User Manual

Steam sterilizer

MELA*tronic*® 23 EN

from software version 5.15

EN

Dear customer,

We thank you for your confidence demonstrated by the purchase of this MELAG product.

As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument 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 EN ISO 13485. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE 0197

Please read this user manual carefully before commissioning the device. The manual includes important safety instructions. Make sure that you always have access to digital or printed version of the user manual.
Should the user manual no longer be legible, is damaged or has been lost, download a new copy from MELAG download centre at www.melag.com.

User Manual MELA*tronic*® 23 EN

from software version 5.15

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Original instructions

Responsible for the contents: MELAG Medizintechnik GmbH & Co. KG
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To ensure the functional effectiveness of this unit and to preserve its value:

1. Prepare the instruments to be sterilized carefully
2. Take proper care of the steam sterilizer
3. Use only pure distilled or demineralized water

Foreword

Thank you for having chosen this MELAG steam sterilizer.

Device description

These instructions use the device description "steam sterilizer“ for the steam sterilizer MELAtronic 23 EN

User manual

The user manual includes important safety information required for operation of the steam sterilizer. Read all the instructions carefully and in the correct order.

Hazard avoidance

Please read the safety information carefully before using the steam sterilizer.

About this manual

Symbols	*Meaning*	*Explanation*
 **Warning**	Health hazard	Indicates a dangerous situation, the non-avoidance of which could result in injuries ranging in seriousness from light to life threatening.
Notice	Observe without fail	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the steam sterilizer.
	Important information	Draws your attention to important information.

Disposal

Electrical and electronic equipment

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.

Accessories and consumption media

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

Packaging

The packaging protects the device against transport damage. The packaging materials have been selected for their environmentally-friendly and recycling properties and can be recycled. Returning the packaging to the material flow reduces the amount of waste and saves raw materials. Dispose of all non-required packaging materials at the collection points of the dual system.

Safety instructions

- Qualified personnel: As with the preceding instrument reprocessing, the sterilization of instruments using this steam sterilizer may only be carried out by competent personnel.
- When opening the door, particularly after interrupting the drying process, residual steam can escape from the steam sterilizer chamber.
- Risk of burns - Use a tray lifter to remove the tray. Never touch the sterile material, the chamber, the door or the mount with bare hands. The components are hot.
- If you connect an external condensate container to the steam sterilizer, be sure to remove the condensing coil for pressure relief (Fig. 1 Pos. 18) from the water storage tank. Check the level of water in the condensate tank every day, and empty this tank to prevent water from overflowing and causing damage to the room. There is no automatic monitor for the level of condensate water.
- The spring safety valve must be able to move freely and not become stuck or blocked. Install the device in such a way that the proper functioning of the spring loaded safety valve is guaranteed.
- Do not sterilize any liquids with this steam sterilizer. It is not approved for the sterilization of liquids. In case of non-observance, the consequences could be burns, delayed boiling and damage to the steam sterilizer.
- This device is not suited for use in areas where there are risks of explosion.
- The appliance must only be serviced and repaired by MELAG or by its authorised technicians (stockist or customer services) using only original parts and following service instructions.
- Documentation media (computer, CF card reader, etc.) must be placed in such a way that they cannot come into contact with liquids.
- Before opening the housing always disconnect from the mains power supply!
- In order to ensure effective sterilization with the steam sterilizer observe the instructions in this User Manual, and in particular ensure that the loading of the steam sterilizer is appropriate for the program selected.
- This device is designed to be operated outside the patient environment. This means that there must be an interval of at least 1.5 metres between the device and the area where patients are being treated, or where they otherwise stand or sit.
- If error messages repeatedly occur during operation of the steam sterilizer, then do not use the steam sterilizer until it has been repaired by authorized service personnel.
- If the power cable is damaged, do not use the steam sterilizer. Call authorized technician and have them replace the damaged cable by an especially prepared cable.
- Store and transport the device in a frost-free environment.
- Avoid strong shocks/vibrations.
- 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.

Symbols on the steam sterilizer

Draws your attention to a hot surface. During operation the twist grip may become hot. Let the steam sterilizer cool down after program completion.

Manufacturer of the medical device

Date of manufacture of the medical device

Identifies a medical device

Article number of the medical device

Medical device serial number from the manufacturer

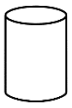
The user manual includes important safety information. Failure to comply with these instructions can result in injury and material damage.

Read this user manual carefully before commissioning the device.

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 the 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.

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.



Information about the chamber volume

Operating temperature of the device

Operating pressure of the device

Electrical connection of the device: AC current

1 Performance Specifications

Intended Use

Area of application

The steam sterilizer is designed for use in a general medical environment in which the instruments used and their packaging do not require a sterilizer with type B cycles.

Sterilization tasks

According to EN 13060, this steam sterilizer is considered as a sterilizer with type S cycles. As an universal steam sterilizer, it is suitable for the sterilization of unwrapped or single wrapped solid instruments and unwrapped simple hollow items.

Warning

Danger of burns from delayed boiling

Failure to observe this can result in a delay in boiling, which could result in burns and damage to the steam sterilizer.

Please observe the following provisions for the use of the steam sterilizer:

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

NOTICE

- 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 cleared for use by MELAG.
- As with the preceding instrument reprocessing, the sterilization of instruments using this steam sterilizer may only be carried out by competent personnel.
- When conducting sterilization procedures, only use instruments and packaging which the manufacturer has cleared for steam sterilization.

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

User Benefits

Universal use

The steam sterilizer sterilizes on the basis of the fractionated flow procedure. This procedure guarantees the complete and effective wetting/penetration of the sterilization material with saturated steam. This procedure can also be used to sterilize single wrapped instruments.

Short time frame

The steam sterilizer uses the integrated steam generation process to generate sterilizing steam.

Overheat control

The sterilization chamber is protected against overheating.

Automatic pre-heating

Activation of the pre-heating function pre-warms the cold chamber or holds it at a specific temperature between two sterilization runs. This reduces program times and reduces the accretion of condensation, thus improving drying results.

Internal feed-water provision in a circulation and one-way system.

The steam sterilizer uses both a feed-water circulation system and a feed-water one-way system, using the external condensate container.

When using the feed water circulation system, the steam sterilizer saves water, as the feed water is used for multiple sterilization cycles.

