Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product. As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world’s leading manufacturer in the instrument 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 system is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.
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1 General guidelines

Please read this user manual carefully before commissioning the device. The manual includes important safety information. The functionality and value-retention of this device depend primarily 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.

Should the user manual no longer be legible, damaged or lost, please obtain a new copy from MELAG. State the device type and your address in an e-mail. The device type is specified on the type plate on the rear of the device.

Symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.</td>
</tr>
<tr>
<td>⚠️</td>
<td>Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.</td>
</tr>
<tr>
<td>📝</td>
<td>Draws your attention to important information.</td>
</tr>
</tbody>
</table>

Formatting rules

<table>
<thead>
<tr>
<th>Example</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>see Chapter 2</td>
<td>Reference to another text section within this document.</td>
</tr>
<tr>
<td>Universal-Program</td>
<td>Words or phrases appearing on the display of the device are marked as display text.</td>
</tr>
</tbody>
</table>

MELAconnect App

You can use the MELAconnect app from any location in your practice, to access the device status and program progress of the MELAG devices incorporated in your practice network.

MELAconnect provides the following functions:

- Accessing the device status and program progress
- Access to user manuals and video tutorials for using the device
- Locating malfunctions and accessing solutions and assistance immediately
- Performing quick paperless documentation of routine checks of MELAG sealing devices
- Contacting the service technician (contact data must be entered manually)

In order to connect the MELAconnect app with your MELAG device, see the MELAconnect [page 65] section.
2 Safety

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

Qualified personnel
- As with the preceding instrument decontamination, the sterilization of instruments and textiles using this steam sterilizer may only be carried out by competent personnel.

Carrying the steam sterilizer
- The steam sterilizer should be transported by min. 6 people. Comply with the corresponding specifications issued by your respective professional association.
- Carry the steam sterilizer using the carrying handles or transport bars included in the scope of delivery (follow the instructions in the user manual and technical manual).
- The carrying handles can be stored in the bracket in the floor unit.

Set-up, installation and commissioning
- Check the device for any damage suffered during transport after unpacking.
- The device should only be set-up, installed and commissioned by MELAG authorized technicians.
- The connections for electrical provision and water supply and discharge must be set-up by trained personnel.
- Using the optional electronic leak detector (water stop) minimizes the risk of water damage.
- The device is not suitable for operation in explosive atmospheres.
- Install and operate the device in a frost-free environment.
- The device is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.
- The documentation media (computer, CF card reader etc.) must be placed in such a way that they cannot come into contact with liquids.
- Observe all the information contained in the technical manual during commissioning.

Power cable and power plug
- Comply with all legal requirements and locally-specified connection conditions.
- Never operate the device if the plug or power cable are damaged.
- The power cable or plug should only be replaced by authorized technicians.
- Never damage or alter the power plug or cable.
- Never unplug by pulling on the power cable. Always take a grip on the plug.
- Ensure that the power cable does not become jammed in.
- Never lead the cable along a source of heat.
- Never fix the power cable with sharp objects.

Decontamination and sterilization
- Follow the manufacturer’s instructions of your textile articles and instruments regarding their decontamination and sterilization.
- Comply with the relevant standards and directives applicable to the decontamination and sterilization of textiles and instruments in Germany e.g. from the RKI and DGSV.
- 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 shown on the display of the steam sterilizer. If necessary, sterilize the affected objects after rewrapping.

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 steam sterilizer. Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

Maintenance

- Maintenance should only be performed by authorized technicians.

- Maintain the specified servicing intervals.

Malfunctions

- Should the device issue the same malfunction message repeatedly, turn off the device and if necessary, inform your stockist.

- The device may only be serviced by authorized technicians.

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

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

Intended use

The steam sterilizer is designed for application in a medical context, e.g. general practitioners and dental practices, day hospitals, outpatient surgeries, ambulant healthcare centres, group practices and hospitals. According to DIN EN 285, this steam sterilizer is a large steam steam sterilizer. As a universal steam sterilizer, it is suited to highly-demanding sterilization tasks. It can be used to sterilize large quantities of instruments with a small inner diameter and transfer instruments - both wrapped or unwrapped - and textiles.

WARNING
Any attempt to sterilize liquids can result in a delay in boiling. This can result in burns and damage to the device.
- Never use this device to sterilize fluids. It is not licensed for the sterilization of fluids.

NOTICE
Failure to comply with these safety instructions can result in damage or can compromise safety.
- Only ever use the steam sterilizer 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 decontamination 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.

Sterilization procedure

The steam sterilizer 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 procedure enables the sterilization of loads common to a doctor's practice or clinic in accordance with DIN EN 285.

The steam sterilizer uses the double-jacket technology to generate the sterilization steam, i.e. the steam sterilizer is fitted with a separate steam generator combined with a double-walled sterilization chamber. After heating, steam is held constantly available in the double-jacket. This gives the walls of the sterilization chamber a defined temperature and protects the sterilization chamber from overheating. This especially effective procedure supports the quick evacuation of the air from the sterilization chamber, the sterilization packaging and instrument cavities. This permits the sterilization of large quantities of instruments or textiles directly one after each other, thereby achieving excellent drying results.

Type of the feed water supply

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

*Internal process monitoring*

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

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

*Door mechanism*

The steam sterilizer constantly checks pressure and temperature in the sterilization chamber and prevents the door from being opened when over-pressure has built up in the chamber. The motor-driven automatic door locking mechanism opens the door slowly by turning the door lock nut. 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.

*Independent registration device (URG)*

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

*Quantity and quality of the feed water*

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

*Automatic emergency shutdown*

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

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

Program phases of a standard sterilization program

<table>
<thead>
<tr>
<th>Program phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Air removal and heating up phase</td>
<td><strong>Air removal</strong>&lt;br&gt;The air removal phase comprises the conditioning and the evacuation. During conditioning, steam is repeatedly injected into and removed from the sterilization chamber. This generates over-pressure and the residual air is removed. Then, during fractionation, the mixture of air and steam is evacuated from the sterilization chamber and steam is injected. This procedure is also called the fractionated pre-vacuum procedure. <strong>Heating</strong>&lt;br&gt;The continued steam injection into the chamber leads to an increase in pressure and temperature which continues until the program-specific sterilization parameters have been reached.</td>
</tr>
<tr>
<td>2. Sterilization phase</td>
<td><strong>Sterilizing</strong>&lt;br&gt;If the pressure and temperature correspond to the program-dependent nominal values, the sterilization phase begins. The corresponding process parameters (pressure and temperature) are held at sterilization level. The sterilization time (holding time) is indicated on the display.</td>
</tr>
<tr>
<td>3. Drying phase</td>
<td><strong>Pressure release</strong>&lt;br&gt;The sterilization phase is followed by pressure release from the sterilization chamber. <strong>Drying</strong>&lt;br&gt;The sterile material is dried using a vacuum (vacuum drying).  <strong>Ventilation</strong>&lt;br&gt;Upon program end, the chamber is filled with sterile air via the air filter and adjusted to the ambient pressure. The corresponding display notification Ventilation is displayed.</td>
</tr>
</tbody>
</table>

Program phases of the vacuum test

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

Scope of delivery

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

Standard scope of delivery

▪ Cliniclave 45 or Cliniclave 45 M
▪ User manual
▪ Technical manual
▪ Record of installation and setup
▪ Manufacturer's inspection report including declaration of conformity with the Medical Devices Directive and pressure equipment directive.
▪ Warranty certificate
▪ Slide rail "Standard"
▪ MELAflash CF card
▪ Protective gloves
▪ Carrying handles
▪ Outlet hose
▪ Open-ended wrench for the validation fitting connection / floor unit rollers
▪ Ring spanner for the validation fitting fastening nuts
▪ Allen key with which to open the door in an emergency
▪ Grease for door locking mechanism
▪ Filter insert housing fan
▪ Bowie & Dick test
▪ Installation package (sent in advance) consisting of:
  – ¾" Rubber seal
  – Surface-mounted siphon
  – ¾" water tap with safety combination

Optional

▪ MELAdem 56 reverse osmosis unit (for Cliniclave 45) or MELAdem 56 M (for Cliniclave 45 M)
▪ Leakage water detector (water stop)
▪ Loading system inc. loading trolley
Views of the device

Front

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

Detailed fore view with an opened service hatch

9. Steam generator level gauge
10. Reset button overheat control RHK1 (safety temperature limiter)
11. Reset button overheat control RHK2 (safety temperature limiter)
12. Reset button overheat control RHK3 (safety temperature limiter)
13. Sterile filter
14. Manometer for display of the pressure in the steam generator/double jacket
15. Opening for emergency activation of the vacuum pump
16. Network cable connection (RJ45) for service
**Rear panel**

17 Fan
18 Pressure and emergency release behind cover plate

**Underside**

19 Wastewater connection
20 Water treatment unit feed water inflow
21 Concentrate line connection from the water treatment unit
22 Water treatment unit cold water inflow
23 Fan
24 Connection for draining the air gap
25 Connection for cleaning/decalcifying the vacuum pump (only for service technicians)
26 Bracket and tensioning carriage for the outlet hose
27 Network cable connection
Symbols on the device

Manufacturer of the medical device

Date of manufacture of the medical device

Medical device serial number from the manufacturer

Article number of the medical device

Information about the chamber volume

Operating temperature of the device

Operating pressure of the device

The user manual includes important safety information. Failure to comply with these instructions can result in injury and material damage.

Please read this user manual carefully before commissioning the device.

This symbol indicates that the device is live. Contact with live parts result in serious injury and danger to life.

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".

In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the Medical device directive. The four-digit number confirms that this is monitored by an approved certification agency.

In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the Pressure equipment directive. The four-digit number confirms that this is monitored by an approved certification agency.

With the adjacent label, the device manufacturer declares that the medical product corresponds to the basic requirements of the European standard EN 1717 - Protecting Drinking Water from Contamination.

This symbol draws attention to an increased danger of crushing resulting from the improper closure of the steam sterilizer door. Please comply with the instructions outlined in the corresponding chapter.
The device may not be disposed as domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of. MELAG devices are synonymous for long-term quality. When you eventually need to decommission your MELAG device, we offer a special disposal service. Simply contact your stockist.

**Colour-touch display**

The operating panel consists of a colour 5 inch touch display.

### Symbols in the status bar

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program/tests</td>
<td>Indicates whether a program/test is running</td>
</tr>
<tr>
<td>Immediate output</td>
<td>Indicates whether immediate output is activated/deactivated</td>
</tr>
<tr>
<td>Additional drying</td>
<td>Indicates whether additional drying is activated/deactivated</td>
</tr>
<tr>
<td>Graphic logs</td>
<td>Indicates whether the graphic log recording is activated/deactivated</td>
</tr>
<tr>
<td>Energy-saving mode</td>
<td>Indicates whether the steam sterilizer is currently in energy-saving mode</td>
</tr>
<tr>
<td>Service area</td>
<td>Indicates whether a service technician is logged-in to the service area</td>
</tr>
<tr>
<td>CF card status</td>
<td>Indicates whether a CF card has been inserted and whether a reading or writing action is in process</td>
</tr>
</tbody>
</table>

### Symbol in the menu bar

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program/tests</td>
<td>Lists all sterilization programs and tests e. g. vacuum test, Bowie &amp; Dick test etc.</td>
</tr>
<tr>
<td>Log output</td>
<td>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.</td>
</tr>
<tr>
<td>Settings</td>
<td>Here you can perform various settings such as date and time, brightness etc. It also enables one-time setting of the &quot;standard&quot; logging settings regarding log output.</td>
</tr>
<tr>
<td>Info/status window</td>
<td>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.</td>
</tr>
<tr>
<td>Service area</td>
<td>Only for service technicians.</td>
</tr>
</tbody>
</table>
## 4 Description of the device

### Symbol in the menu bar

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Help menu icon" /></td>
<td>Help menu Depending on the window selected and the operating situation, gives information regarding operation or the function of the window currently selected.</td>
</tr>
</tbody>
</table>

### Symbols in the action bar

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Door open icon" /></td>
<td>Door open Opens the door of the steam sterilizer</td>
</tr>
<tr>
<td><img src="image" alt="Back icon" /></td>
<td>Back Returns to the previous window</td>
</tr>
<tr>
<td><img src="image" alt="Forwards icon" /></td>
<td>Forwards Navigates to the next window</td>
</tr>
<tr>
<td><img src="image" alt="Cancel/return without saving icon" /></td>
<td>Cancel/return without saving Navigates to the superordinate menu, leaves the window without saving</td>
</tr>
<tr>
<td><img src="image" alt="Zoom (+) icon" /></td>
<td>Zoom (+) Displays further details such as further values after a completed program</td>
</tr>
<tr>
<td><img src="image" alt="Start time pre-selection icon" /></td>
<td>Start time pre-selection Navigates to the &quot;Start time pre-selection&quot; menu</td>
</tr>
<tr>
<td><img src="image" alt="Delete icon" /></td>
<td>Delete Deletes logs from the internal log memory/deletes the log printer or label printer stored as standard</td>
</tr>
<tr>
<td><img src="image" alt="Search icon" /></td>
<td>Search Searches for label printer(s)/log printer(s)</td>
</tr>
<tr>
<td><img src="image" alt="Skip icon" /></td>
<td>Skip Navigates to the next window without entry of the required data</td>
</tr>
</tbody>
</table>

### LED status bar

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

<table>
<thead>
<tr>
<th>Colour of the LED</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue</td>
<td>Standby, program running, drying has not yet begun</td>
</tr>
<tr>
<td>Green</td>
<td>Drying running, program completed successfully</td>
</tr>
<tr>
<td>Yellow</td>
<td>Warning message, software update is running</td>
</tr>
<tr>
<td>Red</td>
<td>Malfunction message, program not completed successfully</td>
</tr>
</tbody>
</table>
Tray mounts for the load

Tray mount for 2 instrument baskets or 4 large trays
A single mount can be inserted in Cliniclave 45; two such mounts can be inserted in Cliniclave 45 M.

