to make further settings. The display switches to the following window.



Here, you have the opportunity to change the following parameters.

Picture change in the slide show:
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 check mark activates/deactivates the screen saver.

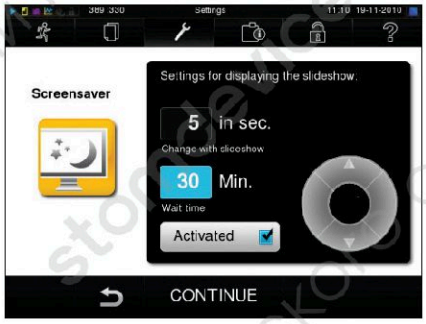
Proceed as follows to change the parameter:

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. Confirm the change with SAVE.

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Switching off the display

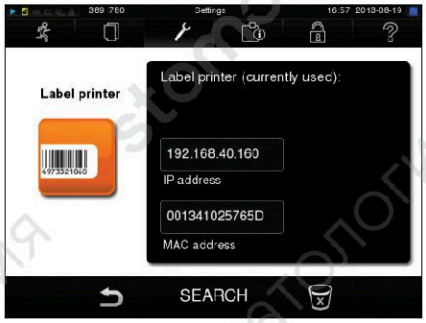
You can switch off the display completely after a specific period. This saves energy. Tapping the display surface maintains the display.



Label printer

The following section provides instructions for the setup of a label printer.

1. Select the `Settings` menu.
2. Navigate to the `Label printer` option. The display switches to the "Label printer" window.
   If a label printer was not previously setup, the IP address and MAC address field are empty.



3. Select SEARCH to display a list of all available log printers in the network.



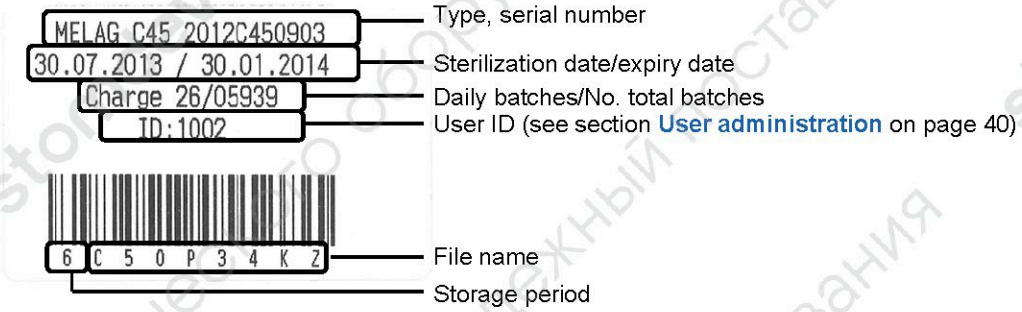
4. Press the  symbol to search for all the label printers available in the practice network.
   If one or more label printers are available in the practice network, these will be displayed in the list of printers.
5. Select the desired label printer from the list and confirm with SAVE.
6. The display returns to the "Label printer" window.
7. Press the  symbol to exit the menu.
8. Working in the `Settings menu` → `Logging` select the label printer for log output.

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PLEASE NOTE

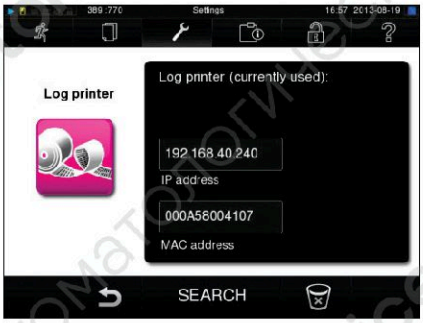
To facilitate easy assignation of a package marked with a label to a specific batch, the sterilization log file name must not be changed.



Log printer

If you wish to output the sterilization log via the log printer MELA*print* 42, you will need to set this on the autoclave once. The following section provides instructions for the setup of a log printer.

1. Select the `Settings` menu.
2. Navigate to the `Log printer` option. The display switches to the "Log printer" window. If a log printer has not been setup, the "IP address" and "MAC address" fields are empty.



3. Select SEARCH to display a list of all available log printers in the network.



4. Press the symbol to search for all log printers available in the network. If one or more log printers are available in the network, these will be displayed in the list of printers.
5. Select the desired log printer from the list and confirm with SAVE.
6. The display returns to the "Log printer" window.
7. Press the symbol to exit the menu.
8. Then, working in the `Settings` menu →`Logging`, select the log printer for the log issue.

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Touch sensitivity



Using the and keys, you can determine the pressure required to activate a pushbutton.

Energy-saving mode

If the autoclave is not switched off during longer operating pauses, it can be operated in energy-saving mode. Then it only consumes 35 W. This reduces the time which the autoclave requires in order to pre-heat the double-jacket steam generator to the necessary start temperature following deactivation.