The one-way system uses fresh feed water for each sterilization procedure.

The quality of the feed water is subject to permanent monitoring via an integrated conductivity sensor. If combined with careful preparation of the instruments, this serves largely to avoid stain accretion on the instruments and soiling of the steam sterilizer.

Feed water supply	The feed water supply for steam generation is conducted automatically via an internal storage tank.
Optimal total operating time	The steam sterilizer uses electronic parameter control. This enables the steam sterilizer to optimize the total operating time of a program in dependence on the load.
High safety via comprehensive safety features	The steam sterilizer constantly checks pressure and temperature in the chamber. The door locking system prevents the door from being opened when excess pressure has been built up. The steam sterilizer electronics has an integrated process evaluation system. It compares the process parameters (such as temperature, time and pressure) during a program run. It monitors the parameters in terms of their threshold values during control and regulation and guarantees safe and successful sterilization. If one or more parameters depart from the threshold values determined, the steam sterilizer issues warning or error messages and if necessary, aborts the program. In the case of a program abort, follow the instructions on the display.
Additional function controls	The test program enables you to perform additional function controls at any time. You can monitor the quality of the feed water using the conductivity measurement.
Effective batch documentation	The steam sterilizer is equipped with a log memory which can save up to 40 program cycles. This saves all the data regarding the program run automatically. You can read out the internal log memory immediately after the program end or at a later point.

2 Device Description

2.1 Device views

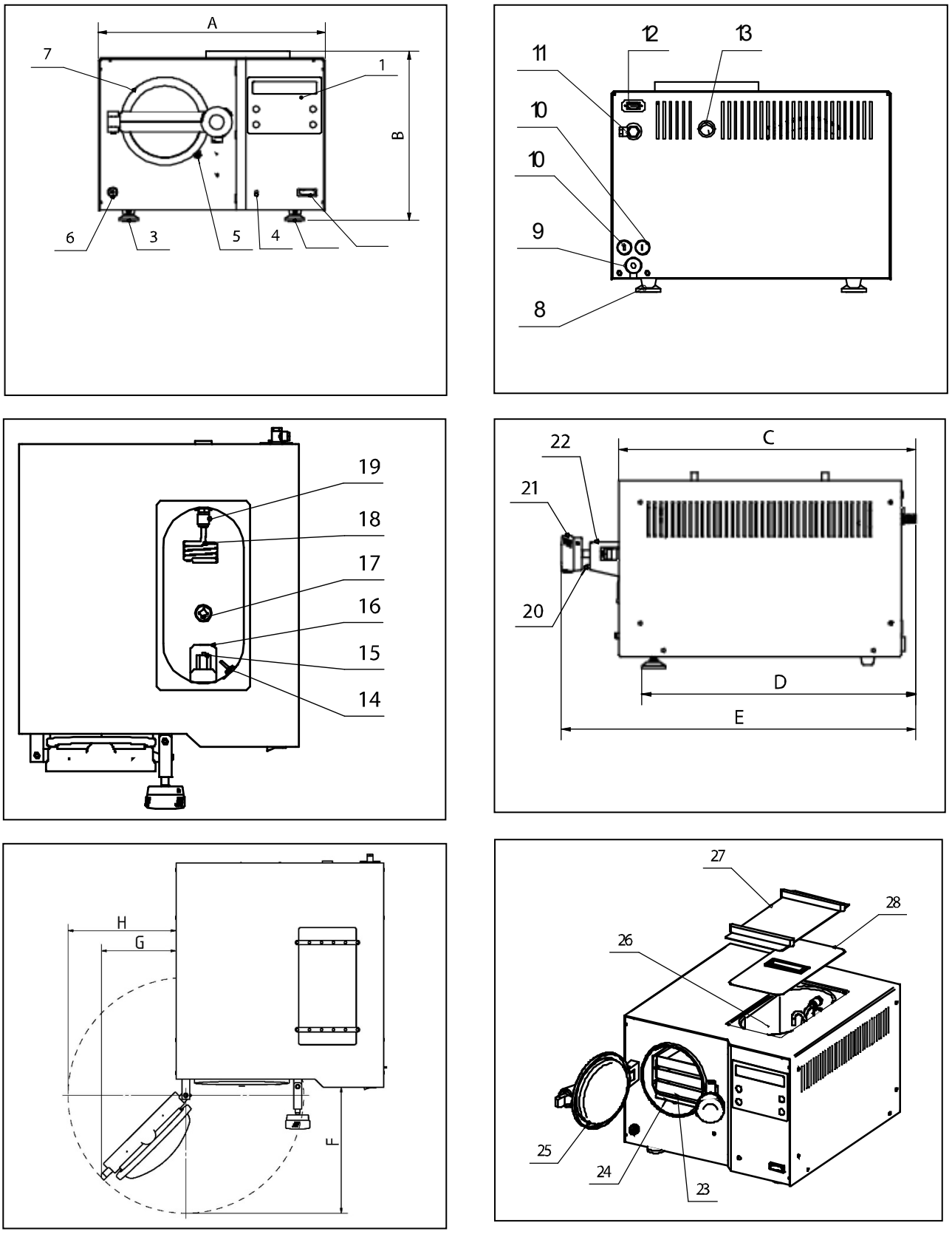


Fig. 1 Device views

Pos.		Pos.	
1	Operation panel	**15**	Safety valve
2	Power switch	**16**	„MAX“- mark
3	Adjustable front feet	**17**	Water supply filter
4	Reset bottom for the overheating protection of the steam generator	**18**	Condensate loop „Pressure release“
5	Door contact switch	**19**	Connector for condensate loop
6	Water drain tap	**20**	Door locking bolt
7	Door	**21**	Door grip
8	Back feet	**22**	Locking latch
9	Mains power cable	**23**	Tray
10	Fuses: 2x 16 A / FF	**24**	Mount
11	Connector for external condensate container	**25**	Door gasket
12	Serial data and printer port (RS232)	**26**	Water storage tank
13	Aeration of the water storage tank	**27**	Housing cover with slides
14	Conductivity sensor	**28**	Lid of water storage tank

Dimensions

Width A	Height B	Depth C	Depth D	Depth E	Depth F	Width G*)	Width H
52 cm	38 cm	59 cm	55 cm	71 cm	32 cm	19 cm	27 cm
*) Min. clearance to the side of the door hinge							