For 2 instrument baskets or 4 large trays

Tray mount for 6 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.

For 6 standard tray cassettes

Tray mount for 8 trays
The sterilization chamber of Cliniclave 45 accommodates up to three mounts of this type and the chamber Cliniclave 45 M up to six mounts.

For 8 trays

Tray mount for 5 sterilization containers / 5 MELAstore-Boxes 100

PLEASE NOTE
We do not recommend using this tray mount in the rear half of the Cliniclave 45 M with the loading system "Standard". In such a case, please use the loading hook or the loading system "Comfort".
The sterilization chamber of Cliniclave 45 accommodates up to three mounts of this type and the chamber Cliniclave 45 M up to six mounts.

For 5 sterilization containers / 5 MELAstore-Boxes 100, 5 standard tray cassettes or 5 trays
5 First steps

Setup and installation

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

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

Feed water supply

Always use high-quality feed water
The steam sterilizer requires distilled or demineralized water to perform steam sterilization. DIN EN 285 recommends compliance with 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 degassing) makes higher conductivity values permissible. As a result, the value of 5 µS/cm recommended in accordance with DIN EN 285 in table 1 can be exceeded. At 15 µS/cm, the mixed-bed resin cartridge of the water treatment unit should be replaced. The display issues a warning message once conductivity has reached 20 µS/cm. At this point at the latest, the mixed-bed resin cartridge should be replaced/the unit should be checked.

The feed water supply in the steam sterilizer
The feed water supply is best effected via the water treatment unit MELAdem 56 or MELAdem 56 M. These water treatment units produce the best-quality water for the steam sterilizer. The MELAdem 56 water treatment units are supplied via the air gap integrated in the steam sterilizer. This prevents the water from flowing back into the drinking water supply and corresponds to the full requirements of EN 1717 (fluid category 5).

PLEASE NOTE
Should you wish to use a water treatment unit from another manufacturer, please first consult with MELAG and comply with the installation instructions.
Switching on the steam sterilizer

✓ The steam sterilizer is connected to the electricity supply.
✓ The feed water supply is secure. The steam sterilizer Cliniclave 45 requires approx. 7 litres and the Cliniclave 45 M requires approx. 13.5 litres feed water for the first filling of the steam generator.

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

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

The feed water level is checked and pre-heated immediately after activation. After device activation, a heating up time of approx. 20 minutes is required, depending on the device type. This time is required for the pre-heating of the double-jacket steam generator.

Opening and closing the door

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

CAUTION
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.

Opening the door

The door is opened by pressing on the door symbol on the display. When opening the door, comply with the following instructions, so as to ensure faultless operation of the door locking mechanism.

► Never use force to open the door.
► Do not pull vigorously at the door to open it. The door opens automatically.
**PLEASE NOTE**

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

---

**Closing the door**

To close the door, press it firmly inwards until the automatic door lock engages. After the door has been closed, the display returns to the program menu. The door is locked pressure-tight upon program start.

Make sure that the brakes on the casters have been engaged.

Never slam the door.

Press the door closely to the housing.

Hold the door closed for min. three seconds until the door lock engages.

---

**Manual door emergency-opening**

**WARNING**

Danger of burns from hot steam. Steam egress from the sterilization chamber is possible e. g. if it is necessary to open the door during a running program or immediately after the end of a program.

This could result in burns.

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

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

1. If the steam sterilizer is still switched on, switch it off at the power switch.

2. Remove the cover cap in order to facilitate emergency door-opening by pressing inwards the cover cap 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 of the cover cap).
3. Lever the cover cap out of the opening at an angle. Observe the retaining brackets whilst doing so.

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

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

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

Preparing the sterilization material

Cleaning and disinfection must always have been performed before sterilization. Only in this way is it possible to guarantee the subsequent sterilization of the sterilization material. The materials used, the cleaning fluid and treatment procedures used are of decisive significance.

Decontaminating textiles

**WARNING**
The incorrect decontamination of textiles, e.g. a textile package can prevent steam penetration and/or produce poor drying results. The textiles could not be sterilized.
This could endanger the health of patient and practice team.

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

- Comply with both the manufacturer’s instructions of the textiles regarding treatment and sterilization as well as the relevant standards and directives e.g. from the RKI and DGSV.
- Arrange the folds in the textiles parallel to each other.
- Stack textiles vertically wherever possible and not too closely together in the sterilization container. This enables the development of flow channels.
- 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 may not be permitted to come into direct contact with the sterilization chamber; otherwise they will become saturated with condensate.

Decontaminating the instruments

**WARNING**
The incorrect decontamination of instruments could result in any dirt residue being loosened by the steam pressure during sterilization.
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.

**NOTICE**
The presence of residual disinfection and cleaning fluids results in corrosion.
This could result in increased maintenance requirements and a restriction of the steam sterilizer function.

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

- Follow both the instrument manufacturer’s instructions regarding decontamination and sterilization and comply with the relevant standards and directives e.g. from the BGV A1, RKI and DGSV.
- Clean the instruments exceptionally thoroughly e.g. using an ultrasonic device or washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with de-mineralized or distilled water and then dry the instruments thoroughly with a clean, non-fuzzing cloth.
Use only those care agents suitable for steam sterilization. Consult the manufacturer of the care agents. Do not use any water repellent agents or oils impermeable to steam.

When using ultrasound devices, care equipment for handpieces and washer-disinfectors, please comply with the manufacturer’s treatment instructions.

**Loading the steam sterilizer**

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

Ensure the following during loading:

- Insert trays or cassettes in the chamber only with their appropriate mount.
- Use perforated trays such as those from MELAG. Only in this way can condensate drain off. The use of a non-perforated base or half-shell to accommodate the sterilization material can result in poor drying results.
- The use of paper tray inserts can also result in poor drying results.
- Wherever possible, please ensure the separate sterilization of textiles and instruments in separate sterilization containers or sterilization packaging. This leads to better drying results.

**Packaging**

Only ever use packaging materials and systems (sterile barrier systems) which fulfil the standard DIN EN ISO 11607-1. The correct use of suitable packaging is important in achieving successful sterilization results. You can use re-usable rigid packaging systems 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**

---

**CAUTION**

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.

---

**CAUTION**

Incorrect stacking of the sterilization containers can result in the dripping condensate being unable to drain off to the chamber floor. This can saturate 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.

Please comply with the following when using closed sterilization containers for sterilization material:

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

**Tip:** 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).
Soft sterilization packaging

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

- Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- If the seam seal tears during sterilization, this could be caused by the choice of undersized packaging. Re-pack the instruments with larger packaging and perform sterilization again.
- Should the seam seal rip during sterilization, extend the sealing pulse on the film 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 sterilizing mixed loads

- Always place textiles at the top
- Place the sterilization containers at the bottom
- Place unwrapped instruments at the bottom
- Place the heaviest loads at the bottom
- Place transparent sterilization packaging and paper bags at the top - except in combination with textiles. In this case, place them at the bottom.
- Place transparent sterilization packages on their edge wherever possible and with the paper side facing downwards.
Load quantities and versions

Max. weight per component

<table>
<thead>
<tr>
<th>Load</th>
<th>Instruments</th>
<th>Textiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. weight per component</td>
<td>2 kg</td>
<td>2 kg</td>
</tr>
</tbody>
</table>

Maximum load quantities for instruments and textiles

The total weight is the sum of the mass of the sterilization material, the packaging materials, the containers and the mount.

<table>
<thead>
<tr>
<th>Load type</th>
<th>Instruments</th>
<th>Textiles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cliniclave 45</td>
<td>Cliniclave 45 M</td>
</tr>
<tr>
<td>Full load</td>
<td>wrapped 35 kg*</td>
<td>70 kg**</td>
</tr>
<tr>
<td></td>
<td>unwrapped 40 kg</td>
<td>80 kg</td>
</tr>
<tr>
<td>Partial load</td>
<td>wrapped 15 kg</td>
<td>30 kg</td>
</tr>
<tr>
<td></td>
<td>unwrapped</td>
<td></td>
</tr>
</tbody>
</table>

*) The drying was checked for 35 kg or 70 kg load with dental containers / MELAstore-Boxes. The drying of other large weights (20-40 kg/40-80 kg wrapped) or other load configurations must be checked individually and locally; additional drying may be required.

Loading versions per sterilization unit (StU)

<table>
<thead>
<tr>
<th>Nature of the mount*</th>
<th>Loading version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mount for 2 instrument baskets or 4 large trays</td>
<td>Max. 4 large trays, max. depth 59 cm</td>
</tr>
<tr>
<td></td>
<td>2x ½ StU sterilization container</td>
</tr>
<tr>
<td></td>
<td>2x ½ StU instrument baskets</td>
</tr>
<tr>
<td>Mount for 6 standard tray cassettes**</td>
<td>Max. 18 standard tray cassettes (6 per mount)</td>
</tr>
<tr>
<td>Mount for 8 small trays***</td>
<td>Max. 24 dental trays, depth 29 cm (8 per mount)</td>
</tr>
<tr>
<td>Mount for dental containers***</td>
<td>Max. 15 dental containers / MELAstore boxes (5 per mount)</td>
</tr>
<tr>
<td>Without mount</td>
<td>Max. sterilization container (1 StU)</td>
</tr>
</tbody>
</table>

*) MELAG mounts, trays, standard tray cassettes etc., see Description of the device [+] page 12

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

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

Please consult the operating manual of the sterilization container used. Never exceed the max. permissible load size and weight.
7 Sterilization

Important information regarding routine operation

Daily routine controls

- Check of the sterilization chamber and seal for its correct condition, see chapter Maintenance [page 69].
- Check of the operational readiness of the recording equipment, see chapter Logging [page 40].
- Perform a Bowie & Dick test (steam penetration test) see chapter Function tests [page 47].

When using the water treatment unit MELAdem 56/56 M

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

<table>
<thead>
<tr>
<th>Pressure in the pressure tank (blue indicator)</th>
<th>Meaning</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 - 4 bar</td>
<td>Recommended operating pressure</td>
<td>----</td>
</tr>
<tr>
<td>&lt; 2.5 bar</td>
<td>Little feed water in the pressure tank</td>
<td>Leave the steam sterilizer switched on so that the water treatment unit can operate.</td>
</tr>
<tr>
<td>&lt; 1 bar</td>
<td>No or insufficient feed water in the pressure tank</td>
<td>Leave the steam sterilizer switched on so that the water treatment unit can operate. A warning or malfunction message will be displayed.</td>
</tr>
</tbody>
</table>
Further routine controls

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

<table>
<thead>
<tr>
<th>When is it necessary to make checks?</th>
<th>How should the checks be made?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before starting routine operation</td>
<td>Installation qualification (IQ); operational qualification (OQ);</td>
</tr>
<tr>
<td></td>
<td>performance qualification (PQ)</td>
</tr>
<tr>
<td>Monthly</td>
<td>Vacuum test</td>
</tr>
<tr>
<td>After 4000 cycles, but at latest after 12 months</td>
<td>Maintenance</td>
</tr>
<tr>
<td>After changes to the steam sterilizer and its supply</td>
<td>Operational qualification (OQ)</td>
</tr>
<tr>
<td>After changes to the configuration</td>
<td>Renewed performance qualification (PQ) for a particular reason</td>
</tr>
<tr>
<td>In established intervals after 1-2 years*</td>
<td>Renewed performance qualification (PQ)</td>
</tr>
</tbody>
</table>

*) in accordance with the mentioned norms and after the validators estimation
Selecting the program

Now 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 sterilization material fits which program and which additional programs are available.

<table>
<thead>
<tr>
<th>Program</th>
<th>Universal-Program</th>
<th>Quick-Program B</th>
<th>Quick-Program S</th>
<th>Gentle-Program</th>
<th>Prion-Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization temperature</td>
<td>134 °C</td>
<td>134 °C</td>
<td>134 °C</td>
<td>121 °C</td>
<td>134 °C</td>
</tr>
<tr>
<td>Sterilization pressure</td>
<td>2.1 bar</td>
<td>2.1 bar</td>
<td>2.1 bar</td>
<td>1.1 bar</td>
<td>2.1 bar</td>
</tr>
<tr>
<td>Sterilization time</td>
<td>5:30 min</td>
<td>5:30 min</td>
<td>3:30 min</td>
<td>20:30 min</td>
<td>20:30 min</td>
</tr>
</tbody>
</table>

Program name | Operating time | Drying | Packaging type
---|---------------|--------|----------------|
Universal-Program |    |        |                |
| partial load      |    |        |                |
| full load textiles|    |        |                |
|                  | c. 23 min | c. 27 min | Single and multiple wrapping |
|                  | c. 35 min | c. 48 min |                |
|                  | c. 26 min | c. 35 min |                |
| Quick-Program B  |    |        |                |
| partial load      |    |        |                |
|                  | c. 22 min | c. 27 min | Single wrapped and unwrapped instruments (no textiles) |
| Quick-Program S  |    |        |                |
| partial load      |    |        |                |
|                  | approx. 17 min | approx. 22 min | Only unwrapped (no textiles) |
| Gentle-Program    |    |        |                |
| partial load      |    |        |                |
| textiles          | approx. 36 min | approx. 45 min |                |
|                  | approx. 42 min | approx. 53 min |                |
|                  | 20 min         | 20 min         |                |
|                  | 4-30 min       | 4-30 min       |                |
|                  | 4-50 min       | 4-50 min       |                |
| Prion-Program     |    |        |                |
| partial load      |    |        |                |
| full load textiles|    |        |                |
|                  | c. 38 min | c. 42 min | Single and multiple wrapped |
|                  | c. 50 min | c. 63 min |                |
|                  | c. 41 min | c. 50 min |                |
|                  | 20 min         | 20 min         |                |
|                  | 20 min         | 20 min         |                |
|                  | 4-50 min       | 4-50 min       |                |

*) Without drying and depending on the load and the set-up conditions e.g. mains voltage and air-pressure. The steam sterilizer requires an additional one-off heating-up time to preheat the double-jacket steam generator after activation. In standard operation, this amounts to c. 20 minutes.