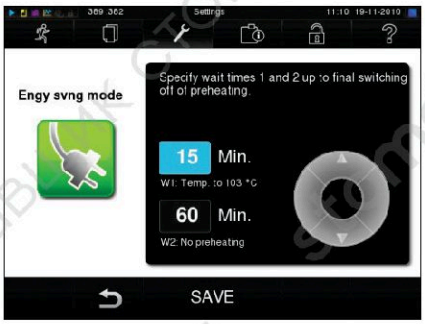
Two waiting times can be set in energy-saving mode:

Waiting time 1 (W1) After a pre-set waiting time of 3 minutes, the double-jacket steam generator is no longer heated or held at a temperature of 103°C.

Waiting time (W2) After a pre-set waiting time of 25 minutes (Cliniclave 45) or 40 minutes (Cliniclave 45 M), the double-jacket steam generator is no longer heated. Accordingly, the length of the program run time increases by a few minutes 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.

Setup of the energy-saving mode is described here:

1. Select the `Settings` menu.
2. Navigate to the `Energy-saving mode` option. The display switches to the "Energy-saving mode" window.



3. Proceed in steps similar to those described in section **Date and time**.

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Chapter 7 – Functional Checks

PLEASE NOTE
Please comply with the national recommendations issued by DIN 58946-7.

Vacuum test

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 autoclave in a cold and dry state as follows:

1. Switch on the autoclave at the power switch.
2. Working in the `Programs & Tests` menu, select the vacuum test.
3. Press START.

Bowie & Dick test

The Bowie & Dick test serves as proof of the steam penetration of porous materials such as textiles. You can perform a routine function check for proof of steam penetration. Use the `Bowie & Dick-Test` program to this end.

Diverse test systems are offered by specialist dealers for the Bowie & Dick test. Evaluation is performed following sterilization and removal of the textile package from the autoclave. Perform the test according to the test system manufacturer information.

> ***We recommend e.g. the Bowie & Dick Test package from 3M No. 1300 or the Lantor Cube™ Autoclave Test.***

Perform the Bowie & Dick test as follows:

1. Switch on the autoclave at the power switch.
2. Working in the `Programs & Tests` menu, select the Bowie & Dick-Test.
3. Press START.

PLEASE NOTE
Treatment indicator strips often exhibit differing intensities in the colour change indicating a different length of storage of the manufacturer batches 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 its even nature.
If the treatment indicator strips/treatment indicator sheet indicates an equal distribution of colour change, the air-removal of the sterilization chamber is without fault.
If the treatment indicator strips or the treatment indicator sheets are uncoloured or exhibit less colour in the centre of the star in comparison to the end, air-removal was insufficient. In such a case, please consult the stockist customer services/MELAG customer services.

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Helix test body system MELA*control*/MELA*control* PRO

The Helix test body system is an indicator and batch control system fulfilling the requirements of DIN EN 867-5. It consists of a test body, the Helix and an indicator strip.

If sterilizing category "critical B" instruments, you should add the MELA*control*/MELA*control* PRO test body to every sterilization cycle as a batch control.

Regardless of this, you can perform a steam penetration test at any time using MELA*control*/ MELA*control* PRO in the Universal-Program.

Intended use of the Helix test body can result in the colouration of the plastic surface. This colouration exercises no influence on the functionality of the Helix test body.

Checking the quality of the feed water

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 over 15 µS/cm is registered, please make sure to change the mixed-bed resin cartridge in the water treatment unit. Only above a conductivity of 20 µS/cm is a warning message issued automatically on the display.

PLEASE NOTE
If, despite all warnings, the autoclave continues to be operated with a conductivity value of 20 µS/cm, a Helix test body should be added to each batch to check the steam for non-condensing gases. A malfunction message will be issued on the display upon 35 µS/cm. Further operation is then no longer possible.

Validation

In accordance with DIN EN 17665 and DIN 58946-7 the sterilization process should be validated before beginning routine operation with the autoclave.

Renewed Qualification (revalidation)

DIN EN 17665 and DIN 58946-7 recommend a renewed Qualification (revalidation) in regular intervals after 1-2 years.

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Chapter 8 – Maintenance

Cleaning

Door seal, chamber, chamber sealing face, mount, trays

Check the chamber, including the door seal and chamber sealing face and the load mount once a week for impurities, deposits or damage. If you find any impurities, remove any trays, cassettes and the mount from the chamber from the front. Clean the soiled components.

When cleaning the chamber, load mount, chamber seal face and door seal, please observe the following:

- Switch off the autoclave before cleaning and remove the plug from the socket.
- Ensure that the chamber is not hot.
- Use a soft, non-fuzzing cloth.
- Use chlorine- and vinegar-free cleaning agents.
- First soak the cloth with the cleaning alcohol or spirit and attempt to remove the impurities with this method.
- Only if the chamber, mount or chamber seal face has persistent soiling should you use a mild stainless steel cleaning agent, with a pH value between 5 and 8.
- To clean the door seal, use a neutral liquid cleaning agent.
- You should not allow cleaning agents to enter the piping coming from the autoclave chamber.
- Do not use any hard objects such as metal saucepan cleaner or a steel brush.

WARNING

Inappropriately performed cleaning can lead to the scratching of and damage of surfaces and the development of leaks in sealing surfaces. This creates conditions favourable to dirt deposits and corrosion in the sterilization chamber.