2.2 Control panel

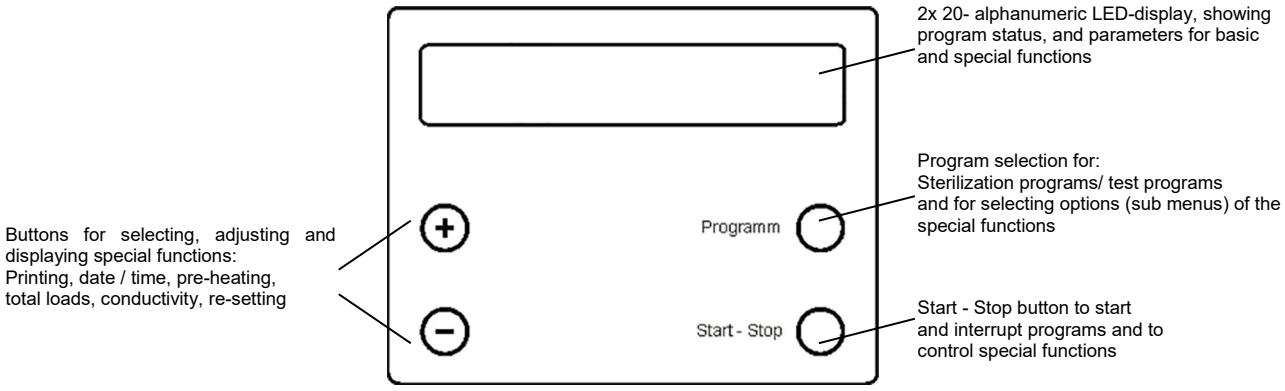


Fig. 2 Control panel

2.3 Performance features of this steam sterilizer

2.3.1 Conformity to European standard

The steam sterilizer fulfills the stipulations of the European standard for Small Steam Sterilizers EN 13060 for steam sterilizers with sterilization cycle of the type S.
Regarding the sterilization performance the steam sterilizer MELAtronic 23 EN is usable for the sterilization of unwrapped solid instruments, for the sterilization of single wrapped solid instruments and unwrapped simple hollow items.

> **NOTICE**
>
> Use the steam sterilizer only for the intended purposes outlined in the related technical documents and only in connection with the devices and components approved by MELAG.
>
> As with the preceding instrument reprocessing, the sterilization of instruments and textiles using this steam sterilizer may only be carried out by competent personnel.
>
> Only use instruments and wrappings which are suitable for steam sterilization according to the manufacturer's information.
>
> **Failure to observe these provisions could result in damage or can compromise safety.**

2.3.2 Fractionated flow method

With the fractionated flow method which is used steam flows into and then out of the steam sterilizer to ensure effective penetration of the items to be sterilized by saturated steam.

2.3.3 Operating range for sterilization

The steam sterilizer features three sterilization programs for temperatures at 134 °C: the “Universal-Program” (for wrapped objects), the “Prion-Program” (a special Universal-Program), the “Quick-Program S” for unwrapped items. The “Gentle-Program” is a sterilization program for unwrapped rubber articles at 121 °C.

2.3.4 Integrated steam generation

The powerful steam generation in the sterilization chamber makes it possible to sterilize large loads of instruments in a short time. This system of steam generation means that excess temperatures in the sterilized chamber are not possible.

2.3.5 One-way / Closed-loop system / Conductivity measurement

The steam sterilizer operates in the standard installation mode, as a circulatory flow system. This means that the water evaporated during each sterilization process is condensed and returned to the water storage tank. This takes place during sub-atmospheric pulsing, and during pressure release. This type of operation is effective for sterilization rates of approx. 2-3 sterilization cycles per work day, if sufficiently long pauses between sterilization are observed. In work with a circulatory water system, however, it is very important to ensure that the instruments to be sterilized have been especially carefully cleaned and rinsed before sterilization. In addition, the water should be checked for dirt and debris every day, and the water must be changed at least once a week.
If the sterilizer is used often, the water in the water storage tank becomes extremely hot, so that complete condensation in the tank is not possible, and steam will exit from the vent openings (Fig. 1, Pos. 13) on the back wall of the steam sterilizer. Under these conditions, an external condensate container (art. no. 00356) can be connected to the steam sterilizer, and the condensing coil (Fig. 1, Pos. 18) can be removed from the water storage tank. The steam sterilizer will now operate with a single-use (non-reusable) water system, and the evaporated water for each sterilization will be condensed in the external condensate container. This configuration has the advantage that the water in the storage tank will not become too hot, and the steam will not be ejected from the steam sterilizer. Another advantage of this installation alternative is that impurities dissolved in the steam will not get into the water of the storage tank – and this means that clean distilled or demineralized water will once again be used for sterilization in the following program cycle.
An integrated electrical conductivity sensor monitors the quality of the demineralized or distilled water used to generate the steam. Using the recommended one-way operation for the steam sterilizer, the increased consumption of demineralized or distilled water can be provided by using a water treatment unit (e.g. the MELAdem 40) with the MELAjet spray gun.
Provided that the instruments are prepared carefully for the sterilization, stains on the load and soiling of the steam sterilizer itself can be prevented.

2.3.6 Electronic Parameter Control EPS

The microprocessor used in the steam sterilizer makes it possible to monitor pressure, temperature and time continuously during a program by Electronic Parameter Control. The overall operating time can then be optimised according the load and the temperature of the steam sterilizer.
The process assessment and monitoring system in the program control compare current process parameters with standard process data and monitors the process relative to limit values for temperatures, times and pressures. This makes it possible to identify faults as they occur, and provides quality assurance for the sterilization process.

2.3.7 Pre-heating / Drying

By activating the "pre-heating" function, the cold steam sterilizer chamber can be warmed up before sterilization, or the temperature can be maintained between sterilization runs. This reduces the duration of cycles and considerably reduces the formation of condensation, thus improving drying results with slightly opened door.

2.3.8 Batch documentation

The memory of the electronic control system stores logs of the previous 40 programs.
For effective hard-copy documentation and for checking purposes e.g. a log printer MELAprint 42/44 can be connected to print out a log immediately after completion of a program, or to print out logs from the memory.
By connection of a computer, the program MELAview/MELAtrace can also transfer the logs to the computer, for permanent archiving of all results, and for printing out these results as needed.