**) When taking into account the specified load quantities, the program-specific drying times (time-controlled drying) 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. Activation of intelligent drying subjects the drying phase to automatic monitoring and ends as soon as the load is dry.
### Additional programs

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

### Additional program options

**Additional drying**

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 you can activate the additional drying function retrospectively during a running program, see Additional drying [page 60].

**Start time pre-selection**

---

**NOTICE**

Unsupervised operation of electrical devices, including this steam sterilizer at the operator’s risk. MELAG accepts no liability whatsoever for any damage resulting from unsupervised operation.

---

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

Please note, the security query means that this function is not possible for Quick-Program S. To set a program start to a particular number, proceed as follows:

1. After selecting the program, press the symbol in the action bar. The display switches to the settings window.
2. For example, to change the time, tap directly on the parameters **Hour** or **Minutes**. The selected field is highlighted light blue.

3. Change e.g. the hour by pressing the pushbuttons and .

4. Then press START. The display remains in the start time pre-selection window.

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

**Automatic shutdown**

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

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

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

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

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

2. With activated user authentication:
   Enter the user PIN or press (if possible) the button to skip this stage (see User administration [p. page 56]). Please note: Only ever use the “Skip user authentication” function in an emergency.

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

Program run

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

Air removal and heating up phase

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

Sterilization phase

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

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

The sterilization phase is unsuccessful if the operator or the system (responding to an malfunction) aborts the program run. A system abort returns the steam sterilizer to a pressureless state. This explains why a system abort takes longer as an abort by the operator.
Drying phase
The steam sterilizer provides excellent drying of the sterilization material. Depending on the setting, drying is performed either via the time-controlled drying or the pre-set intelligent drying (see Intelligent drying [page 61]). If difficult-to-dry items require better drying, you can undertake the following steps to improve drying:

- Load the steam sterilizer properly. Stand e.g. the transparent and paper sterilization packaging upright. Comply with section Loading the steam sterilizer [page 25]. Use the optional package holder if necessary.
- Time-controlled drying: Activate function Additional drying, to extend the drying time by 50%.
- Intelligent drying: Activate function. Additional drying to restrict the criteria for ending the drying phase.

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

- The steam sterilizer has been assigned an IP address and is integrated in the practice network.

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

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

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

WARNING
Hot steam can be released from the emergency release valve under the rear of the steam sterilizer following a program abort effected with the power switch. This could result in burns.
- Never abort a program by switching off at the mains.
Program abort before the start of drying

⚠️ WARNING
Danger of infection from early program abort

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

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

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

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

1. Press CANCEL on the action bar.

2. Confirm the security query with YES.

3. After a short time, you can open the door by pressing the symbol. The display shows a warning; the log records the sterilization as NOT successful.
Program abort after the start of drying

⚠️ CAUTION
Given a premature abort of the drying phase, certain circumstances may mean that it is impossible to comply with the max. residual moisture required by DIN EN 285 (textiles < 1 %, metal < 0.2 %).

This impairs the storage stability of the sterilized equipment.

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

Should you abort a program after drying has started, the sterilization is having been completed successfully. The steam sterilizer issues a malfunction message. You then need to expect insufficient drying, especially in the case of wrapped sterilized equipment and a full load. Sterile storage requires sufficient drying. To ensure this, please allow programs with wrapped sterilized equipment to continue to the end of the drying phase as far as is possible. Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

Proceed as follows to abort the program during drying:

1. Press STOP on the action bar.

2. Confirm the security query with YES.

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

Program end

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

Working in Menu Settings → Logging if immediate output after program end is activated (= Immediate output), the log of the completed program will be outputted to the activated output medium after opening the door.

The approval process

According to RKI "Hygiene requirements for the treatment of medical products", instrument treatment ends with the documented approval for storage and application of the sterilized equipment. The approval process consists of batch indication and batch approval and must be performed by authorized and expert personnel. This is ensured by the activated user authentication. To do so, enter the user PIN (see Settings [page 50]).

PLEASE NOTE

Skipping user authentication means that the batch is not approved.

- Only ever use the "Skip user authentication" function in an emergency.

Batch indication comprises the checking of the indicators used in the sterilization program e. g. MELAcontrol/MELAcontrol PRO. Approval of the indicator strip is possible only if it changes colour entirely.

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

Removing the sterilized equipment

CAUTION

Danger of burns from hot metal surfaces

- Allow the device to cool sufficiently before opening.
- Do not touch any hot metal parts.
**CAUTION**

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

- Should the packaging be damaged or have burst, re-pack the sterilization material and re-sterilize it.

---

**CAUTION**

The weight of the tray mount could cause it to slide out. This could result in burns.

- Safety demands that you remove the trays / instrument baskets individually from the steam sterilizer; never remove the whole tray mount with load at once.

---

If you remove the sterilized equipment from the device directly after the end of the program, it is possible that the instruments can be partially damp. According to the Arbeitskreis für Instrumentenaufbereitung (AKI; red brochure 11. Edition; p. 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."

Comply with the following specifications when removing the sterilized equipment:

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

---

**Storing sterile instruments**

The maximum storage time is dependent on the packaging and the storage conditions. For standard-conform packaged sterilized equipment – (if protected from dust) it can amount to up to six months. Comply with the provisions of DIN 58953, part 8 and the criteria specified below for the storage of sterilized equipment:

- Comply with the maximum storage duration in accordance with the packaging type.
- Do not store the sterilized equipment in the decontamination room.
- Store the sterilized equipment in a dust-protected environment e.g. in a closed instrument cabinet.
- Store the sterilized equipment in an environment protected against moisture.
- Store the sterilized equipment in an environment protected against excess temperature variations.
8 Logging

Batch documentation

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

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

Capacity of the internal log memory

The steam sterilizer is equipped with an internal log memory. This saves all the data regarding the sterilization program automatically. 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 "Internal log memory is almost full" will appear on the display.

If this warning appears, working in the Settings menu → Logging provide the pre-determined output media and output the logs affected (→ Log output menu).

Shortly afterwards, the following message is displayed: Internal log 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 steam sterilizer log memory (up to the last 40 logs) is automatically deleted.

Output media

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

- MELAflash CF card
- Label print-out with the MELAprint 60 label printer
- MELAprint 42/44 log printer
- A computer (via the practice network)

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

Detailed information regarding the activation and setting of log output is to be found in the chapter settings, logging [page 50].
Using the CF card as an output medium

**NOTICE**

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 device and/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 square in the upper right-hand corner of the display lights up during reading and writing access.

The card slot for the CF card is located on the right-hand side of the display housing. Proceed as follows in order to insert the CF card in the slot.

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

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

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

Using the computer as an output medium

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

Further information pertaining to the requirements and setting of the computer as an output medium is available in the chapter Settings, logging [ page 50].

Reading out a text log on the computer

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

Each text log (e.g. PRO, .STR, .STB etc.) must be linked with the text editor to enable the computer to open them automatically with a text editor. The meanings of the endings are outlined in the section Subsequent log output [ page 43]. The following examples show how you can link the Windows 7 editor with a specific text log.

2. If the file ending is unfamiliar, Windows 7 will display the following message:

3. Select “Select a program from a list of installed programs” and confirm with “OK”.

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

**Using the label printer as an output medium**

The use of a label printer facilitates batch traceability. Using the sterilization date, the storage duration, batch number, user ID of the person approving the application for use, the steam sterilizer 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 “Approval” by the person conferred with the task of decontamination are given. All information regarding the correct sterilization procedure can be attributed to the instruments used in patient records.

**PLEASE NOTE**

To facilitate easy assignation of a package marked with a label to a specific batch, the sterilization log file name must not be changed.
**Outputting text logs automatically after program end**

(Immediate output)

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

If the output medium selected for this purpose has not been connected, the logs are saved in the internal memory and a warning is issued. The steam sterilizer provides the option of outputting this log at the next possible opportunity. Graphic logs cannot be saved in the internal log memory; they are lost. Further information pertaining to the output of graphic logs is available in the section [Outputting graphic logs (optional) page 51].

The following points must be fulfilled for immediate output:

- The date and time have been set correctly.
- The output medium must have been selected and connected.
- Immediate output must be activated in Menu Settings → Logging.

Information regarding the setting of immediate output and the desired output medium is provided in the chapter Settings, logging [page 50].

**Subsequent log output**

Menu Log output 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 media are pre-selected as standard, which are also selected under Settings → Logging as far as automatic immediate output has been activated.

Menu Log output provides various opportunities for log output. Menu Logging list displays all the program logs present in the memory. You can sort the list according to date, time, program and outcome by pressing on the column headings. Here is an overview of all possible output media.

<table>
<thead>
<tr>
<th>Designation</th>
<th>File ending</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last log</td>
<td>.PRO</td>
<td>The log of the last successful completed program is outputted.</td>
</tr>
<tr>
<td>Logs of the day</td>
<td>.PRO</td>
<td>The log of the last successful program of the current day is outputted.</td>
</tr>
<tr>
<td>Logs of the week</td>
<td>.PRO</td>
<td>Logs of all successfully completed programs of the week - Monday to Sunday - will be outputted</td>
</tr>
<tr>
<td>Logs of the month</td>
<td>.PRO</td>
<td>Logs of all successfully completed programs performed in the current month will be outputted.</td>
</tr>
<tr>
<td>All logs</td>
<td>.PRO</td>
<td>The logs of all successfully completed programs will be outputted.</td>
</tr>
<tr>
<td>Last fault log</td>
<td>.ML</td>
<td>The last malfunction log is outputted.</td>
</tr>
<tr>
<td>Fault logs of the day</td>
<td>.ML</td>
<td>The malfunction logs of the current day are outputted.</td>
</tr>
<tr>
<td>etc.</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Legend log file</td>
<td>.LEG</td>
<td>Contains an explanation of all abbreviations contained in the log.</td>
</tr>
<tr>
<td>Status log</td>
<td>.STA</td>
<td>A summary of all important settings and system states (counter, measured values etc.)</td>
</tr>
<tr>
<td>Fault in standby</td>
<td>.STB</td>
<td>This log type is generated following malfunctions during a time at which no program was active.</td>
</tr>
<tr>
<td>System log</td>
<td>.LOG</td>
<td>A sort of logbook listing all malfunctions and changes to the system in order of their incidence.</td>
</tr>
<tr>
<td>Delete all logs</td>
<td></td>
<td>Deletes all logs stored in the internal log memory. Warning: All logs will be deleted which were not previously outputted to another output medium.</td>
</tr>
</tbody>
</table>
**Outputting a log from the log list**

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

1. Navigate to Menu Log output and select Logging list.

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

3. Select a log and press CONTINUE.

4. Select an output medium if required and press OUTPUT.

**Outputting the daily / weekly log etc.**

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

1. Navigate to Menu Log output and select option Logs of the week.
2. Press CONTINUE.

3. Select an output medium if required and press OUTPUT.

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

**Finding a log**

- **PLEASE NOTE**
  If possible, do not rename the directories, otherwise logs will be stored in both the renamed directory as well as the new device directory generated automatically by the steam sterilizer.

**Storage location for logs**

When transferring the logs to a CF card, they will be stored in a separate folder in the main directory. Direct transfer of the logs to a computer via the network and using the MELAG FTP server allows you to work directly in the FTP server to determine directly where on your computer the device directory with log files is to be saved. With output via TCP and e.g. MELAtrace, you can work directly in the program to determine the folder in which they are to be saved.

**Log directory**

A folder is created on all memory media (CF card or computer) after log output containing the encoded serial number of the steam sterilizer concerned. The folder name consists of five characters identical with the first five characters of every log, e.g. B5002. This folder contains sub-folders with the month of log generation e.g. 01_2016 for January 2016. This contains all logs generated by the steam sterilizer this month. The device directory is entered in the main directory on the CF card.

The steam sterilizer checks the 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.