- Comply with all information regarding cleaning of the part affected.

Housing parts

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

WARNING

Inappropriately performed cleaning can lead to the scratching of and damage of surfaces and the development of leaks in sealing surfaces. This creates conditions favourable to dirt deposits and corrosion in the sterilization chamber.

- Comply with all information regarding cleaning of the part affected.

Reverse osmosis unit MELA*dem* 56/MELA*dem* 56 M

The conductivity is measured automatically before every program run in order to enable timely maintenance of the water treatment unit. Poor water quality will trigger the following display message: "`Poor feed water quality`". A program start is still possible. If the water quality falls further, the display shows the message "`Feed water quality insufficient`". A program start is then no longer possible. Conductivity measurement can also be performed in standby mode by working in the `Programs and Tests` menu.

Further information and detailed maintenance instructions are listed in the operating manual of the water treatment unit.

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Avoiding staining

Only after cleaning instruments properly prior to sterilization is it possible to avoid residue from the load or the instrument treatment from being released during sterilization. Loosened dirt residue can clog the autoclave filter, nozzles and valves and deposit themselves on the instruments and chamber as deposits and stains (see page 16, **Preparing the sterilization material**).

All steam-conducting parts of the autoclave consist of non-rusting material. This rules out the possibility of stain or rust development being caused by the autoclave. The development of rust is always extraneous rust.

Incorrect instrument treatment can result in the accretion of rust even on stainless steel instruments of leading manufacturers. Often, an instrument which drops rust can suffice to cause the development of rust on another instrument or in the autoclave.

Remove foreign rust from the instruments using chlorine-free stainless steel cleaning fluid (see section **Cleaning**) or send the damaged instruments to the manufacturer.

Greasing the door spindle

Grease the door spindle at regular intervals of three months. Proceed as follows:

1. Clean the spindle with a non-fuzzing cloth.
2. Grease the door lock nut in the autoclave door and the locking spindle with the grease (use around a fingernail's width - c. 0.5 ml) included in the scope of delivery.

Changing the filter on the housing fan

Replace the filter on the fan housing on the floor trough after receiving corresponding notification on the display/after six months at the latest.

Maintenance

WARNING

Continuing operation despite maintenance messages can result in malfunctions in the autoclave.

- Maintenance should only be performed by trained customer services technicians, or stockist technicians. Consult your stockist or the nearest MELAG customer services point.
- Maintain the specified servicing intervals.

Regular maintenance is vital to ensure reliable operation and value retention of the autoclave.

All function and safety-relevant components and electrical units are checked during maintenance and replaced where necessary. Maintenance is performed in accordance with the maintenance instructions pertinent to this autoclave.

Maintenance should be performed annually or after every 4000 program cycles.

The autoclave will issue a maintenance message at the relevant time.

A NOTE CONCERNING NATIONAL PRESSURE VESSEL REQUIREMENTS

National pressure vessel requirements may ask the user of pressure vessel, such as autoclaves, to carry out safety inspections. Please check the download area from our website and find our recommendation in accordance with German requirements. Fore more information ask your local authorities.

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Chapter 9 – Operating Pauses

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 sterilized equipment, you can load the autoclave again and start the autoclave afresh.

Pause times

Duration of the operating pause	Measures
Between the two sterilization runs	▪ Hold the door closed in order to save energy (double-jacket steam generator is heated consecutively). ▪ Set the energy-saving mode correspondingly, see **Chapter 6 – Settings**.
Longer pauses e.g. overnight or the weekend	▪ Switch off the power at the power switch. ▪ Set the door ajar to prevent the door seal from sticking. ▪ Shut off the cold water inflow. ▪ If present, shut off the water inflow of the water treatment unit.
Longer than two weeks	▪ Perform vacuum test. ▪ Then perform an empty sterilization run in Quick-Program S (see page 48, **Chapter 7 – Functional Checks**).

After pauses, perform the checks described in **Chapter 7 – Functional Checks** depending on the length of pause.

Decommissioning

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

1. Empty the double-jacket steam generator.
2. Switch off the autoclave at the power switch.
3. Remove the plug from the socket.
4. Shut off the cold water inflow and if present, the water inflow of the water treatment unit.
5. Wait until the air gap has emptied automatically.

Transport

Please observe the following whilst carrying the autoclave:

- The autoclave should always be carried by four people. In exceptional cases, the Cliniclave 45 can be carried by two persons. In such cases, observe and comply with the corresponding specifications issued by your respective professional association.
- Transport the autoclave with the carrying handles from MELAG and screw these on the intended locations on the autoclave. The carrying handles can be stored in the bracket in the floor unit intended for this purpose.
- Please observe that the distance between the base plate and the setup surface is low.

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WARNING

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

- Please ensure that you comply with the transport instructions.

Transport within the practice

Please observe the following during transport, within a room or the practice:

- After switching off the autoclave, wait until the pressure display manometer for the pressure display double-jacket steam generator (page 9, Fig. 1/(18)) shows zero bars before moving the autoclave.
- Remove the plug, allow the autoclave to cool.
- Close the water intake and then remove the hose connections in the floor of the autoclave.
- Should you wish to leave the mounts and trays or cassettes in the chamber during transport, protect the surface of the door plate. To do so, place some foam or bubble wrap between the door plate and mount.
- Close the autoclave door before moving it.
- Move the autoclave with floor unit in the installation location solely for maintenance purposes.
- Do not roll the autoclave over any uneven surfaces or thresholds.