PLEASE NOTE

For further information of the protocol printer (for example for the duration of for he log printouts) please refer to the respective user manual.

3 Installation and initial start-up

3.1 Setting up the steam sterilizer

The steam sterilizer should be set up in a dry place which is protected against dust.
The base should be stable, and able to support the weight of the steam sterilizer. At the same time, the work surface must provide convenient access to the steam sterilizer, and the display must be clearly visible.
The load capacity of the installation surface of the steam sterilizer must be at least 39 kg (for hydraulic pressure test: at least 51 kg). The optional condensate container for waste water loads the installation surface with a maximum of 14 kg.
The space required by the steam sterilizer can be seen from the external dimensions (as in Section 2.1). A minimum additional space of 5 cm should be allowed on either side and above the steam sterilizer in order to ensure that heat can escape. If the additional condensate container shall be connected to the steam sterilizer you need an adequate space below the steam sterilizer for the container.
Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.
For the supply with demineralized water from the integrated water storage tank (Fig. 1 Pos. 26) you need at least a space of 30 cm or more above the steam sterilizer.
The electrical power supply should be a separate 220-240 V AC circuit with a 16 A fuse and optionally protected with a 30 mA residual current device.

3.2 Carrying straps

Take the steam sterilizer out of the packaging by means of the carrying straps. The blue straps themselves are each removed by undoing two retaining screws, which must then be screwed firmly back in place without washers. Therefore you need a TORX-key.

3.3 Levelling

In order to ensure that the steam sterilizer will work reliable, the steam sterilizer should be installed in a horizontal position (this should be checked with a spirit level on the top of the device) as shown in the pictures below.

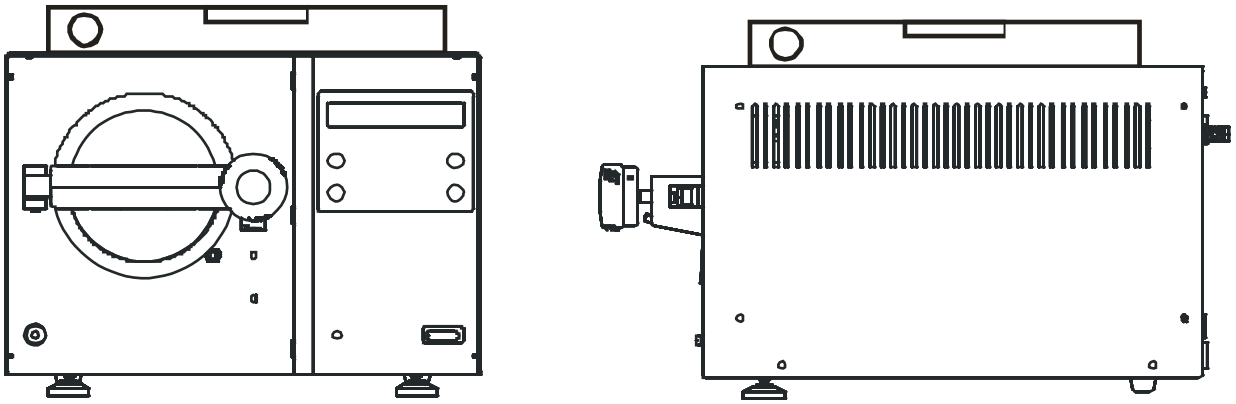


Fig. 3 Levelling the steam sterilizer with a spirit level

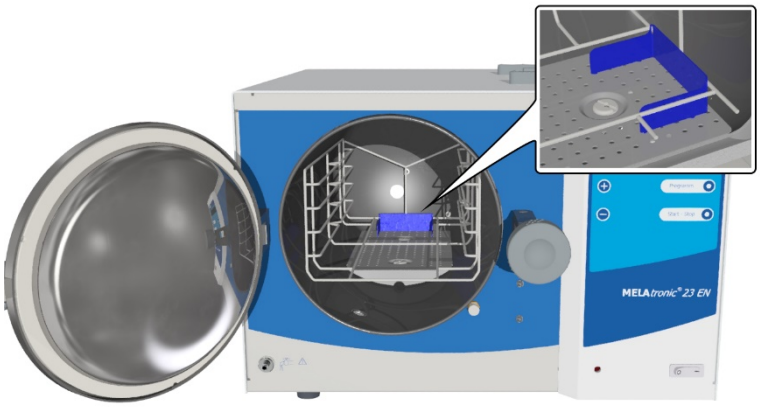
3.4 Mains power supply

The electric cable of the steam sterilizer is plugged into a mains socket rated at 220-240 V, 50/60 Hz. The power rating of the MELAtronic 23 EN is 1600 W. In order to avoid overloading the electricity supply, we recommend using a separate electrical circuit fitted with a 16 A fuse and optionally protected with a 30 mA residual current device.

3.5 Stopper for mount

PLEASE NOTE
Insert the stopper for the mount to prevent accidental sliding out when removing the trays.

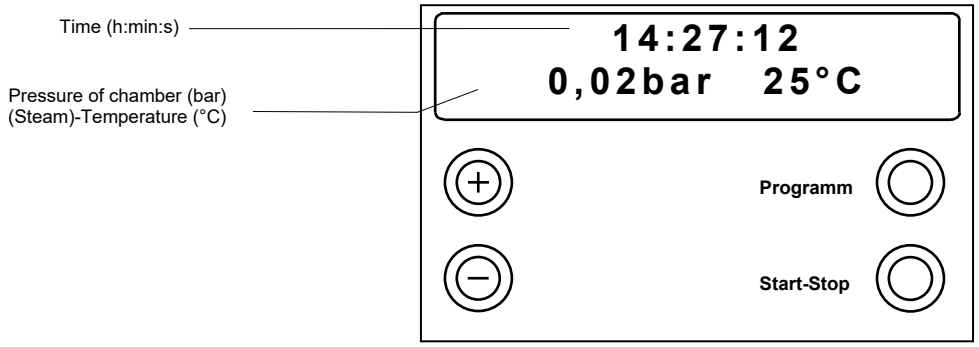
- Insert the tray mount into the sterilisation chamber.
- Insert the stopper for the holder according to the following illustration so that the hooks engage in the hole pattern of the lower cover plate:



3.6 Switch on the steam sterilizer

NOTICE
Unsupervised operation of electrical devices, including this steam sterilizer occurs at the operator's risk.