Further information pertaining to the meaning of the file endings on the logs is available in section Subsequent log output [page 43]
### 15 Program: Universal-Program
20 Program type: 134 °C wrapped
25 Date: 07.12.2016
30 Daily batch: 11 Total: 00011
34 ID load: 1001
35 ID approval: 1001
36 Indicators changed: deactivated
37 Batch approved: deactivated
======
40 Universal-Program successfully completed
42 ==
======
45 Temperature: 135.4 +0.18/-0.19 °C
50 Pressure: 2.18 +0.01/-0.01 bar
55 Plateau time: 05 min 30 s
60 Conductivity: 6 µS/cm (1293:72.9)
65 Start time: 20:19:28
70 End time: 21:07:47 (48:19 min)
======
80 SN:2015C450901
======

### Step – Program step
**Time** (min:sec) which has elapsed since the program start

<table>
<thead>
<tr>
<th>Step</th>
<th>Time t[m:s]</th>
<th>Pressure P[mbar]</th>
<th>Temperature T[°C]</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP-S</td>
<td>0:00 0:00</td>
<td>1014 115.6</td>
<td></td>
</tr>
<tr>
<td>SKI1</td>
<td>0:37 0:37</td>
<td>1786 112.6</td>
<td></td>
</tr>
<tr>
<td>SF12</td>
<td>4:11 0:29</td>
<td>509 112.3</td>
<td></td>
</tr>
<tr>
<td>SF13</td>
<td>4:35 0:24</td>
<td>1646 118.7</td>
<td></td>
</tr>
<tr>
<td>SF21</td>
<td>4:48 0:13</td>
<td>1306 118.3</td>
<td></td>
</tr>
<tr>
<td>SF22</td>
<td>5:38 0:50</td>
<td>191 113.8</td>
<td></td>
</tr>
<tr>
<td>SF23</td>
<td>6:13 0:35</td>
<td>1833 121.6</td>
<td></td>
</tr>
<tr>
<td>SF31</td>
<td>6:34 0:21</td>
<td>1311 119.4</td>
<td></td>
</tr>
<tr>
<td>SF32</td>
<td>7:23 0:49</td>
<td>208 111.4</td>
<td></td>
</tr>
<tr>
<td>SF33</td>
<td>8:01 0:38</td>
<td>1923 121.2</td>
<td></td>
</tr>
<tr>
<td>SF41</td>
<td>8:24 0:23</td>
<td>1309 119.0</td>
<td></td>
</tr>
<tr>
<td>SF42</td>
<td>8:58 0:34</td>
<td>411 103.9</td>
<td></td>
</tr>
<tr>
<td>SF43</td>
<td>9:28 0:30</td>
<td>1733 117.8</td>
<td></td>
</tr>
<tr>
<td>SH01</td>
<td>10:17 0:49</td>
<td>2873 131.9</td>
<td></td>
</tr>
<tr>
<td>SH02</td>
<td>10:37 0:20</td>
<td>2881 132.0</td>
<td></td>
</tr>
<tr>
<td>SS01</td>
<td>11:27 0:50</td>
<td>3068 134.1</td>
<td></td>
</tr>
<tr>
<td>SS02</td>
<td>16:57 5:30</td>
<td>3182 135.5</td>
<td></td>
</tr>
<tr>
<td>SA00</td>
<td>17:42 0:45</td>
<td>1302 112.1</td>
<td></td>
</tr>
<tr>
<td>SI01</td>
<td>22:44 5:02</td>
<td>1116 116.7</td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SH10</td>
<td>48:12 0:27</td>
<td>812 115.4</td>
<td></td>
</tr>
<tr>
<td>SB20</td>
<td>48:18 0:06</td>
<td>923 115.7</td>
<td></td>
</tr>
<tr>
<td>SP-E</td>
<td>48:19 0:01</td>
<td>926 115.6</td>
<td></td>
</tr>
</tbody>
</table>

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

---

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

---

**Fig. 1: Example log of a successfully completed program**
9 Function tests

Vacuum test

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

Perform a vacuum test in the following circumstances:

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

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

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

2. Working in the Programs & Tests menu, select vacuum test and press START.

The evacuation pressure and the equilibration time or measuring time are shown on the display. 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, a corresponding message will be issued on the display.

Bowie & Dick test

The Bowie & Dick test serves as proof of steam penetration of porous materials such as e.g. textiles. You can perform a routine function check for proof of steam penetration. Use test program Bowie & Dick test for this purpose. Specialist stockists provide various test systems for the Bowie & Dick test.

Depending on the application, use either a test system for hollow body instruments or for porous sterilization material (laundry etc.). Combination test systems can also be used. Perform the Bowie & Dick test in accordance with the test system manufacturer's specifications.

Perform the Bowie & Dick test as follows:

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

2. Place the test system in the sterilization chamber of the steam sterilizer and close the door.
3. Working in Menu Programs & Tests
   select Bowie & Dick test and press START.

**Evaluation of the indicator following the colour change**

Depending on the manufacturer batch, treatment indicator strips often exhibit differing intensities in the colour change resulting from different lengths of storage or other influences. Of crucial importance for evaluating the Bowie & Dick test is not the strength of contrast in the colour change on the test sheet, but its even nature. If the treatment 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/authorized customer services.

**MELAcontrol / MELAcontrol PRO test body system**

The test body system is an indicator and batch control system fulfilling the requirements of DIN EN 867-5. It consists of a test body and an indicator strip. When sterilizing category "critical B" instruments, you should add the MELAcontrol/MELAcontrol PRO test body system to every sterilization cycle as a batch control. Regardless of this, you can perform a steam penetration test in the Universal-Program at any time using MELAcontrol/MELAcontrol PRO. Intended use of the test body system can result in the colouration of the plastic surface. This colouration exercises no influence on the functionality of the test body system.
Feed water quality

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

**PLEASE NOTE**

If, despite all warnings, the steam sterilizer continues to be operated from a conductivity of 20 µS/cm, a 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 ISO 17665 and DIN 58946-7, the device should be validated before beginning routine operation.

**Renewed Qualification (revalidation)**

DIN EN ISO 17665 and DIN 58946-7 recommend a renewed evaluation (revaluation) in regular intervals after 1-2 years.
10 Settings

Logging

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

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

Immediate log output

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

Deactivate immediate output

If log output is not to be performed 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:

✓ You are in Menu Settings → Logging.

1. Remove the checkmark in front of option Immediate output.

2. Press repeatedly on CONTINUE, until you come to the summary window.

3. Press SAVE, to save the setting.
Outputting graphic logs (optional)

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

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

- You are in Menu **Settings → Logging**.
- Immediate issue is activated.

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

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

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

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

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

6. Press repeatedly on **CONTINUE**, until you come to the summary window.
7. Press SAVE, to save the setting.

Explanation of the possible settings for graphic recording:

<table>
<thead>
<tr>
<th>Interval</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF card (CFC) recording interval</td>
<td>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.</td>
</tr>
<tr>
<td>PC recording interval</td>
<td>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.</td>
</tr>
<tr>
<td>PC backup interval</td>
<td>in sec. – Indicates the time interval in which the graphic data from the steam sterilizer is saved on the computer. In the example, the backup interval is set to 1 second.</td>
</tr>
</tbody>
</table>

Log output in English

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

1. Press repeatedly on CONTINUE until you reach the log output menu.
2. Select the Log printer as an output medium.
3. In addition, select Log printer language: English.
4. Press repeatedly on CONTINUE until you come to the summary window.
5. Press SAVE to save the setting.
   ◗ The output of the text logs on the MELAprint log printer is in English.
Using the computer as an output medium

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

- You are in Menu Settings → Logging.
- The steam sterilizer is connected to a computer via a network cable (RJ45).
- Depending on the output type, an FTP server / service or a suitable program e. g. MELAtrace / MELAview is installed.

1. Press CONTINUE until you navigate the output media selection window.

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

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

Connection via FTP

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

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

2. Press this pushbutton to change the pre-set TCP user data. The display switches to the settings window.
3. Enter the user name and password and confirm with SAVE.

**Connection via TCP**

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

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

2. Press on this pushbutton to change the pre-set TCP port. The display switches to the settings window.

3. Delete the most up-to-date TCP port using button C; enter another TCP port.

4. Confirm with SAVE.

**IP addresses**

**PLEASE NOTE**

Those setting up the (practice) network will require in-depth understanding of the network technology.

Errors in the handling of IP addresses can result in malfunctions and data loss in your practice network.

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

The device is equipped as standard with IP addresses which all belong to a common network with the subnet mask stated in the following depiction.

<table>
<thead>
<tr>
<th>Device</th>
<th>IP address</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam sterilizer</td>
<td>192.168.40.40</td>
<td>Preset works side</td>
</tr>
<tr>
<td>Computer</td>
<td>192.168.40.140</td>
<td>Preset works side</td>
</tr>
<tr>
<td>MELAprint 42/44 log printer</td>
<td>192.168.40.240</td>
<td>Preset works side</td>
</tr>
<tr>
<td>MELAprint 60 label printer</td>
<td>192.168.40.160</td>
<td>Preset works side</td>
</tr>
<tr>
<td>Gateway</td>
<td>192.168.40.244</td>
<td>Not relevant within a network</td>
</tr>
</tbody>
</table>
If a device is to be integrated in a pre-existing (practice) network, observe and comply with the following:

- The IP addresses listed in the table have not yet been assigned in the (practice) network.
- The device cannot be automatically administered in a dynamic (practice) network (i.e., a DHCP network).

1. Select Menu Settings → Logging. The setting wizard opens.

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

3. Select e.g. the steam sterilizer. The settings window opens.

4. Select the number block which you wish to change directly.

5. Use the C button to delete the numbers. Enter a new number block and confirm with SAVE.

6. Proceed in a similar fashion with the other devices which are to be integrated in the network.

<table>
<thead>
<tr>
<th>Device</th>
<th>IP address</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subnet mask</td>
<td>255.255.255.0</td>
<td>Possibly to be adopted by customer network</td>
</tr>
</tbody>
</table>

![Image](image-url)
Log format

Different data is issued depending on the nature of the logging format.

- The logging format is determined under Settings → Logging.

You can choose between the following formats.

<table>
<thead>
<tr>
<th>Format</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format 0</td>
<td>Short form - only the log header is outputted.</td>
</tr>
<tr>
<td>Format 1</td>
<td>The log header and the program steps are outputted.</td>
</tr>
<tr>
<td>Format 2</td>
<td>Standard format - in addition to the log header and the program steps, a key is displayed explaining the individual program steps. In logs outputted via the log printer MELAprint, the corresponding legend row is always located under the row to which it refers.</td>
</tr>
</tbody>
</table>

User administration

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

Adding a user

1. Select Menu Settings → User administration.
2. Entry of the Admin PIN is necessary to navigate to Menu **User administration** and perform the settings there. Enter the Admin PIN (standard 1000) and confirm with LOGIN. The display switches to window **User administration**.

3. Select Menu **User list**, to display the user list.

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

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

6. Accept all the settings with **SAVE**, then leave the menu.

7. Exit the menu by pressing this button.
Deleting a user

1. Select the User administration option 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 warming is issued.

4. Confirming the warning with YES will set the PIN number of this ID to “0”.

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

Changing the Admin PIN

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

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

User authentication for sterilization

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

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

**Determining options for the user authentication**

1. Select Menu Settings → User administration.
2. Entry of the Admin PIN is necessary to navigate to Menu User administration and perform the settings there. Enter the Admin PIN (standard 1000) and confirm with LOGIN. The display switches to window User administration.

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

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

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

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

6. Accept all the settings with SAVE, then leave the menu.
10 Settings

Formatting the CF card

NOTICE
- All data saved on the CF card is deleted during formatting.
  - Check whether important data is stored on the CF card.
  - Save any logs or other data on the computer or another memory medium.

1. Insert the CF card in the steam sterilizer card slot correctly (tangible raised bar on the edge pointing back right). Do not use force.

2. Select the Settings → Format CF card. The display switches to the corresponding window.

3. To start formatting, press the OK button. Confirm the security query with YES. You can remove the CF card as soon as formatting has been completed.

Additional drying

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

Activating/deactivating additional drying for all program runs

1. Select Menu Settings → Additional drying. The display switches to the settings window.

2. Press pushbutton YES or NO to choose whether additional drying should be performed during all subsequent program runs.

3. Confirm with SAVE.

Activating/deactivating additional drying for the current program run

You can activate or deactivate additional drying exclusively for the current program during the program run and into the sterilization phase. The settings during the program run are not carried over for the subsequent program runs.
1. Select the desired program.
2. Press START.
3. Select Menu **Settings**. The display switches to the following window.

4. Place or remove the checkmark against option **Additional drying** and confirm with **SAVE**.

### Intelligent drying

In contrast to a conventional time-controlled drying procedure, with which the duration of the drying phase is determined by the program, the duration of the intelligent drying is automatically calculated using the residual moisture in the sterilization chamber. A number of factors play a role in this process including e.g. the nature of the load, wrapped or unwrapped, the load quantity, the distribution of the load in the sterilization chamber etc. Comply with the specifications in section **Loading the steam sterilizer** [page 25].

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

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

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

3. Confirm with **SAVE**.
Date and time
Correct batch documentation requires the correct date and time setting on the steam sterilizer. Ensure that you take into account the clock change in autumn and summer, as this is not adjusted automatically. Once the time has been set on the steam sterilizer, it is very accurate. Set the date and time as follows:

1. Select menu Settings → Date & time. The display switches to the settings window.

2. Select the parameters which you wish to change (day, month, year / hour, minute). The marked parameter is depicted light blue, here e.g. the day.

3. Change the respective value via the push-buttons. Repeat this step for all the parameters which you wish to change.

4. Confirm the changes with SAVE.
   ▶ The display will be restarted after saving and then changes automatically to menu Programs & Tests.