Transport over long-distance/dispatch

Observe the following provisions during transport (e.g. a move or dispatch):

- For transport over longer distances, during the danger of frost and/or for despatch, an authorized person must prepare the autoclave according to instructions and empty the double-jacket steam generator and the container of the free run entirely (see **Emptying the double-jacket steam generator**).
- Do not roll the autoclave with the floor unit over long distances. Place the floor unit in the setup location and then place the autoclave on the floor unit.

WARNING

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

- Please ensure that you comply with the transport instructions.

Emptying the double-jacket steam generator

You have the option of draining the water in the double-jacket steam generator easily via the `Draining` program.

In order to do so, the autoclave is heated once, building up pressure in the double-jacket so that the water can be drained fully from the double-jacket steam generator.

Switch off the autoclave in the program end graphic “Draining completed” so that the autoclave does not feed water back into the double-jacket.

Recommissioning after relocation

When recommissioning after a move, proceed as with the first commissioning (see page , **Chapter 2 – First steps**).

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Chapter 10 – Description of function

The sterilization procedure

The autoclave sterilizes on the basis of the fractionated vacuum procedure. This guarantees the complete and effective wetting/penetration of the sterilization material with saturated steam. This option enables the sterilization of loads common to a doctor's practice or clinic.

The autoclave uses a separate steam generator with a double-jacket. This is combined with a double-jacket around the sterilization chamber. After heating, steam is held constantly available in the double-jacket. This maintains the walls of the sterilization chamber at a defined temperature. Optimized total operating time.

The sterilization material is dried using a vacuum (vacuum drying). This brings the best drying results even when using wrapped sterilization material.

Type of the feed water supply

The autoclave works with a feed water one-way system. This means that it uses fresh feed water for each sterilization procedure. The quality of the feed water is subject to permanent monitoring via an integrated conductivity sensor. If combined with careful preparation of the instruments, this serves largely to prevent stain accretion on the instruments and soiling of the autoclave.

Internal process monitoring

The autoclave uses electronic parameter control. This enables the autoclave to optimize the total operating time of a program in dependence on the load.

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

The volume and quantity of the feed water is checked.

The autoclave electronics has an integrated process monitoring system. It compares the process parameters (such as temperature, time and pressure) during a program run. It monitors the parameters in terms of their threshold values during control and regulation and guarantees safe and successful sterilization.

An autoclave monitoring system checks the device components for their functionality and their plausible interaction.

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.

If one or more parameters exceeds ore-determined threshold values, the autoclave issues warning or malfunction messages and if necessary, aborts the program. In the case of a program abort, follow the instructions on the display.

Emergency shut-down

The autoclave is equipped with an emergency shut-down mechanism; i.e. the autoclave shuts down automatically if the internal process monitoring system registers a fault which represents a particular hazard situation.

Reactivation of the autoclave is only possible after the malfunction has been remedied.

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Program sequence

A program runs in three phases. After program start, you can follow the program run in the display.
It shows the chamber temperature and pressure as well as the time until the end of sterilization/the drying.

Regular sterilization program

Program phase	Description
1. Air-removal phase	In the air removal phase, steam is repeatedly injected into the sterilization chamber to generate over-pressure. The mixture of air and steam is then removed repeatedly. (Fractionated vacuum procedure)
2. Heating phase	The heating-up phase follows after the evacuation phase. The pressure and the temperature climb with continuous steam introduction in the chamber until the sterilization parameters are reached.
3. Sterilization phase	After the sterilization parameters pressure and temperature have been met, the sterilization phase begins. The sterilization time is indicated on the display. Pressure is released after the end of the sterilization time.
4. Drying phase	The drying phase begins after the pressure release. Upon program end, the chamber is filled with sterile air via the air filter and adjusted to the ambient pressure.
5. Ventilation	At the end of a program run the chamber pressure is adapted to the ambient pressure. The corresponding display message "Ventilation" is displayed.

Vacuum test

Program phase	Description
1. Evacuation	The chamber will be evacuated until the pressure for the vacuum test has been reached.
2. Equilibration time	An equilibration time of five minutes will follow.
3. Measuring time	The measurement time amounts to ten minutes. The pressure increase within the chamber is measured within the measurement time. The evacuation pressure and the equilibration time or measuring times are shown on the display.
3. Ventilation	The chamber is ventilated after the end of the measuring time. Then the message will be shown on the display with an indication of the leakage rate. Should the leakage rate be too high (i.e. over 1.3 mbar), the display will indicate that the vacuum test has not been passed.
4. Test end	The display shows the test results, the batch number, the total number of batches and the leakage rate.

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Chapter 11 – Malfunctions

Messages

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

Warning messages

Warning messages are displayed when necessary. These contain instructions which apply to you, the operator. Warning messages are not malfunction messages. They help to ensure malfunction-free operation and to recognize undesirable situations. Observe these warnings early in order to avoid malfunctions.