Switch on the power using the switch on the front of the steam sterilizer (Fig. 1 Pos. 2).
Symbols on the power switch:
I Switching the device on
O Switching the device off
The steam sterilizer is in the start status:



PLEASE NOTE
When switching off the device via the power switch, wait three seconds before switching it back on.

3.7 Filling the water storage tank

Remove the lid of the housing (Fig. 1 Pos. 27) and the lid of the water tank (Fig.1 Pos. 28) below. Fill the water tank with ca. 3 Litres of purified feed water. Do not fill more water into the tank than up to the "MAX" mark (Fig. 1 Pos. 16). The cooling coils in the water storage tank should always be covered with water. This will

allow the steam flowing out to condense. It will also eliminate excessive consumption of distilled or demineralised water. For this reason, be sure to top up with distilled or demineralised water as soon as necessary. Or, better: drain out the remaining water through the water drain tap (Fig. 1, Pos. 6) and refill with fresh distilled or demineralised water up to the MAX mark.

3.8 Connecting the external condensate container (option)

To operate the steam sterilizer in the one-way water system, and to avoid discharge of steam during frequent sterilization work, an external condensate container (art. no. 00356) can be connected to the steam sterilizer. This external condensate container is not part of the equipment provided originally with the steam sterilizer. Please proceed as follows to connect the condensate tank to the steam sterilizer:
Remove the blind cap from the connection point for the external condensate container (Fig. 1, Pos. 11), on the back wall of the steam sterilizer. Connect the drain pipe (supplied with the external condensate container) to the connection point, and tighten it securely with the coupling ring. Fill up the external condensate container up to the MIN mark with ordinary tap water, and place the tank under the steam sterilizer.
Insert the free end of the drain pipe, as far as it will go, onto the plug-on coupling in the top of the external condensate container. The drain pipe should not have any kinks or dips, and it should lead continuously downward (without any upward loops).
Finally, remove the condensing coil for the pressure release (Fig. 1, Pos. 18) in the water storage tank. Remove this coil by pressing toward the rear the locking ring of the plug-in connector for the condensate loop (Fig. 1, Pos. 19). After removing this coil, store it safely where you can find it easily.

4 Sterilization

4.1 Supply with feed water

The steam sterilizer automatically monitors the availability of cooling water and purified water, as well as the quality of the distilled / demineralized water before starting a program.
In order to allow an immediate program start and to avoid error messages or interruptions of programs check before the first sterilization at the start of the working day, that the internal water supply has sufficient water in the water storage tank. If necessary, refill with water of appropriate quality (see Section 7.4).
Before the first sterilization the quality of the feed water has to be checked by pressing the button „-“ after the steam sterilizer is switched on. Is the conductivity of the water higher than 65 µS/cm, the feed water has to be exchanged and fresh purified water has to be filled into the water storage tank.
If the water storage tank is dirty, the water has to be drained and the water storage tank must be cleaned before refilling the tank with fresh purified feed water (see Section 7.4).

4.2 Preparing instruments for sterilization

MELAG - rust-free materials
All parts of the steam sterilizer which come into contact with steam are made on non-rusting materials: the pressure chamber and the door of stainless steel, steam pipes of Teflon, and screws and magnet-valves of bronze.
Film rust
The use of these materials means that no parts of the steam sterilizer can initiate rust formation. Where rust does attack the steam sterilizer or instruments sterilized in it, tests repeatedly show that this has been brought into the steam sterilizer on instruments (film rust).
Even top-quality stainless steel instruments can form rust if they are not handled properly, e.g. if they are treated with the wrong chemical cleaning or disinfecting agents.
Preparing items for sterilization
The example of the formation of film rust shows how important it is to prepare items properly before sterilization. Instruments must be disinfected and cleaned immediately after use in accordance with UVV/VBG 103, or similarly strict national codes of practice in a disinfectant and / or cleaning solution at the correct concentration for the correct length of time.
MELAG recommends the use of cleaning aids such as ultrasonic baths, cleaning and maintenance equipment such as MELAclean as well as thermo-disinfecting devices.
It is essential that the instruments are well cleaned in order to avoid dirt and contamination being separated from the load in the steam sterilizer and clogging filters, valves, and nozzles. In particular locks, joints, and hinges must be cleaned thoroughly with a brush before sterilization. No traces of cleaning and disinfecting agents should be allowed to enter into the sterilization chamber of the steam sterilizer, since this can give rise to corrosion! The instruments should be rinsed off with demineralized water and then dried off before being loaded in the steam sterilizer. Instruments must be oiled in accordance with the manufacturer's instructions in order to ensure their long working life.
Brand-new instruments
The cleaning procedures described above must also be followed before sterilizing brand-new instruments. These often carry small amounts of grease, oil and soiling from the manufacturing process.
PLEASE NOTE: Carefully follow all instructions provided by manufacturers of instruments for the preparation of their products for first-time sterilization and for subsequent sterilizations.
Reprocessing unwrapped instruments
Unwrapped sterile material loses its sterility on contact with ambient air. If you intend to store your instruments sterilely, pack them in suitable packaging before sterilization.

4.3 Loading the steam sterilizer

It is of crucial importance for effective sterilization and good drying that the steam sterilizer is loaded properly: In the appendix you will get information how to load the steam sterilizer.
When loading the steam sterilizer, take account of the following points:
Tray rack
Normally, the steam sterilizer should be used in conjunction with a tray rack, since this ensures that steam penetration and drying are as good as possible. In exceptional situations (e.g. when using sterilization containers from other manufacturers), and after consultation with your stockist or with MELAG, the tray rack can be removed and the container can be placed directly in the steam sterilizer chamber.