Brightness

1. Select Settings → Brightness. The display switches to the settings window.

2. Press the pushbuttons ◀ or ▶ to adjust the brightness and contrast on the display.

3. Accept all the settings with SAVE and then leave the menu.
Volume

1. Select Settings → Volume. The display switches to the settings window.

2. Press the [-] or [+] pushbutton to adjust the volume.

3. Accept all the settings with SAVE and then leave the menu.

View

You can choose between classic and modern view.

**Switching from MODERN to CLASSIC**

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

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

3. Press CONTINUE.
4. Tap on a colour box to change the background colour, e.g. blue. The background colour changes immediately and the white frame around the colour box shows which colour has just been selected.

5. Confirm the settings with SAVE. The display changes automatically to the Settings menu.

**Switching from CLASSIC TO MODERN**

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

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

3. Confirm the settings with SAVE. The display changes automatically to the Settings.
MELAconnect

MELAconnect serves the monitoring of the decontamination process deployed in your MELAG steam sterilizer on your mobile end device (e.g. smartphone, tablet).

The following requirement must be fulfilled:

✓ MELAconnect is installed on your mobile end device.
✓ You are in Menu Settings → Connectivity.

1. Select MELAconnect.

2. Open MELAconnect on your mobile end device.

3. Follow the instructions in MELAconnect and read in the QR code to connect your device to MELAconnect. Alternatively, you can enter the IP address of your device in MELAconnect manually.

With manual entry of the IP address: Owners of multiple steam sterilizers of the identical device type can differentiate between their devices by viewing serial number on the display to check whether MELAconnect has been connected to the correct device.

Key tone

1. Select Settings → Key tone. The display switches to the settings window.

2. Press YES or NO to determine whether a tone should be emitted every time a pushbutton is pressed. This can be deactivated at any time.
3. Accept all the settings with SAVE and then leave the menu.

**Screensaver**

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

**Select images for the slide show**

1. Select `Settings → Screensaver`. The display switches to the settings window.

2. Tap on a picture to select it. The white frame around the picture indicates which picture is currently selected.

3. Repeated tapping on the picture selects/deselects it for the slide show.

   - The checkmark on the lower right-hand corner indicates whether the picture has been selected for the slide show.

4. Press CONTINUE to make further settings.

**Set the display duration of the images and the waiting time of the slide show.**

Proceed as follows to alter one of the named options:

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

2. Change the respective parameter value via the pushbuttons.

3. Confirm the settings with SAVE. The display switches automatically to the `Settings` menu.

**Explanation of the slide show options**

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

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

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

### Sensitivity
1. Select **Settings → Touchscreen sensitivity**. The display switches to the settings window.

2. You can determine the pressure required to activate a pushbutton, using the [-] and [+] pushbuttons.

3. Accept all the settings with **SAVE** and then leave the menu.

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

- **Waiting time 1 (W1)**: After a pre-set waiting time of 3 minutes, the temperature of the double-jacket steam generator will sink to 103 °C. The program run time becomes c. 2 minutes longer upon the next start.
- **Waiting time 2 (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 about five 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 Menu **Settings → Energy saving mode**. The display switches to the settings window.

2. Select waiting time 1 directly by touching the minute display. The area is displayed light blue.

3. Change via the push-buttons and the minutes.

4. Repeat the step for waiting time 2.

5. Press CONTINUE.

**Switching off the display**

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

1. Set the checkmark next to "Activated" and set the number of seconds after which the display is to be deactivated.

2. Confirm the settings with SAVE. The display changes automatically to the **Settings** menu.

3. You can switch the display back on by touching the screen.
11 Maintenance

Servicing intervals

<table>
<thead>
<tr>
<th>Interval</th>
<th>Measure</th>
<th>Device components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly</td>
<td>Check for soiling, deposits or damage</td>
<td>Sterilization chamber inc. door seal and chamber sealing face, mount for the load</td>
</tr>
<tr>
<td>After 3 months</td>
<td>Greasing the locking spindle and door-lock nut</td>
<td>Door mechanism</td>
</tr>
<tr>
<td>After max. 6 months at the latest or following a display notification</td>
<td>Replace the filter</td>
<td>Floor housing fan</td>
</tr>
<tr>
<td>After 4000 cycles, but after 12 months at the latest</td>
<td>Maintenance</td>
<td>By the authorized customer services working in accordance with the maintenance instructions</td>
</tr>
<tr>
<td>As required</td>
<td>Cleaning the surfaces</td>
<td>Housing parts</td>
</tr>
</tbody>
</table>

Cleaning

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

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

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

Check the chamber, chamber sealing face, the door seal and the mount for the load **weekly** for soiling, deposits or damage.

If you find any impurities, remove the trays, cassettes and mount from the chamber from the front. Clean the soiled components and the chamber.

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

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

**Housing parts**

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

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

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

Incorrect instrument decontamination 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 steam sterilizer. Remove extraneous rust from the instruments using a chlorine-free stainless steel cleaning agent (see section Cleaning [page 69]) or send the damaged instruments to the manufacturer for treatment.

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

Grease the door spindle

Grease the door spindle Every 3 months as follows:

1. Clean the locking spindle and door-lock nut with a non-fuzzing cloth.

2. Grease the door lock nut in the steam sterilizer door and the locking spindle with the grease (use around a fingernail’s width - approx. 0.5 ml) included in the scope of delivery. The grease will be distributed by the closing of the door.

Changing the filter on the housing fan

Replace the filter on the housing fan on the underside of the device, if a malfunction message is issued, which is due to the filter (see Malfunctions [page 75]), or after 6 months at the latest.

Maintenance

Maintenance

NOTICE

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

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

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

Maintenance work is to be performed regularly in accordance with the 4000 program cycles but must be performed after 12 months. The steam sterilizer will issue a maintenance message at the relevant time.
Maintenance of the reverse osmosis unit

The conductivity of the feed water is measured automatically before every program run. Poor water quality will trigger the following notification in the display of the steam sterilizer: **Poor feed water quality.** A program start is still possible. Perform maintenance on your reverse osmosis unit.

If the water quality falls further, the display of the steam sterilizer will show the message **Feed water quality insufficient.** A program start is no longer possible.

Further information and detailed maintenance instructions are listed in the operating manual of the reverse osmosis unit.

When in standby mode, the conductivity can also be measured manually in Menu **Programs & Tests.**
12 Pause times

Frequency of sterilization

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

Operating pauses

<table>
<thead>
<tr>
<th>Duration of the operating pause</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short pauses between two sterilization processes</td>
<td>• Keep the door closed to save energy</td>
</tr>
<tr>
<td></td>
<td>• Set the energy-saving mode correspondingly</td>
</tr>
<tr>
<td>Pauses which last longer than an hour</td>
<td>• Switch off the steam sterilizer</td>
</tr>
<tr>
<td>Longer pauses e.g. over night or the weekend</td>
<td>• Switch off the steam sterilizer</td>
</tr>
<tr>
<td></td>
<td>• Push the door to, to prevent premature wear and the sticking of the door seal.</td>
</tr>
<tr>
<td></td>
<td>• Shut off the cold water inflow and if present, the water inflow of the water treatment unit.</td>
</tr>
<tr>
<td>Longer than two weeks</td>
<td>• Perform a vacuum test.</td>
</tr>
<tr>
<td></td>
<td>• After a successful vacuum test, perform an empty sterilization run in Quick-Program S</td>
</tr>
</tbody>
</table>

After pauses, perform the checks described in chapter Function tests [page 47] depending on the length of pause.

Decommissioning

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

1. Empty the double jacket steam generator, see Emptying the double jacket [page 72].
2. Switch off the steam sterilizer at the power switch.
3. Disconnect the power plug from the socket and if necessary, allow the steam sterilizer to cool.
4. Should the steam sterilizer need to be transported, wait until the container on the air gap has emptied automatically (c. ten minutes).
5. Close the water feed.
6. Shut off if present, the water inflow of the water treatment unit.

Emptying the double jacket

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

1. Switch on the steam sterilizer at the power switch.
2. Working in Menu Programs & Tests select program Drain and press START.

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

**Transport**

---

**CAUTION**

Danger of injury from incorrect carrying.

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

- The steam sterilizer should be transported by min. 6 people.
- Transport the steam sterilizer using the carrying handles or transport bars included in the scope of delivery.
- Wear protective gloves and safety shoes when moving the steam sterilizer.
- Comply with the safety regulations issued by your professional association.

---

**Preparing the steam sterilizer for transport**

1. Decommission the steam sterilizer, see Decommissioning [page 72]. **PLEASE NOTE:** It is not necessary to empty the steam generator when transporting the steam sterilizer within the practice (level ground).
2. Disconnect the outlet hose and inflow hose from the connections on the walls. Guide both hoses and the power cable into the floor unit.
3. Remove the plastic caps on the side walls.
4. Screw in the four carrying handles.
5. Should you wish to leave the mounts and trays or cassettes in the sterilization chamber during transport, protect the surface of the round blank. To do so, place e. g. some foam or bubble wrap between the round blank and mount.
6. Close the steam sterilizer door before moving it.
7. Release the holding brake on the casters.

**Transport within the practice**

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

- Prepare the steam sterilizer for transport (see Transport [page 73]).
- Use the casters to transport the device. It is not necessary to carry the device.
- Protect the practice floor from any damage from the weight of the device.
- Do not roll the steam sterilizer over any uneven surfaces or thresholds. Use the carrying handles to lift the device and comply with the specifications issued by your professional association regarding uneven floor surfaces or thresholds.
Transport over long-distance / dispatch

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

- For transport over longer distances, during the danger of frost and/or for dispatch, an authorized technician must prepare the steam sterilizer in accordance with the instructions and empty the steam sterilizer and the air gap container completely (see Decommissioning [page 72]).
- Use the casters to transport the device.
- Only carry the device in exceptional circumstances, e.g. between different floor levels without an elevator or for loading purposes within the scope of relocations. The steam sterilizer should be transported by min. 6 people. Comply with the specifications issued by your professional association.
- Only ever carry the steam sterilizer over short distances.
- Take appropriate measures to secure the steam sterilizer for dispatch. Consult your stockist or an authorized MELAG customer service provider.

Proceed as follows:

1. Prepare the steam sterilizer for transport (see Transport [page 73]).
2. Empty the sterilization chamber.
3. Remove the carrying handles from both sides of the device.
4. If required, fit the transport bars instead. The spacers must sit between the side wall of the device and the transport bar.

PLEASE NOTE

Ordering further transport bars

If the device and floor unit are delivered separately, the transport bars will be included in the scope of delivery. Should you not be in possession of the requisite transport bars, (e.g. loss or following delivery of your device within the scope of “complete dispatch”) you can order the transport bars (transport bar set for Cliniclave 45/45 M/45 D/45 MD, art. no.: 82820). Consult your stockist or an authorized MELAG customer service provider.

5. Fix the transport bars by screwing the four bolts tight using an open-end wrench (AF 19)

Recommissioning after relocation

When recommissioning after a move, proceed as with the first commissioning; see Technical Manual.
13 Malfunctions

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

<table>
<thead>
<tr>
<th>Nature of the display notification</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Messages</td>
<td>A number of notifications are messages providing information. Messages are not malfunction messages or warnings. They support the operation of the steam sterilizer.</td>
</tr>
<tr>
<td>Warnings</td>
<td>Warning messages are displayed when necessary. These contain instructions which apply to you, the operator. Warnings are not malfunction messages. They help to ensure malfunction-free operation and to recognize undesirable situations. Comply with these warnings early in order to avoid malfunctions.</td>
</tr>
<tr>
<td>Malfunction messages</td>
<td>Malfunction messages are issued when it is not possible to ensure safe operation or safety of sterilization. These can appear on the display shortly after activating the steam sterilizer or during a program run. If a malfunction occurs during a program run, the program will be aborted. Aborting a program before the drying phase means that the load is unsterile. If necessary, repack the load and repeat the sterilization for the sterilization material affected.</td>
</tr>
</tbody>
</table>

**WARNING**

Danger of infection from early program abort

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

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

**Before contacting customer services**

Ensure that you have complied with all instructions relating to a warning or malfunction message issued on the display of the steam sterilizer. The following table contains a summary of the most important events. Should you be unable to find the relevant event in the table below, or your efforts do not redress the problem, you can contact your nearest stockist or an authorized MELAG customer service provider. To enable us to give the best possible service, please have your steam sterilizer serial number and a detailed description of the malfunction to hand.

**Displaying events in MELAconnect**

You can arrange for the direct transfer the warning and malfunction messages to your mobile end device using the MELAconnect app. Proceed as follows:

1. Then press the key of the notification to display the QR code.
2. Open MELAconnect on your mobile end device and navigate to the troubleshooting menu.
3. Activate the QR code symbol on your mobile end device.
4. Scan the QR code from the display of your steam sterilizer.

The event and suggestions for the solution will be displayed on your mobile end device.