Malfunction messages

Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization.

These can appear on the display shortly after switching on the autoclave or while a program is running. If a fault occurs during a program run, the program will be aborted.

DANGER!

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

- If necessary, repack the load and repeat the sterilization for the sterilization material affected.

Before you call customer service

Ensure that you have complied with all instructions relating to a warning or malfunction message issued on the display of the autoclave. The following table contains a summary of the most important events. The events contain possible causes and the corresponding operator information.

Should you be unable to find the relevant event, or your efforts do not redress the problem, you can contact your nearest stockist or authorized MELAG customer service provider. To enable us to give the best possible service, please have your autoclave serial number and a detailed description of the fault to hand.

The following situations can occur after longer pauses:

General events

Incident	Possible cause	What you can do
Conductivity too high	Poor feed water	Change the feed water or mixed-bed resin when using a water treatment unit
The door is not open despite running motor	The door seal sticks to the sealing face	Switch off the autoclave and pull strongly on the door in order to open it.

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Incident	Possible cause	What you can do
Poor drying results	In addition to an orderly device function, the drying depends to a large extent on the correct set-up and loading of the autoclave.	▪ Check that the autoclave is set up correctly. The autoclave must be level. ▪ Check that the waste water hose has been installed correctly. This must be installed at a constant decline without sagging and tensioned in the tensioning carriage in the floor unit. ▪ The base of the sterilization chamber must be free. Remove any instruments, filter paper or other objects which have fallen onto the chamber floor. ▪ Ensure the correct load of the autoclave. Do not overload the autoclave. Please ensure that there are no textiles in direct contact with the chamber wall and floor. ▪ Use the `Additional drying` option.

Event no.	Possible causes	What you can do
61	Water inflow tap to the water treatment unit not open	Open the water inflow tap to the water treatment unit
63 **64** **65**	Mixed-bed resin in the water treatment unit exhausted	Replace the mixed-bed resin cartridge in the water treatment unit
67 **68**	Water outlet not guaranteed	Check the waste water hose, enable water outflow, check the siphon.
72 **73** **74** **75**	The feed water quality declines (>20 µS/cm), Mixed-bed resin cartridge will soon be empty	You can still perform all work with the autoclave and should replace the mixed-bed resin cartridge as soon as possible.
76	see event 67	
102	Kinked or sagging waste water hose	Check the waste water hose for installation at a constant incline without sagging.
113	Autoclave switched off during a program run Mains connection not connected fully Power plug disconnected Power outage in the building	Do not switch off the autoclave at the power switch whilst a program is running. Check the on-site electrical connection. Operate the device on a separate electrical circuit.
116	Maximum permissible difference between the theoretical temperature and that measured by temperature sensor 1 (AIN01) is too large	Upon repeated occurrence, inform your stockist.
117	Temperature sensor 1 or 2 is defective; temperature difference is too large.	Upon repeated occurrence, inform your stockist.
118	Maximum admissible sterilization temperature has been exceeded at temperature sensor 1 (AIN01).	Upon repeated occurrence, inform your stockist.
119	Minimum admissible sterilization temperature not reached at temperature sensor 1 (AIN01).	Upon repeated occurrence, inform your stockist.
123 **124** **125** **126**	Ambient temperature too high, installed autoclave receives too little or no cooling air, autoclave is overloaded, The autoclave was operated without a mount with the result that e.g. the textile package has come into direct contact with the chamber and absorbed a large amount	Comply with the setup information. Check the load, comply with the loading information.

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Event no.	Possible causes	What you can do
	of condensate.	
128	see event 102	
129	Autoclave overloaded, poor electricity supply (over-sized domestic installation to the socket, damaged socket, multiple devices on a single socket/fuse)	Check the load Check the network supply
134	see event 123	
135	Cold water inflow not open, water inflow hose kinked, Shut-off valve in cellar is off/filter in cellar is blocked If present: Leak detector (water stop) without function	Open the cold water inflow Check the cold water inflow hose Check or arrange a check of the house water connection and shut-off valve Unplug the leak detector (water stop) and reconnect after 30 seconds; switch noise at the leakage water valve (black box on the water tap) must be audible.
136	Ambient temperature too high, ventilation slits covered, minimal lateral clearance not maintained, Door remains permanently open.	Comply with the setup conditions Close the door
175 176	ACOUT1 main heating/ACOUT2 control heating, electrical supply interrupted, event 175 and 176 could occur in alternation.	1. Depress reset button overheat control RHK1 (Fig. 1/(14) 2. Clear malfunction message, 3. Switch off autoclave and then back on again 4. Proceed with sterilization/perform an empty sterilization run.
183	see event 123	
192	Reference to subsequent rinsing process	Ensure water supply to water treatment unit
231	CF card not inserted	Insert a CF card in the card slot and repeat the procedure
239	The CF card is full	Working on the computer, move the logs from the monthly directory to newly-created directories.
248	Residual moisture in chamber or vacuum test started with load	Repeat vacuum test, when autoclave is cold and empty
351	4000 sterilization programs have been run/a year has elapsed since commissioning or the last servicing.	Contact a MELAG customer services provider or your stockist to arrange servicing. The autoclave can still be started.
377	An attempt was made to output a log via the log printer but a log printer was has not been connected	Connect the log printer
386	The internal log memory is almost completely full	Read-out the internal log memory onto a memory medium of your choice via the `Log output` menu
387	The internal log memory is almost completely full	Read-out the internal log memory (for malfunction logs) onto a memory medium of your choice via the `Log output` menu
394	Immediate output is activated in the `Settings` menu →`Logging`, and the CF card is has been selected as output medium, but has not yet been inserted.	Insert a CF card into the card slot and press YES if you wish to output the logs not yet outputted onto a CF card.
395	Immediate output is activated in the `Settings` → menu `Logging`, and the log printer is has been selected as output medium, but has not yet been connected.	Connect the log printer and press YES if you wish to print the logs not yet outputted.