Trays
Trays for objects which are to be sterilized must be perforated, in order to get safe sterilization results and to allow condensation to run away. MELAG trays are recommended. If you use dishes or trays without perforations, then the sterilization will not be safe and the steam sterilizer will not dry properly.
Closed sterilization containers
Closed sterilization containers must be perforated on two sides, in order to ensure that steam can penetrate and condensate can run out. All MELAG sterilization containers meet these requirements.
If sterilization containers are stacked in the steam sterilizer, it is important to ensure that the perforations are not blocked.
Transparent sterilization packaging
If you use transparent sterilization packaging, such as MELAfol, then the items should be stood vertically on the tray. For the steam sterilizer the package holder should be used. The packaging should never be laid flat one on top of the other.

> **NOTICE**
> If seals split open during sterilization it may be necessary to increase the length of the impulse on the sealing device or to use a double-seal.

Maximum loads
Do not exceed the maximum loads of the steam sterilizer.
Mixed loads
If different types of packaging are included in a load, then:
- Instruments and sterilization containers should be at the bottom
- Transparent and paper sterilization packaging should be at the top

Liquids
The steam sterilizer is not suitable for the sterilization of liquids!
Suitability for sterilization
Relevant information provided by manufacturers of instruments about sterilization should be strictly observed.

4.4 Capacity/Weight

Mount	Trays	Sterilization containers
mount “A” art. no. 40248 package holder art. no. 22420	max. 5 trays art. no. 00230	4x 17K 2x 23M 1x 23G

4.5 Closing the door

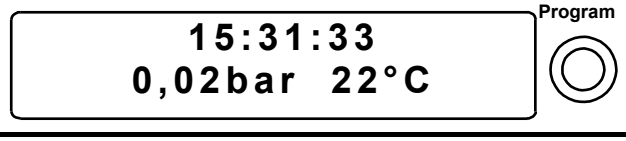
PLEASE NOTE
Please close the door only when the steam sterilizer is switched on so that the door locking bolt goes back. It is a precondition to close the door fully by turning the hand wheel.

The door is closed by putting the door latch over the door beam and turning the hand wheel until the door is closed.

4.6 Program selection

A program should be selected which is appropriate for the physical properties of the items being sterilized (and in particular their heat resistance) and the type of packaging (if any part of the load is wrapped, then either the "Universal-Program" or the "Gentle-Program" must be used).

By pressing the "Program" button it is possible to review the display of the following programs for selection:

Program name/Display message	Parameter/Application
	**Universal-Program** at 134 °C, 2 bar, and a sterilization time of 5.5 min for the sterilization of single wrapped itemsor unwrapped solid instruments and unwrapped simple hollow items. The maximum loads must not be exceeded.
	**Quick-Program S** at 134 °C, 2 bar and a sterilization time of 3.5 min for the sterilization **only of unwrapped and solid instruments** (no hollows) for rapid re-use. The maximum loads must not be exceeded.
	**Gentle-Program** at 121 °C, 1 bar, sterilization time 20.5 min for the sterilization of all types of single wrapped or unwrapped solid instruments items, unwrapped simple hollow items or thermolabile goods (plastic, rubber). The maximum loads must not be exceeded.
	**Prion-Program** (a special Universal-Program) at 134 °C, 2 bar, and with sterilization time extended to 20.5 min, for sterilization of all types of single wrapped or unwrapped solid instruments items, unwrapped simple hollow items. This program is recommended for sterilization of instruments used in situations in which the danger of infection by pathologically modified proteins is suspected: for example, Creutzfeld-Jacob and BSE). The maximum loads must not be exceeded.
	**Initial state** (no program selected)

4.7 Select automatic pre-heating

The steam sterilizer is a pre-heating function by means of which the steam sterilizer chamber can be heated to the necessary temperature before a program starts, or can be maintained at this temperature between cycles. This not only shortens the time for each cycle but also reduces condensation on the walls of the chamber which helps to provide very good drying performance.
If the automatic preheating is activated, then this begins as soon as the power is switched on.
In the default setting on delivery the automatic preheating is on.
The current setting for the automatic preheating can be changed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number"	Function: Last batch number
2.	Press "+" (or "-") until the display shows the submenu "autom. Preheating".	Function: autom. Preheating
3.	Press "Program", and the display shows the current option, here "Preheating YES"	autom. Preheating YES
4.	Pressing the "Program" button now alternates between the options "Preheating YES/NO", here e.g. "NO"	autom. Preheating NO
5.	When the desired option has been selected press "Start-Stop" and return to the "Function" menu, then...	Function: autom. Preheating
6.	...press "Start-Stop" again to return to the starting display	14:27:12 -0,02bar 25°C

4.8 Program start

Press the "Start-Stop" button once the desired program is shown on the display. The availability of feed water will be checked automatically, with a conductivity measurement.

Start

At the start of the Quick-Program S there will be an additional message "WARNING! Only unwrapped instruments". This message must be acknowledged by pressing "Start" again.

4.9 Program progress

After starting the program, it will then progress automatically. The display shows the current program status as follows:

Program status		Display message
1.	**1st fractionation and following** Depending on the program chosen and the temperature of the chamber at the start of the program, a number of cycles of steam inflow and outflow follow to ensure adequate penetration of super-heated steam into the items being sterilized.	1. Fractionation 0.69 115°C
2.	**Heating phase** A heating-up phase follows. The continuous introduction of steam raises pressure and temperature in chamber to the values needed for the program.	Heat up 1.80 bar 117°C
3.	**Sterilization phase** When the required pressure and temperature have been reached the sterilization proper then begins. The display shows alternately the pressure and temperature and the time remaining.	Sterilization 2.18 bar 135°C Sterilization still 2 min, 12s
4.	**Pressure release** After completion of the sterilization time, the pressure is released and the steam generator emptied. Pressure and temperature fall.	Pressure release 0.85 bar 96°C
6.	**Program end** After ventilation of the chamber the program is completed. The last batch number of the day is displayed. If a printer or another output medium is attached and the immediate output is set to "YES", the log will be printed-out immediately. By pressing the button "+", the door is unlocked ...	Universal-Program Run successfully Last batch number 3 Quit with "+"
7.	**Open door** … and can be opened after the display shows "Open door please".	Open door please

4.10 Program finished

The chamber pressure is adapted to the ambient pressure at the end of a program. If the program was successfully finished, an appropriate notification appears on the display.

Universal-Program
Run successfully

4.11 Manually terminate program

A program can be terminated at any time by pressing the "Start-Stop" button. If the program has not yet reached the drying phase then the items will be **non-sterile!**
CAUTION! Steam may escape when the steam sterilizer door is opened.
If the sterilization phase of the program had not been completed, then it is advisable to carry out an empty sterilization run before reusing the steam sterilizer.