Alternatively, you can enter and search for the event number directly in MELAconnect.
# Messages

<table>
<thead>
<tr>
<th>Incident</th>
<th>Possible causes</th>
<th>What you can do</th>
</tr>
</thead>
<tbody>
<tr>
<td>248</td>
<td>The vacuum test was performed, despite residual moisture in the chamber or with a load.</td>
<td>Repeat vacuum test, when steam sterilizer is cold and empty</td>
</tr>
</tbody>
</table>

## Warning and error messages

<table>
<thead>
<tr>
<th>Event</th>
<th>Possible causes</th>
<th>What you can do</th>
</tr>
</thead>
</table>
| 61    | When using a MELAG water treatment unit:  
   a) Residual air is in the feed system of the water treatment unit or after initial commissioning or after replacing the mixed-bed resin cartridge.  
   b) The pressure tank of MELAdem 56/56 M has not been filled sufficiently and/or the tap on the pressure tank has not been opened completely. | a) Acknowledge the malfunction message and start the program repeatedly until the malfunction message is no longer displayed.  
   b) Please note that after initial commissioning of a MELAdem 56/56 M it takes approx. 1 hour until the pressure tank is sufficiently full with water. Check whether the tap on the pressure tank has been opened completely. |
|       | When using a central water treatment unit:  
   c) The central water supply has been interrupted or the flow pressure is insufficient. | c) Check whether inflow valves from the central system to the steam sterilizer are open. Arrange for an inspection of the flow pressure of the central water treatment unit via a flow pressure gauge (min. 0.5 bar at 5 l/min.). |
|       | When using an external water storage container:  
   d) Air is located in the intake line from the storage container to the steam sterilizer.  
   e) The suction filter of the external water storage container is blocked. | Check whether sufficient feed water is in the storage container; the end of the intake hose is submerged in water and that no air is being drawn in. Please note that the container may stand max. 1.5 m deeper than the steam sterilizer otherwise water cannot be drawn in.  
   e) Check whether the filter in the external water storage container is soiled or blocked and clean if necessary. |
| 63    | Very poor feed water quality (conductivity ≥ 35 µS).  
   a) The mixed-bed resin cartridge, pre-filter or the activated coal filter of MELAdem 56/56 M is exhausted.  
   b) Poor quality of the feed water in the external water storage container. | a) Replace the mixed-bed resin cartridge and if necessary, the pre-filter and the activated carbon filter of MELAdem 56/56 M in accordance with the applicable operating manual. Please note: The notification may also continue to be shown after the filter has been changed until the water remaining in the pressure tank has been consumed. Start the Draining program once or twice to rinse the poor feed water from the pressure tank. The rinsing of the pressure tank means that it can take 2.5 hours for the tank can to be filled and ready.  
   b) Drain and replace the feed water in the external water storage container. |
<p>| 64    | see event 63                                                                 |                                                                                                           |
| 65    | see event 63                                                                 |                                                                                                           |</p>
<table>
<thead>
<tr>
<th>Event</th>
<th>Possible causes</th>
<th>What you can do</th>
</tr>
</thead>
</table>
| 67    | The wastewater is unable to drain.  
  a) The outlet hose is kinked or sags.  
  b) The siphon or the building-side outlet line is blocked.  
  c) Quick-Program B and S are mainly used.  
  These programs do not do not have automatic rinsing. | a) Check the installation of the outlet hose.  
  This must be installed without kinking or sagging and at a constant decline.  
  If necessary, tighten the outlet hose to the underside of the steam sterilizer using tensioning carriage.  
  b) Check whether the building siphon is blocked. Please note: If multiple devices are operated simultaneously, we recommend the installation of an additional siphon.  
  c) Start another program e.g. the Universal-Program, Gentle-Program or Prion-Program to perform the necessary rinsing. |
| 72    | Poor feed water quality (conductivity ≥ 20 µS/cm).  
  The mixed-bed resin cartridge, pre-filter or the activated coal filter of MELAdem 56/56 M is exhausted. | Replace the mixed-bed resin cartridge and if necessary, the pre-filter and the activated carbon filter of MELAdem 56/56 M in accordance with the applicable operating manual. Please note: The notification may also continue to be shown after the filter has been changed until the water remaining in the pressure tank has been consumed. Start the Draining program once or twice to rinse the poor feed water from the pressure tank. The rinsing of the pressure tank means that it can take up to 2.5 hours for the tank can to be filled and ready. |
| 73    | see event 72 |
| 74    | see event 72 |
| 75    | see event 72 |
| 76    | see event 67 |
| 81    | a) The door was not pushed closed for long enough with sufficient force; as a result, the thread has become caught.  
  b) The door spindle and/or the door lock nut were not greased regularly and are dry. | a) Close and hold the door with force for approx. 3 seconds until the spindle engages in the door lock and the door is pulled in automatically. A motor sound is audible.  
  b) Grease the door spindle and the door lock nut regularly with the grease included in the scope of delivery (see Maintenance [page 69]) |
| 82    | a) There are objects in the door area. The door was blocked from outside during the opening process.  
  b) A residual vacuum is present in the sterilization chamber. Pressure equalization has not been concluded.  
  c) The door seal sticks to the seal face of the sterilization chamber. | a) Always keep the area in front of the door free so that it can open unhindered.  
  b) 1. Wait two minutes and then confirm the notification with OK.  
  2. Should the door not open independently, switch off the steam sterilizer, wait five minutes and then switch it back on. Try again to open the door.  
  If the door does not open, inform the authorized customer services/stockist technician.  
  c) If it has proven possible to open the door (e.g. using the manual door emergency-opening, see Manual door emergency-opening [page 22]) clean the door seal and the seal face on the sterilization chamber (see Cleaning [page 69]). |
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| 83    | The door does not reach a pressure-tight state after the program start.  
  a) The door seal and/or the seal face is soiled and or damaged.  
  b) The load blocks the closing sequence.  
  c) The closing mechanism is stiff. | a) Check the door seal and the seal face in the sterilization chamber for soiling, foreign bodies or damage.  
  b) Check whether the load is blocking the door.  
  c) Check the door spindle and the door lock nut for damage. Clean and grease the door spindle and the door lock nut with the grease included in the scope of delivery. |
| 84    | see event 82    | Check the installation of the outlet hose. This must be installed without kinking or sagging and at a constant decline. |
| 102   | The wastewater cannot flow off.  
  a) The outlet hose is kinked or sags.  
  b) The siphon or the building-side outlet line is blocked, or multiple devices have been connected to a single siphon.  
  c) The chamber filters are blocked. | b) Check whether the building siphon is blocked. Please note: If multiple devices are operated simultaneously, we recommend the installation of an additional siphon.  
  c) Check whether the chamber filters (on the fixing points under the slide rail at the front and back) are soiled/blocked e.g. with packaging residue. If necessary, clean the chamber filters. |
| 103   | The sterile filter is soiled/blocke | 1. Check whether the sterile filter suction aperture (centre aperture) behind the service hatch of the steam sterilizer is blocked. If yes, replace the sterile filter.  
  2. If nothing can be recognized, remove the sterile filter and perform a program run without a load. If the program has been ended successfully, the sterile filter is blocked. In this case, replace the sterile filter. |
| 104   | see event 103   | |
| 113   | a) The steam sterilizer was switched off at the power switch during a program run.  
  b) The power plug has been disconnected or has not been connected correctly in the socket.  
  c) Power outage in the building supply or the building-side RCD switch has tripped. | a) Never switch off the steam sterilizer at the power switch during a program run.  
  b) Check whether the power plug is connected, the power cable has suffered damage or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket.  
  c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
<p>| 114   | see event 102   |</p>
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| 124   | a) The steam sterilizer is overloaded.  
       b) The steam sterilizer was operated without a mount and the load (especially the textiles) come into direct contact with the chamber wall.  
       c) The chamber filters in the floor of the sterilization chamber are blocked.  
       d) The cooling water in the steam sterilizer is too warm. | a) Comply with the maximum permissible load quantities, see Loading the steam sterilizer [page 24]. Perform a vacuum test if necessary (see Vacuum test [page 47]).  
       b) Always operate the steam sterilizer with a mount and comply with the loading information (see Loading the steam sterilizer [page 24]).  
       c) Check whether the chamber filters (on the fixing points under the slide rail at the front and back) are soiled/blocked e. g. with packaging residue. Clean the chamber filter if necessary.  
       d) Check whether the cold water inflow hose warms up during operation. If it does, check whether the hose has been connected to the warm water connection by mistake. Please note: In summer, a heat accumulation in the supply line can lead the water to warm up. Restart the program so that new, cold water is flushed. |
| 125   | see event 124 | |
| 126   | see event 124 | |
| 127   | see event 124 | |
| 131   | see event 102 | |
| 132   | The steam sterilizer is overloaded or load objects are arranged unfavourable. | Comply with the maximum permissible load quantities (Loading the steam sterilizer [page 24]). The load may have no direct contact to the pressure inlets or may not cover them. |
| 133   | see event 124 | |
| 135   | a) The cooling water hose is kinked.  
       b) The inflow filter in the Aqua-Stop of the inflow hose is blocked by soiling on the building side.  
       If a leakage water detector (water stop) is installed:  
       c) The leakage water detector is without function.  
       d) The inflow filter in the leakage water detector is blocked by soiling in the building supply. | a) Check the installation of the inflow hose. It must be installed without kinking and may not be crushed.  
       b) Unscrew the inflow hose on the water inflow tap and check the inflow filter; clean it if necessary.  
       c) Unplug the leakage water detector control device from the socket, wait approx. 30 seconds and plug it back in again. A switching noise on the leakage water valve (black box on the water inflow tap) must be audible.  
       d) Clean the inflow filter in the leakage water detector valve as follows:  
       1. Close the water inflow tap and start a vacuum test.  
       2. Wait until the device displays a malfunction message and then switch it off.  
       3. Unscrew the leakage water detector valve on the water inflow tap and check the inflow filter; clean it if necessary. |
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| 136   | a) The surrounding temperature of the steam sterilizer is too hot.  
b) The steam sterilizer is installed. The minimum clearance to the surrounding surfaces has not been maintained.  
c) The door was left open after loading or unloading and hot steam has escaped from the sterilization chamber.  
d) The filter in the base plate fan is soiled. | Switch off the steam sterilizer and allow it to cool for approx. 1 hour.  
a) The ambient temperature must be below 40 °C. We recommend a maximum temperature of 26 °C.  
b) Maintain the minimum clearances to the surrounding surfaces (see information in the technical manual).  
c) Always close the door after loading or unloading.  
d) Check whether the fan filter in the steam sterilizer base plate is clogged and replace it if necessary. |
| 175   | The overheat control of the control heater on L1 (RHK1) has tripped. This notification may be issued in alternation with "E176: ACOUT 02 open". | 1. Switch off the steam sterilizer and push in fully the reset button RHK1 behind the service hatch of the steam sterilizer until a switching noise is audible.  
2. Acknowledge the malfunction message.  
3. Switch off the steam sterilizer and back on again and then perform an empty sterilization run if necessary. The steam sterilizer is now ready for operation. |
| 176   | The overheat control of the control heater on L1 (RHK1) has tripped. This notification may be issued in alternation with "E175: ACOUT 01 open". | 1. Switch off the steam sterilizer and push in fully the reset button RHK1 behind the service hatch of the steam sterilizer until a switching noise is audible.  
2. Acknowledge the malfunction message.  
3. Switch off the steam sterilizer and back on again and then perform an empty sterilization run if necessary. The steam sterilizer is now ready for operation. |
<p>| 182   | The mains voltage is too low, poor building voltage supply (e.g. undersized installation, defective socket, multiple devices on a single socket/fuse). | Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
| 183   | see event 124                                                                   |                                                                                 |
| 186   | see event 132                                                                   |                                                                                 |
| 187   | see event 102                                                                   |                                                                                 |
| 203   | No log output options have been set.                                             | Check the configuration in the menu &quot;Settings&quot; &gt; &quot;Logging&quot;.                     |
| 204   | The internal log memory is full.                                                 | Output the log saved in the steam sterilizer on any output medium or adapt the general output options in the &quot;Settings&quot; &gt; &quot;Logging&quot; menu. |
| 207   | see event 203                                                                   |                                                                                 |
| 208   | see event 204                                                                   |                                                                                 |
| 211   | see event 204                                                                   |                                                                                 |</p>
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| 214   | The steam sterilizer has not recognized the CF card; it cannot be read, it is full or it is damaged. | 1. Check whether the CF card has been inserted correctly (do not insert under voltage).  
2. Make sure that the CF card is not larger than 4 GB.  
3. Check whether the write-protection has been set on the CF card by mistake.  
4. Test the CF card on a computer.  
5. Check whether the memory on the CF is full. If the memory is full, transfer the log files on the CF card to a computer and delete the files on the CF card.  
6. Transfer the log files on the CF card to a computer and re-format the CF card in the steam sterilizer.  
7. The CF card is defective or incompatible. It is possible that a non-MELAG CF card has been used. Please note: We recommend using only original MELAG CF cards. |
| 215   | see event 214                                                                    |                                                                                                                                                 |
| 218   | The attempt was made to overwrite a write-protected log with a log of the same name. | 1. Transfer the log file the CF card to another computer and delete the file from the CF card.  
2. Insert the empty CF card in the card slot and enter the log again. |
| 221   | The CF card or a sub-directory of the CF card is full.                           | 1. Transfer the present log files from the CF card to a computer.  
2. Re-format the CF card in the steam sterilizer. |
| 223   | The CF card has not been recognized.                                             | 1. Transfer the present log files from the CF card to a computer.  
2. Format the CF card in the steam sterilizer.  
3. Try again.                                                                                           |
| 224   | see event 223                                                                    |                                                                                                                                                 |
| 228   | see event 223                                                                    |                                                                                                                                                 |
| 229   | The CF card was removed from the slot during a writing/reading action.           | Never remove the CF card from the slot whilst it is being written or read. Insert the CF card in the card slot and repeat the procedure.        |
| 231   | The CF card cannot be located/has not been inserted.                             | Check whether the CF card has been inserted correctly or insert it in the slot again. Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again. |
| 232   | see event 229                                                                    |                                                                                                                                                 |
| 236   | File malfunction on the CF card                                                  | 1. Transfer the present log files from the CF card to a computer.  
2. Format the CF card in the steam sterilizer.  
3. Try again.                                                                                           |
| 237   | The CF card has not been recognized.                                             | Check whether the CF card is write-protected and remove the write protection. Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again. |
## Event | Possible causes | What you can do
--- | --- | ---
238 | a) It is not possible to format the CF card because it is larger than 4 GB.  
b) The CF card is defective or incompatible.  
c) The CF card is write-protected. | a) Only use CF cards with max. memory size of 4 GB.  
b) Attempt to format the CF card on the computer.  
The CF card is defective or incompatible. It is possible that a non-MELAG CF card has been used.  
Please note: We recommend using only original MELAG CF cards.  
c) Disable the write-protection on the CF card.