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Event no.	Possible causes	What you can do
396	Immediate output is activated in the `Settings` menu →`Logging`, and the computer has been selected as output medium, but has not yet been connected/has not been switched on.	Press YES if you wish to output the logs not yet transferred to the computer.
408	see event 135	
414	Kinked waste water hose Autoclave is overloaded, The autoclave was operated without a mount with the result that e.g. the textile has come into direct contact with the sterilization chamber and absorbed a large amount of condensate. This condensate vaporized upon evacuation and forms a large amount of steam. Cooling air ingress holes on the base plate are covered e.g. by paper.	Check the waste water hose for kinks or pinching; Observe the maximum loads; Use a mount; Check for packaging residue in the chamber.
428 439	Kinked waste water hose Poor installation (multiple devices attached to a single siphon, sagging waste water hose) Packaging residue chokes the pressure release filter in the sterilization chamber.	Check the waste water hose for kinks or pinching; Check for packaging residue in the sterilization chamber.
433	Maximum permissible difference between the theoretical temperature and that measured by temperature sensor 2 (AIN02=Display) is too large	Upon repeated occurrence, inform your stockist.
434	Maximum admissible sterilization temperature has been exceeded at temperature sensor 2 (AIN02=Display).	Upon repeated occurrence, inform your stockist.
435	Minimum admissible sterilization temperature not reached at temperature sensor 2 (AIN02=Display).	Upon repeated occurrence, inform your stockist.
457	The date or time was set incorrectly	Check the date and time settings and re-set if necessary.
458	The date or time was set incorrectly; The autoclave was switched-off at the time of start time pre-selection.	Switch on the autoclave before activating the start time pre-selection and if necessary, check the settings for date and time.
488	The date or time was set incorrectly	Check the settings for date and time and reset if necessary
489 490 491	The fan filter in the base plate could be choked. The ambient temperature is too high.	Change the fan filter in the base plate. Ensure sufficient ventilation and cooling of the operating room. Arrange for the air-conditioning/ventilation system(s) to be checked.
495 496	The inflow valve is closed. The inflow hose is kinked.	Open the inflow valve and check the inflow hose for kinks.
499 500	Insufficient feed water in the water treatment unit pressure tank	Check the pressure on the pressure tank manometer of the water treatment unit. This must be a minimum of 2.5 bars (red line). Otherwise, wait until the water treatment unit has produced sufficient feed water. Check the hoses of the water treatment unit for kinks.
541	The vacuum pump receives too little cooling water via SV cooling water	Open the water intake tap fully. Blocked central filter in the cellar. Water inflow hose kinked

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Event no.	Possible causes	What you can do
543	Drainage line blocked	Check the waste water hose for kinks Check the siphon for blockage
595 596	Packaging residue or soiling in the pressure sensors of the chamber nozzles.	Check the load; do not place any packaging immediately in front of the inputs or chamber nozzles.

Opening the door manually

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

1. If the autoclave is activated, switch it off at the power switch.
2. To remove the cover caps in order to facilitate emergency door-opening, press the cover cap inwards on the centre side of the door (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).
3. Lever the cover cap out of the opening at an angle. Observe the retaining brackets whilst doing so.





4. Insert the 10 mm Allen key included in the scope of delivery in the door-lock nut behind the opening. The Allen key can be stored in the bracket in the floor unit intended for this purpose.



5. Turn the Allen key to open the door **in an anti-clockwise direction**.
6. Remove the Allen key after opening and return the cover caps.

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DANGER!

Where necessary e.g. during a running program or immediately after the end of a program, steam can be emitted from the sterilization chamber upon opening the door.

Danger of burns!

- Should steam be issued from the rear of the device after its deactivation, wait until it has finished. Wait a further 5 minutes 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.

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Glossary

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

Aqua dem
→ Demineralized water

Aqua dest
→ Distilled water

Authorized persons
Depot technicians or MELAG-specified customer services trained by MELAG.

Batch
Collection of sterilization material which has been processed together in the same sterilization program.