	Operation	Display message
1.	Press the "Start-Stop" button To confirm, press the "Start-Stop" once again within 5 seconds. If no confirmation is given then the program resumes normally.	Stop program? Press ‚STOP‘
2.	If confirmation is given then the program stops. The pressure inside the steam sterilizer will then be equalised by pressure release.	Program stopped Pressure release 1.52 bar 112°C
	After pressure equalisation, the display will alternately show the messages "Terminated" and an offer to quit the program termination.	Stop / End 0.02 bar 88°C Acknowledge with button ‚-‘
3.	To acknowledge the program termination, press the " **-** " button. After a short time the display shows the selected program.	Gentle - Program 121°C wrapped

4.12 Removing the sterilized items

CAUTION!

Danger of burns from hot metal surfaces.

Never touch the sterile material, the chamber, the door or the mount with bare hands. The components are hot. Always use the appropriate aids to lift the trays (MELAG tray lever, standard tray-lifter) or wear suitable hand protection.

Note the following with regard to the door:

During and after a running program, the round blank in particular can become hot. Never touch the round blank directly. Hold the door by the door grip to open it.

Unwrapped sterilized items can be removed immediately after a successful sterilization cycle.
If the sterilized items are wrapped, please also follow the hints in the next section.

4.13 Drying / Sterile storage

It is important for sterile storage that the items have been properly dried.

PLEASE NOTE
The steam sterilizer provides very good drying if the steam sterilizer has been properly loaded (see section 4.3), if the program has not been interrupted before its completion, and the sterilized items have air-dried after a successful sterilization cycle about 30 minutes when door opened about 5 cm and the preheating is activated.

Directly after sterilization there may still be residual condensation on the items or the container. Because the items are hot on removal, this will usually evaporate quickly.

After removing wrapped sterile items, the wrapping should be checked for any signs of damage. If it is defective (e.g. split seals) then the sterilization of the items must be repeated after the items have been re-wrapped.
After cooling, wrapped sterilized objects should be stored in a place where they are **protected from dust** (e.g. instrument cupboard). Given proper storage, DIN 58953-8: 2010 gives the following guidelines for the maximum storage periods for sterilized objects: in basic wrapping (e.g. transparent sterilization package) up to 6 months.

4.14 Display last batch number

After every completed program you automatically see on the display the last batch number of the day.
You can also allow the display of the last batch number whenever necessary:

Operation		Display message
1.	Hold down "+" button and also press "-", select "Function" menu, submenu "Last batch number""	Function: Last batch number
2.	Press button "Program", to display the current batch number of the day.	Last batch number 3

Operation		Display message
3.	Close by pressing "Start-Stop" (back to the menu "Function"), then …	Function: Last batch number
4.	press "Start-Stop" again to return to the starting display.	14:27:12 -0.02bar 25°C

4.15 Total batch counter

The steam sterilizer has a counter of the total number of cycles that have been started, and this be displayed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-", select "Function" menu, submenu "Last batch number"	Function: Last batch number
2.	Press "+" (or "-") until the display shows the submenu "Batch counter".	Function: Batch counter
3.	Press "Program", the display shows the current total batch number count, e.g.:	Batch counter 367
4.	Close by pressing "Start-Stop", and return to the "Function" menu, then	Function: Batch counter
5.	Press "Start-Stop" again to return to the starting display	14:27:12 -0.02bar 25°C

5 Logging

In order to document the progress of the sterilization program, then the processor memory stores logs of the last 40 cycles. These logs can be downloaded at a later stage via the serial interface (RS232).
When the memory is full (40 program runs) then before the start of the next run the oldest log will automatically be overwritten. If a log printer or another output medium is connected (and operable) and the option "Immed. output? NO" has been selected, then confirmation will be requested before the oldest log is overwritten (see Section 9.1).

The following possibilities can be used for output of the logs:

- Computer, e.g. with MELAtrace/MELAview*
- Log printer MELAprint 42/44
- MELAflash CF-Card-Printer
- MELAnet Box

The installation and the operation of these devices is provided in Section 5.2 and the following.

*From device version 5.11 is the software version MELAview 3 required.

5.1 Set date and time

Correct batch documentation requires the correct date and time setting on the steam sterilizer. The date and time can be reset if necessary (e.g. winter time / summer time) as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number"	Function: Last batch number
2.	Press "+" (or "-"), until the display shows the submenu "Date/Time".	Function: Date / Time
3.	Press "Program", the display shows the current hour (24-hour clock) (here for example 17.00)	Date / Time Hour : 17

Operation		Display message
4.	By pressing the "+" (or "-") button the following options can be selected	Date / Time Minute : 23 Date / Time Second : 13 Date / Time Day : 14 Date / Time Month : 05 Date / Time Year : 19
5.	After finding the required option, e.g. "Minute", press the "Program" button and the current value flashes	Date / Time Minute : 23
6.	Press "+" or "-" to increase or reduce the value:	Date / Time Minute : 28
7.	Press "Program" to confirm the new value, which then stops flashing. If more adjustment are necessary, return to Point 4 and begin again,...	Date / Time Minute : 28
8.	...or press "Start-Stop" to return to the "Function" menu, and	Function: Date / Time
9.	Press "Start-Stop" again to return to the starting display	14:27:12 -0.02bar 25°C

5.2 Use log printer MELAprint 42/44 as output medium

5.2.1 Connecting the log printer

In order to connect a log printer to the steam sterilizer then a printer cable should be connected between the 9-pole socket on the front of the steam sterilizer (see Fig.1, Pos. 3) and the 25-pole on the back of the printer (ensuring a good connection and tightening the locking screws).
The power supply to the log printer is provided by the power unit supplied with the log printer, which connects to the socket on the rear of the log printer.

The log printer is ready for operation when the voltage lamp "P" shines and the status display (On line / Off line) "SEL". The operating manual of the log printer includes further details, including the assembly of an external paper feed, inserting paper, and the general operation of the log printer.