240 | The CF card has not been recognized. | Make sure that the CF card has been inserted in the slot correctly.  
Upon repeated incidence, transfer the present log files from the CF card to a computer and format the CF card in the steam sterilizer and then try again.

249 | The door does not close. The door seal and/or the seal face is soiled. | Check and clean the door seal and seal face on the sterilization chamber for soiling, foreign bodies or damage (see Cleaning page 69).

305 | The connection cable behind the display is loose or has a loose contact. | Remove the display from the bracket and check whether the connection cable has been connected to the display correctly and has not suffered damage.

351 | The maximum operating interval or the number of batches since initial commissioning or the last maintenance have been reached. Maintenance is necessary. | Arrange for maintenance with an authorized customer services/stockist technician. You can continue to operate the steam sterilizer until the maintenance.

353 | The steam sterilizer was switched off too early after alteration of the settings. | Always wait until the alterations in the steam sterilizer have been fully accepted before switching off the steam sterilizer. This is indicated in the display by changing into the previous menu or through the start screen.

367 | The internal malfunction log memory is full. | Ensure that the selected output media are suitable for your instruments and are ready. Working in the ”Log output” menu, output the non-outputted logs.

377 | An attempt was made to output logs via the log printer but a log printer is not connected | Check whether the log printer has been connected correctly. If you do not wish to output any logs in the log printer, deactivate the log printer as an output medium (see Logging page 50).

386 | The internal program log memory is almost full. | Ensure that the selected output media are suitable for your instruments and are ready. Working in the ”Log output” menu, output the non-outputted logs at the next opportunity.

397 | a) The network cable has been disconnected or is damaged.  
b) The network cable is not compatible.  
c) The computer is not switched on.  
d) The network connection was not configured correctly.  
e) The documentation software on the computer was not started. | a) Check whether the network cable has been connected correctly or is damaged.  
b) Check whether a 1:1 network cable has been connected. A 1:1 cable must be used for the direct connection between steam sterilizer and computer.  
c) Switch on the computer.  
d) Check the network settings (see Logging page 50).  
e) Start the documentation software.
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| 402   | The door is blocked and cannot be closed.  
a) The door seal and/or the seal face is soiled and/or damaged.  
b) The load blocks the door area.  
c) The closing mechanism is stiff. | a) Check the door seal and the seal face in the sterilization chamber for soiling, foreign bodies or damage.  
b) Check whether the load is blocking the door.  
c) Check the door spindle and the door lock nut for damage. Clean and grease the door spindle and the door lock nut with the grease included in the scope of delivery. |
| 407   | see event 83   |                 |
| 408   | a) The tap has not been opened or has been opened only insufficiently.  
b) The building water pressure is too low or fluctuates.  
c) The inflow hose is kinked.  
d) The inflow filter in the Aqua-Stop of the inflow hose or the leakage water detector (if present) is blocked by soiling.  
If a leakage water detector (water stop) is installed:  
e) The leakage water detector is without function. | a) Open the water inflow tap completely and check whether the central water inflow tap is open.  
b) Check the pressure of the building water supply. The minimum flow pressure should amount to 1.5 bar at 8 l/min.  
c) Check the installation of the inflow hose. It must be installed without kinking and may not be crushed.  
d) Clean the inflow filter in the aqua stop of the inflow hose or the leakage water detector valve as follows:  
1. Turn off the water inflow tap.  
2. Switch off the steam sterilizer.  
3. Unscrew the cold water inflow hose or the leakage water detector valve on the water inflow tap and check the inflow filter; clean it if necessary.  
e) Unplug the leakage water detector control device from the socket, wait approx. 30 seconds and plug it back in again. A switching noise on the leakage water valve (black box on the water inflow tap) must be audible. |
| 414   | The wastewater cannot flow off.  
a) The outlet hose is kinked or sags.  
b) The siphon or the building-side outlet line is blocked, or multiple devices have been connected to a single siphon.  
c) The chamber filters are blocked.  
d) The steam sterilizer is overloaded.  
e) The steam sterilizer has been operated without an insert rack. | a) Check the installation of the outlet hose. This must be installed without kinking or sagging and at a constant decline.  
b) Check whether the building siphon is blocked. Please note: if multiple devices are operated simultaneously, we recommend the installation of an additional siphon.  
c) Check whether the chamber filters (on the fixing points under the slide rail at the front and back) are soiled/blocked e. g. with packaging residue. Clean the chamber filters if necessary.  
d) Comply with the maximum permissible load quantities (see [Loading the steam sterilizer](page 25)). Perform a vacuum test if necessary (see [Vacuum test](page 47)).  
e) Only ever operate the steam sterilizer with an insert rack inserted. |
| 416   | see event 214   |                 |
| 417   | see event 397   |                 |
| 428   | see event 102   |                 |
| 434   | Overheat on temperature sensor 2. | 1. Switch off the steam sterilizer and allow it to cool for 15 minutes.  
2. Start it again. The steam sterilizer is now ready for operation. Should this repeat, please contact the service technician. |
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<td>438</td>
<td>The steam sterilizer must be validated.</td>
<td>Arrange for validation of the steam sterilizer.</td>
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<tr>
<td>439</td>
<td>see event 102</td>
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<tr>
<td>457</td>
<td>The date or time was set incorrectly.</td>
<td>Check the date and time settings and correct if necessary (see Date and time [page 62]).</td>
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<tr>
<td>458</td>
<td>a) The date or time was set incorrectly. b) The start time pre-selection timer has run down but the steam sterilizer was switched off at the time for which the start time was selected.</td>
<td>a) Check the date and time settings and correct if necessary (see Date and time [page 62]). b) Please note: The steam sterilizer must be switched on at time for which the start time is selected.</td>
</tr>
<tr>
<td>465</td>
<td>a) The connection to the label printer has been interrupted. b) The label printer has not been switched on.</td>
<td>a) Check whether the power cable is connected to the socket and the Ethernet cable of the label printer is correctly connected with the steam sterilizer. b) Switch on the label printer The Power LED must illuminate green.</td>
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<td>488</td>
<td>see event 457</td>
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<td>489</td>
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<td>496</td>
<td>see event 408</td>
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<tr>
<td>499</td>
<td>a) The shut-off valve of the MELAdem 56/56 M pressure tank is closed. b) Insufficient pressure in the pressure tank of the MELAdem 56/56 M (&lt; 1 bar). c) Leak or kinked hoses in the feed water supply. d) The supply from an external feed water supply has been interrupted/the flow pressure is too low (e.g. central water treatment). e) Insufficient flow pressure on the cold water inflow of the MELAdem 56/56 M. f) The water supply on the steam sterilizer is set to a pressureless water treatment unit, but a pressurized unit e.g. MELAdem 56/56 M, has been connected.</td>
<td>a) Connect the shut-off valve of the MELAdem 56/56 M pressure tank. b) Check the pressure on the manometer of the MELAdem 56/56 M. If the pressure is under 1 bar, leave the steam sterilizer activated until the pressure in the pressure tank has risen over 1 bar. The pressure pump of the MELAdem 56/56 M must function audibly. Do not switch off the steam sterilizer after sterilization; leave it switched on for c. 30 minutes. c) Check all the hoses of the feed water supply from the MELAdem 56/56 M to the steam sterilizer for leaks and kinks. d) 1. Check whether all the taps in the feed water inflow line of the house water supply are open. 2. Check the flow pressure (min. 1 bar). e) Check the flow pressure of the house water supply using a flow pressure gauge (min. 0.5 bar at 5 l/min). f) If a MELAdem 56/56 M or another pressurized device is connected, check whether in the menu &quot;Settings&quot; &gt; &quot;Device settings&quot; &gt; &quot;Water supply&quot; the option YES is selected.</td>
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<td>500</td>
<td>see event 499</td>
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| 543   | a) The outlet hose is kinked, blocked or has insufficient tension.  
       b) The outlet line is blocked.  
       c) Multiple devices have been connected to a single siphon. | a) Check the installation of the outlet hose. It must be installed without kinking and may not be crushed. Depending on the device type and its position, the outlet hose must be stretched taught below the floor trough using a tensioning carriage.  
       b) Check whether the building siphon is blocked.  
       c) If multiple devices are operated simultaneously, we recommend the installation of an additional siphon. |
| 545   | a) The building fuse via residual current device has tripped.  
       b) The power plug has been disconnected or has not been connected correctly in the socket.  
       c) Malfunction in the electrical installation. | a) Switch the residual current device back on or replace it if necessary.  
       b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket.  
       c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
| 546   | a) The building fuse L1 has tripped.  
       b) The power plug has been disconnected or has not been connected correctly in the socket.  
       c) Malfunction in the electrical installation. | a) Switch the fuse L1 back on or replace it if necessary.  
       b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket.  
       c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
| 547   | a) The building fuse L2 has tripped.  
       b) The power plug has been disconnected or has not been connected correctly in the socket.  
       c) Malfunction in the electrical installation. | a) Switch the fuse L2 back on or replace it if necessary.  
       b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket.  
       c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
| 548   | a) The building fuse L3 has tripped.  
       b) The power plug has been disconnected or has not been connected correctly in the socket.  
       c) Malfunction in the electrical installation. | a) Switch the fuse L3 back on or replace it if necessary.  
       b) Check whether the power plug is connected, the power cable has suffered damage, or a loose contact or loose plug connections is the cause. Plug the power plug back into the mains socket.  
       c) Arrange for an inspection of the building-side installation (e.g. automatic circuit breaker) and test the steam sterilizer at another socket or on another circuit. |
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<td>553</td>
<td>The vacuum pump has suffered a blockage e.g. following long shutdown periods.</td>
<td>A vacuum pump can be unblocked in the following fashion: 1. Acknowledge the malfunction message. 2. Switch off the steam sterilizer, disconnect the power plug and open the service hatch. 3. Insert a 6 mm Allen key into the opening to its fullest extent to effect an emergency turning of the vacuum pump. Insert until the key takes a grip and then turn it in both directions to free the blockage of the vacuum pump. Repeat until the Allen key can be turned easily. 4. Then remove the key again. 5. Close the service hatch, connect the power plug and switch on the device. The steam sterilizer is now ready for operation. Should this repeat, please contact the service technician.</td>
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<td>576</td>
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<td>593</td>
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<tr>
<td>594</td>
<td>a) The chamber fittings (pressure plate) in the sterilization chamber are soiled or covered. b) The condensate guard is slipped.</td>
<td>a) Check the sterilization chamber interior for packaging or soiling. The load should have no contact with the sterilization chamber. b) Check the position of the condensate guard in the sterilization chamber and correct the alignment. The condensate guard must sit directly below the temperature sensors.</td>
</tr>
<tr>
<td>595</td>
<td>see event 594</td>
<td></td>
</tr>
<tr>
<td>596</td>
<td>see event 594</td>
<td></td>
</tr>
<tr>
<td>597</td>
<td>see event 594</td>
<td></td>
</tr>
<tr>
<td>598</td>
<td>see event 594</td>
<td></td>
</tr>
<tr>
<td>599</td>
<td>see event 594</td>
<td></td>
</tr>
<tr>
<td>629</td>
<td>An unpermitted feed water flow was detected.</td>
<td>Switch off the device and switch on again.</td>
</tr>
<tr>
<td>635</td>
<td>The label printer was selected as an output medium, but a label printer could not be located.</td>
<td>Check the configuration in the menu &quot;settings&quot; &gt; &quot;Label printer&quot;.</td>
</tr>
<tr>
<td>637</td>
<td>Label printer label roll exhausted.</td>
<td>Insert a new label roll in the label printer.</td>
</tr>
<tr>
<td>645</td>
<td>The label printer was selected as an output medium, but a label printer could not be located.</td>
<td>Check the configuration of the log printer in the menu &quot;Settings&quot; &gt; &quot;Log printer&quot; menu.</td>
</tr>
<tr>
<td>646</td>
<td>a) The user name or password for log-in to the FTP server is incorrect. b) The user name or password for log-in to the FTP server has not been setup correctly.</td>
<td>a) Check whether the user name and password set on the steam sterilizer corresponds with those set on the FTP server (see Settings [page 50]). b) Check the FTP server settings and the connection to the steam sterilizer.</td>
</tr>
<tr>
<td>692</td>
<td>see event 132</td>
<td></td>
</tr>
<tr>
<td>Event</td>
<td>Possible causes</td>
<td>What you can do</td>
</tr>
<tr>
<td>-------</td>
<td>----------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>693</td>
<td>see event 132</td>
<td></td>
</tr>
<tr>
<td>694</td>
<td>see event 132</td>
<td></td>
</tr>
<tr>
<td>900</td>
<td>System state is incorrect</td>
<td>Switch the device off and then on again.</td>
</tr>
</tbody>
</table>
### 14 Technical data