BGV A1
Specifications from professional associations (Berufsgenossenschaftliche Vorschriften) – the principles of prevention

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

CF card
Compact Flash Card; a memory card for digital data

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

Conductivity
is the opposite of electrical resistance; measured in micro-Siemens/centimetre (µS/cm); the greater the amount of dissolute matter in the water, the better it can conduct electrical current and thus the higher its conductivity. Distilled water should register zero conductivity in an ideal case.

Conductivity measurement
Measurement of the Conductivity

Contamination
Here: the impurification of the sterilizer load through undesirable or damaging materials

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

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

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

DIN 58953
Standard – sterilization, sterile equipment supply

DIN EN 285
Standard – sterilization - steam sterilization - large sterilizers

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

DIN EN 868
Standard – packaging materials and systems for medical products requiring sterilization

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

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

Double-jacket steam generator
Serves the quick generation of steam outside the sterilization chamber, surrounds the sterilization chamber

Dynamic pressure test of the sterilization chamber
serves to prove that the rate of pressure variations during a sterilization cycle does not exceed a particular value which could result in the damage of the packaging material. [DIN EN 285]

Empty chamber test
Test run without a load, performed to assess the performance of a sterilizer without the influence of a load; facilitating verification of the temperatures maintained in comparison to the temperatures set. [DIN EN 285]

Evacuation
Creation of a vacuum in a vessel

Feed water
Used to produce steam for sterilization. The guide values for water quality in accordance with DIN EN 285, Appendix B, table B.1

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

FTP
(engl.: (File Transfer Protocol) is a data transmission procedure serving to transport 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 (upload).

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

Hollow body A
An article open on one side to which the following applies:
1 ≤ L/D ≤ 750 and L ≤ 1500 mm or an article with an opening on both sides which is:
2 ≤ L/D ≤ 1500 and L ≤ 3000 mm and which does not correspond to a hollow body article B
L…length of hollow body article
D… Diameter of hollow body article
[→ DIN EN 285]

Hollow body B
An article open on one side to which the following applies:
1 ≤ L/D ≤ 5 and D ≥ 5 mm or an article with an opening on both sides which is:
2 ≤ L/D ≤ 10 and D ≥ 5
L…length of hollow article
D… diameter of hollow article
[→ DIN EN 285]

Hub
(engl.: serving the connection of multiple computers in a network e.g. via Ethernet in a star-shaped connection. All devices in the network are connected to the hub.

Massive load – verification of a massive load
Serves to prove that the necessary sterilization conditions have been reached within the entire load with the values set in the control. The load must represent the largest weight of massive instruments designed for sterilization in a sterilizer in accordance with DIN EN 285. [DIN EN 285]

MELAG network adapter
Ethernet adapter for the log printer MELAprint®42; a printer connection on one side (RS232) and an Ethernet bushing on the other for connection to a network cable

Mixed loads
wrapped and unwrapped sterilization material within a single load

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

Porous
Permeable for fluids and air e.g. textiles

Porous full load – test of porous full load
Serves to prove that the values set on the control satisfy the necessary sterilization conditions in porous loads with a maximum mass for which the sterilizer is designed in accordance with DIN EN 285 [DIN EN 285]

Porous partial load – test of porous partial load
Serves to prove that the values set on the control allow steam to enter the pre-determined test package quickly and equally [DIN EN 285]

Porous small components
Made of materials which are able to absorb fluids

Pre-heating time
→ Heat-up phase

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

Self monitoring system
→ Process monitoring system

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

Solid
Without hollows or gaps, solid, compact, closed

Soft sterilization packaging
eg. a paper bag or transparent sterilization packaging

Standard conform
Satisfies all relevant standards

Sterile barrier system
Sterile barrier systems Closed minimum packaging which prevent the occurrence of microorganisms, e.g. bags closed with sealing, closed reusable containers, folded sterilization cloths

Sterilization chamber
The interior of a sterilizer, accommodates the sterilizing material

Sterilization material
Unsterile, sterilizabe material which is still to be sterilized.

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

TCP
(transmission control protocol) refers to a standard protocol for connecting computers and networks.

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

Vacuum drying
Gentle drying: the drying load is subject to under-pressure. This reduces the boiling point and thus leads to evaporation even at low temperatures.

VDE
Verband der Elektrotechnik, Elektronik und Informationstechnik e.V. (German: The Association of Electrotechnology, Electronics and Information Technology)

Water ring pump
Vacuum pump which generates the vacuum for sterilization and is cooled with water.

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Technical Data

Model name	Cliniclave®45	
	Table-top device	**with floor unit**
Device dimensions (HxWxD)	91 x 65 x 91 cm	160 x 65 x 91 cm
Sterilization chamber (diam. x depth)	Ø 44 cm x 72 cm	
Effective capacity	1 StU	
Volume of the sterilization chamber	105 litres	
Weight (empty)	190 kg	255 kg
Operating weight	200 kg	275 kg
Electrical connection	3x380-415 V 50/60 Hz, 16 A separate fuse, FI protection 30 mA	
Electrical power	10,500 W	
Max. acoustic power	72 dB(A)	
Waste heat (with max. solid load)	1.4 kWh	
Ambient temperature	5-40 °C (ideal range16-26 °C)	
Relative humidity	30-60 %	
Length of power cable	2.3 m (1.6 m when using a floor unit)	
CE marking	CE 0535, CE 0035	
Degree of protection (following IEC 60529)	IP20	
Cold water connection		
Min. flow pressure	1.5 bars at 8 l/min	
Consumption (max.)	8 l/min	
Max. static water pressure	10 bars	
Quality	Drinking water, water hardness 4-12° dH (in accordance with DIN EN 285)	
Waste water connection		
Max. through-flow amount	Short term max. 9 l/min.	
Waste water temperature	Short term max. 90 °C	
Feed water		
Flow pressure/ consumption	0.5 bars with a through-flow volume of 5 l/min.	
Quality	Distilled or demineralized water in accordance with DIN EN 285, Appendix C (with central demineralization system max. conductivity 5 µS/cm)	

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Model name	Cliniclave® 45 M
Device dimensions (HxWxD)	160 x 65 x 153 cm
Sterilization chamber (diam. x depth)	Ø 44 cm x 134 cm
Effective capacity	2 StU
Volume of the sterilization chamber	200 litres
Weight (empty)	315 kg 340 kg (with floor unit and MELA*dem* 56 M)
Operating weight	370 kg
Electrical connection	3x380-415 V 50/60 Hz, 32 A separate fuse, FI protection 30 mA
Electrical power	13,500 W
Max. acoustic power	72 dB(A)
Waste heat (with max. solid load)	2.0 kWh
Ambient temperature	5-40 °C (ideal range16–26 °C)
Relative humidity	30–60 %
Length of power cable	1.8 m from the floor unit
CE marking	CE 0535, CE 0035
Degree of protection (following IEC 60529)	IP20
Cold water connection	
Min. flow pressure	1.5 bars at 8 l/min
Consumption (max.)	8 l/min
Max. static water pressure	10 bars
Quality	Drinking water, water hardness 4-12° dH (in accordance with DIN EN 285)
Waste water connection	
Max. through-flow amount	Short term max. 9 l/min.
Waste water temperature	Short term max. 90 °C
Feed water	
Flow pressure/ consumption	0.5 bars with a through-flow volume of 5 l/min.
Quality	Distilled or demineralized water in accordance with DIN EN 285, Appendix C (with central demineralization system max. conductivity 5 µS/cm)

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Appendix A – Accessories

Designation	Dimensions (W x D x H)	Order no.
Floor unit for Cliniclave 45, door hinge left	65 x 86 x 73 cm	11045
Floor unit for Cliniclave 45, door hinge right	65 x 86 x 73 cm	11047
Floor unit for Cliniclave 45 M, door hinge left or right	65 x 145 x 73 cm	11048
Mounts		
Mount for 2 instrument baskets (1/2 StU) or 4 instrument trays (1/4 StU)	32.5 x 60 x 27.7 cm	04517
Mount for 6 standard tray cassettes	20 x 28.7 x 30 cm	02518
Mount for 8 instrument trays	20 x 28.7 x 30 cm	02519
Mount for 5 dental containers	20 x 28.7 x 30 cm	04518
Standard tray cassettes		
Standard tray cassette, perforated with filter cloth	19 x 29 x 4 cm	00289
Standard tray cassette, perforated without filter cloth	19 x 29 x 4 cm	00286
Instrument trays and baskets		
Instrument tray small	18.8 x 29 x 2.3 cm	00280
Instrument tray large (1/4 StU)	31 x 59 x 5 cm	00450
Instrument basket (1/2 StU)	27 x 57 x 13 cm	00260
Loading system		
Slide rail "standard" for Cliniclave 45	34.5 x 64 x 8.5 cm	80560
Slide rail "standard" for Cliniclave 45 M	34.5 x 126 x 8.5 cm	80580
Transport trolley	43 x 87 x 105 cm	01145
Slide rail "comfort" for Cliniclave 45	32 x 65 x 8.2 cm	80550
Slide rail "comfort" for Cliniclave 45 M	32 x 127 x 8.5 cm	80570
Batch slider	33.2 x 62.3 x 2.7 cm	46891
Loading hook for Cliniclave 45	4 x 50 x 3 cm	28887
Loading hook for Cliniclave 45 M	4 x 110 x 3 cm	28888
Test body system		
MELA*control* consisting of a Helix test body and 250 indicator strips		01080
MELA*control* PRO consisting of a Helix test body and 40 indicator strips		01075
Water treatment unit		
MELA*dem* 56 reverse osmosis unit		11056
MELA*dem* 56 M reverse osmosis unit		11057
For documentation:		
MELA*flash* CF card		01043
MELA*flash* card reader		01048
MELA*trace* Documentation-, Load management and Clearance software		21183
Label printer MELA*print* 60		01160
Network cable 5 m (required for MELA*print* 60)		15811
Log printer MELA*print* 42		01042
MELAG Network adapter for MELA*print* 42		40295

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Designation	Dimensions (W x D x H)	Order no.
Other		
Package holder, short	18.4 x 28 x 8.7 cm	22410
Package holder, long	18.4 x 37 x 8.7 cm	22420
Leak detector (water stop)		01056
Installation package		09027

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