<table>
<thead>
<tr>
<th><strong>Device type</strong></th>
<th><strong>Cliniclavé 45</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device dimensions (H x W x D)</td>
<td>158 x 65 x 91 cm</td>
</tr>
<tr>
<td>Empty weight</td>
<td>244 kg</td>
</tr>
<tr>
<td>Operating weight&lt;sup&gt;1&lt;/sup&gt;</td>
<td>254 kg</td>
</tr>
<tr>
<td>Max. Floor loading (hydraulic pressure test)&lt;sup&gt;2&lt;/sup&gt;</td>
<td>400 kg (100 kg per device roller)</td>
</tr>
</tbody>
</table>

### Sterilization chamber

| **Chamber diameter/depth** | Ø 44 cm | 72 cm |
| **Packing space** | 1 sterilization unit |
| **Chamber volume** | 105 litres |

### Electrical connection

| **Electricity supply** | Star connection: 3x380-415 V + N + PE, 16 A, 50/60 Hz |
| Delta connection: 3x220-240 V + PE, 32 A, 50/60 Hz |
| **Electrical power** | 10.5 kW |
| **Building fuses** | Star connection: 3x16 A, RCD 30 mA |
| Delta connection: 3x32 A, FI protection 30 mA |
| **Length of the power cable** | 1.8 m from floor unit |

### Surrounding conditions

| **Max. Noise emission** | 72 dB(A) |
| **Max. Waste heat (with maximum load)<sup>3</sup>** | 1.4 kW |
| **Ambient temperature** | 5-40 °C (ideal range 16-26 °C) |
| **Degree of protection (following IEC 60529)** | IP20 |
| **Relative humidity** | max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative humidity at 40 °C |
| **Max. height** | 2000 m |

### Cold water connection

| **Min. flow pressure** | 1.5 bar |
| **Max. water consumption** | 8 l/min |
| **Max. static water pressure** | 10 bar |
| **Water quality** | drinking water, water hardness 4-12 °dH (in accordance with DIN EN 285) |

### Feed water connection

| **Min. flow pressure** | 0.5 bar |
| **Max. water consumption** | 5 l/min |
| **Static water pressure** | 5 bar |
| **Water quality** | DIN EN 285, Appendix B, table B.1 |

### Wastewater connection

| **Max. through-flow volume** | short-term max. 9 l/min |
| **Effluent temperature** | short-term max. 90 °C |

---

<sup>1</sup>This applies for an operational and filled device; depending on the load, it can increase by up to 40 kg.

<sup>2</sup>This applies to a max. (solid) load and with an opened door.

<sup>3</sup>When using a MELAdem 56, an additional weight of 33 kg (8.25 kg per caster) must be taken into account.
<table>
<thead>
<tr>
<th>Device type</th>
<th>Cliniclave 45 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device dimensions (H x W x D)</td>
<td>158 x 65 x 153 cm</td>
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<tr>
<td>Empty weight</td>
<td>315 kg</td>
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<tr>
<td>Operating weight&lt;sup&gt;4&lt;sup&gt;</td>
<td>370 kg</td>
</tr>
<tr>
<td>Max. Floor loading (hydraulic</td>
<td>610 kg (152.5 kg per device roller)</td>
</tr>
<tr>
<td>pressure test)&lt;sup&gt;5&lt;sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Sterilization chamber</td>
<td></td>
</tr>
<tr>
<td>Chamber diameter/depth</td>
<td>Ø 44 cm</td>
</tr>
<tr>
<td>Packing space</td>
<td>2 sterilization units</td>
</tr>
<tr>
<td>Chamber volume</td>
<td>200 litres</td>
</tr>
<tr>
<td>Electrical connection</td>
<td></td>
</tr>
<tr>
<td>Electricity supply</td>
<td>Star connection: 3x380-415 V + N + PE, 32 A, 50/60 Hz</td>
</tr>
<tr>
<td></td>
<td>Delta connection: 3x220-240 V + PE, 63 A, 50/60 Hz</td>
</tr>
<tr>
<td>Electrical power</td>
<td>13.5 kW</td>
</tr>
<tr>
<td>Building fuses</td>
<td>Star connection: 3x32 A, RCD 30 mA</td>
</tr>
<tr>
<td></td>
<td>Delta connection: 3x63 A, FI-protection 30 mA</td>
</tr>
<tr>
<td>Length of the power cable</td>
<td>1.8 m from floor unit</td>
</tr>
<tr>
<td>Surrounding conditions</td>
<td></td>
</tr>
<tr>
<td>Max. Noise emission</td>
<td>72 dB(A)</td>
</tr>
<tr>
<td>Max. Waste heat (with maximum</td>
<td>2.0 kW</td>
</tr>
<tr>
<td>load)&lt;sup&gt;5&lt;sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Ambient temperature</td>
<td>5-40 °C (ideal range 16-26 °C)</td>
</tr>
<tr>
<td>Degree of protection (following</td>
<td>IP20</td>
</tr>
<tr>
<td>IEC 60529)</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative</td>
</tr>
<tr>
<td></td>
<td>humidity at 40 °C</td>
</tr>
<tr>
<td>Max. height</td>
<td>2000 m</td>
</tr>
<tr>
<td>Cold water connection</td>
<td></td>
</tr>
<tr>
<td>Min. flow pressure</td>
<td>1.5 bar</td>
</tr>
<tr>
<td>Max. water consumption</td>
<td>8 l/min</td>
</tr>
<tr>
<td>Max. static water pressure</td>
<td>10 bar</td>
</tr>
<tr>
<td>Water quality</td>
<td>drinking water, water hardness 4-12 °dH (in accordance with DIN EN 285)</td>
</tr>
<tr>
<td>Feed water connection</td>
<td></td>
</tr>
<tr>
<td>Min. flow pressure</td>
<td>0.5 bar</td>
</tr>
<tr>
<td>Max. water consumption</td>
<td>5 l/min</td>
</tr>
<tr>
<td>Static water pressure</td>
<td>5 bar</td>
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<tr>
<td>Water quality</td>
<td>DIN EN 285, Appendix B, table B.1</td>
</tr>
<tr>
<td>Wastewater connection</td>
<td></td>
</tr>
<tr>
<td>Max. through-flow volume</td>
<td>short-term max. 9 l/min</td>
</tr>
<tr>
<td>Effluent temperature</td>
<td>short-term max. 90 °C</td>
</tr>
</tbody>
</table>

<sup>4</sup> This applies for an operational device filled with water. Depending on the load, it can increase by up to 80 kg.

<sup>5</sup> When using a MELAdem 56 M, an additional weight of 42 kg (10.5 kg per caster) must be taken into account.

<sup>6</sup> This applies to a max. (solid) load and with an opened door.
You can obtain the specified articles and an overview of further accessories from your stockist.

<table>
<thead>
<tr>
<th>Category</th>
<th>Dimensions</th>
<th>Art. no.</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Cliniclave 45</td>
<td>Cliniclave 45 M</td>
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<tr>
<td><strong>Mounts</strong></td>
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<tr>
<td>Tray mount for 2 instrument</td>
<td>32.5 x 60 x 27.7 cm</td>
<td>04517</td>
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<tr>
<td>baskets (1/2 StU) or 4 trays</td>
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<tr>
<td>(1/4 StU)</td>
<td></td>
<td></td>
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<tr>
<td>Mount for 6 standard tray</td>
<td>20 x 28.7 x 30 cm</td>
<td>02518</td>
<td></td>
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<tr>
<td>cassettes</td>
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<td>Tray mount for 8 trays</td>
<td>20 x 28.7 x 30 cm</td>
<td>02519</td>
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</tr>
<tr>
<td>Mount for 5 dental containers</td>
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<td><strong>Standard tray cassettes</strong></td>
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<td>Standard tray cassette,</td>
<td>29 x 19 x 4 cm</td>
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<td>perforated (with filter cloth)</td>
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<td>Standard tray cassette,</td>
<td>29 x 19 x 4 cm</td>
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<tr>
<td>perforated (without filter cloth)</td>
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<tr>
<td><strong>Instrument basket and trays</strong></td>
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<td>Instrument tray small</td>
<td>18.8 x 29 x 2.3 cm</td>
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<td>Tray large (1/4 StU)</td>
<td>31 x 59 x 5 cm</td>
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<tr>
<td>Instrument basket (1/2 StU)</td>
<td>19 x 29 x 4 cm</td>
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<tr>
<td><strong>Loading system</strong></td>
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<tr>
<td>Slide rail &quot;Standard&quot;</td>
<td>34.5 x 64 x 8.5 cm</td>
<td>80560</td>
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<tr>
<td>Slide rail &quot;Standard&quot;</td>
<td>34.5 x 126 x 8.5 cm</td>
<td>--</td>
<td>80580</td>
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<tr>
<td>Loading trolley</td>
<td>43 x 87 x 105 cm</td>
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<tr>
<td>Slide rail &quot;Comfort&quot;</td>
<td>32 x 65 x 8.2 cm</td>
<td>80550</td>
<td>--</td>
</tr>
<tr>
<td>Slide rail &quot;Comfort&quot;</td>
<td>32 x 65 x 8.2 cm</td>
<td>--</td>
<td>80570</td>
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<tr>
<td>Batch slider</td>
<td>33.2 x 62.3 x 2.7 cm</td>
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<td>Loading hook</td>
<td>4 x 50 x 3 cm</td>
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<td><strong>Test body system</strong></td>
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<td>MELAcontrol consisting of a</td>
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<td>Helix test body and 250</td>
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<tr>
<td>indicator strips</td>
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<td>01075</td>
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<tr>
<td>Helix test body and 40</td>
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<tr>
<td>indicator strips</td>
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<td>Category</td>
<td>Dimensions</td>
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<tr>
<td><strong>Water treatment</strong></td>
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<tr>
<td>MELAdem 56 reverse osmosis unit</td>
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<td>11056</td>
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</tr>
<tr>
<td>MELAdem 56 M reverse osmosis unit</td>
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<td>11057</td>
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<td><strong>For documentation:</strong></td>
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<td>MELAflash CF card</td>
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<td>01043</td>
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<tr>
<td>MELAflash card reader</td>
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<td>01048</td>
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<tr>
<td>MELAtrace documentation software</td>
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<td>21138</td>
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<tr>
<td>MELAprint 60 label printer</td>
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<tr>
<td>Network cable (1:1), 2,5 m</td>
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<td>15817</td>
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<tr>
<td>Network cable (1:1), 5 m</td>
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<tr>
<td>MELAprint 44 log printer</td>
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<td>01144</td>
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</tr>
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<td>Ethernet adapter for MELAprint 42/44</td>
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<td>40295</td>
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</tr>
<tr>
<td><strong>Other</strong></td>
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<tr>
<td>Water stop (leakage water detector)</td>
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<td>01056</td>
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<tr>
<td>Package holder, short</td>
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<td>22410</td>
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<tr>
<td>Package holder, long</td>
<td>18.4 x 37 x 8.7 cm</td>
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<td></td>
</tr>
<tr>
<td>Installation set</td>
<td></td>
<td>09027</td>
<td></td>
</tr>
</tbody>
</table>
Glossary

AKI
Abbr.: working group instrument preparation ("Arbeitskreis Instrumentenaufbereitung")

Authorized technician
The term “authorized technician” refers to an employee of a customer service provider or stockist who has been trained and authorized by MELAG to perform maintenance and installation work on MELAG devices. Only they may carry out this work.

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

BGV A1
BGV is the abbreviation for Berufsgenossenschaftliche Vorschriften (regulations from a professional association). A1 stands for principles of prevention

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

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

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

Conductivity
Conductivity refers to the ability of a conductive chemical material or mixture to conduct or transfer other materials or particles.

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

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

Demineralized water
Water without the minerals usually found in normal spring or tap water; is produced through ion ex-

change of normal tap water. It is used here as feed water.

DGSV
Abbr.: Deutsche Gesellschaft für Sterilgutversorgung (German Society German Society for Sterile Supply). The DSGV training centres are specified in DIN 58946, part 6 as "Requirements of personnel".

DIN 58953
Standard – sterilization, sterile equipment supply

DIN EN 285
Standard – Sterilization – Steam sterilizers – 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 inspection of type B and type S small sterilizers.

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

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). It is used here as feed water.

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

Evacuation
Creation of a vacuum in a vessel

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

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

FTP
Abbr.: (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.

**Heat-up phase**

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

**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

**Process evaluation system**

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

**RKI**

Abbr.: "Robert-Koch-Institute". It is one of the most important bodies for the safeguarding of public health in Germany.

**Soft sterilization packaging**

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

**Sterile barrier system**

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

**Sterilization chamber**

The interior of a sterilizer accommodates the sterilization material

**Sterilization material**

Unsterile, sterilizable 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**

Abbr.: 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)
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10829 Berlin
Germany

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

Original instructions

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

Your stockist