5.2.2 Initialising the log printer

After connecting the log printer to the steam sterilizer it must be registered with the steam sterilizer processing unit (initialised). Proceed as follows:

Operation		Display message
1.	Switch on steam sterilizer Display shows: 1. Line: Time 2. Line: Pressure of chamber Temperature inside chamber	14:27:12 0.02bar 25°C
2.	Hold down "+" button and also press "-" button. The "Function" menu with the submenu "Last batch number" is shown	Function: Last batch number
3.	Navigate with the button "+" up to the display where the submenu "Batch counter" is shown.	Function. Batch output
4.	Press "Program", the menu "Batch output", submenu "Output medium" is shown	Batch output Output medium
5.	Press "program" again, display shows submenu "No output medium"	Output medium No output medium
6.	Press "+" (or "-") button until display shows "MELAprint"	Output medium MELAprint
7.	Press "Program" button, Confirm the setting, return to menu "Batch output"	Batch output Output medium
8.	Press "Start-Stop" button, return to the "Function" menu	Function: Batch output

Operation		Display message
9.	Press "Start-Stop" button, Quit the "Function" menu and return to the starting display	14:27:30 0.02bar 25°C

5.2.3 Test output

In order to verify the functional reliability of the log printer and its communication with the steam sterilizer, a test output can be carried out:

Operation		Display message
1.	Hold down "+" button and also press "-", Select "Function" menu, submenu "Last batch number"	Function: Last batch number
2.	Press "Program" button, Select "Function" menu, submenu "Batch output"	Function: Batch output
3.	Press "Program" button, the display shows the menu "Batch output", submenu "Output medium"	Batch output Output medium
4.	Press "+" (or "-") until the display shows "Test output"	Test output
5.	Then press the "Program" button for a test output (or press "Start-Stop" to terminate)	Please wait Output
6.	Then press "Start-Stop" to return to the "Function" menu	Function: Batch output
7.	and press "Start-Stop" again to return to the starting display	14:27:12 -0.02bar 25°C

5.3 Computer as output medium

Logs and archives can also be kept by using a computer. This requires a suitable connection between the serial port of the computer and the printer port of the steam sterilizer.
For data transfer and data processing to a computer you can install the program MELAtrace/MELAview on your computer.

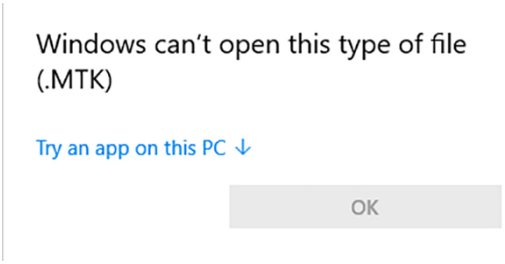
When the steam sterilizer has been connected to the computer you have to register it at the steam sterilizer. The initialising of the computer has to be done as described in Section 5.2.2 but under step 6 the selection "Computer" with the buttons "+" or "-" has to be made.

5.3.1 Reading out a text log on the computer

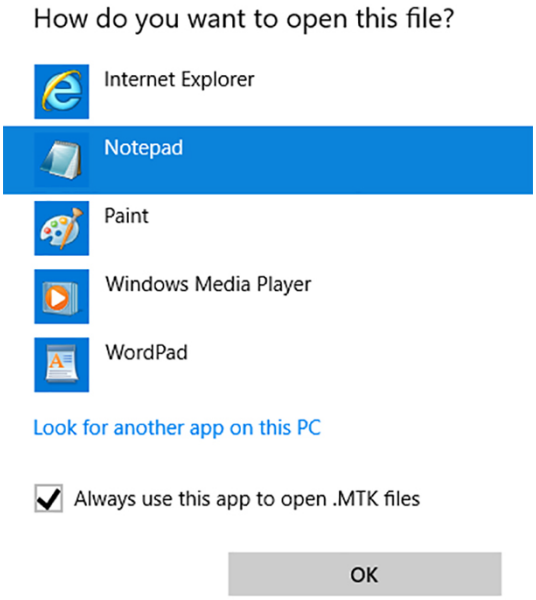
All text logs can be opened and printed using a text editor, a word processing program or a spreadsheet program. Graphic logs can only be displayed with the MELAtrace/MELAview documentation software.

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 Output selected logs subsequently. The following example shows how you can link the Windows 10 editor with a specific text log.

- In Windows Explorer double click on the log file.
- If the file ending is unfamiliar, Windows 10 will display the following message:



- Select “Try an app on this PC”.
- Mark the editor and confirm with “OK”.



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

5.4 Employing other devices as output medium

For installation and operation of other output devices (e.g. MELAflash CF-Card-Printer, MELAnet Box) you find detailed information in the operating manual for the devices themselves.
In order to initialise the devices proceed as described in Section 5.2.2, under step 6 select "MELAflash" or "MELAnet" in the "Function" menu as output medium.

5.5 No output medium

In order to select the option "No output medium" proceed as described as in Section 5.2.2. Under Point 6, however, use the "+" or "-" button to reach the setting "No output medium".

5.6 Output of the logs

5.6.1 Automatic immediate log output

When a log printer or another output medium is fully installed, a log output can be produced automatically at the end of each program run by selecting the following options after switching on the steam sterilizer:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number"	Function: Last batch number
	navigate with button "+" (or "-") until the display shows "Function: Batch output"	Function: Batch output
2.	Press "Program" button, Select "Batch output" menu, submenu "Output medium"	Batch output Output medium
3.	Press "+" button, select submenu "Immed. output" Display shows current option, here e.g. "NO"	Immed. Output NO
4.	The button "Program" can be used to switch between "YES" and "NO". Press "Program" button, set option to "YES"	Immed. Output YES
5.	Press "Start-Stop" button, Confirm the setting and return to "Function" menu, submenu "Batch output"	Function: Batch output
6.	Press "Start-Stop" button, Quit the "Function" menu and return to the starting display	14:27:30 0.02bar 25°C

5.6.2 Output selected logs subsequently

In order to output a log subsequently and independently from the time of the end of a program (an output medium is connected and initialised) proceed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number"	Function: Last batch number
	navigate with button "+" (or "-") until the display shows submenu "Batch output"	Function: Batch output
2.	Press "Program" button, select "Batch output" menu, submenu "Output medium"	Batch output Output medium
3.	Press "+" (or "-") until the submenu "Output last cycle" appears on the display Press "Program" button, the cycle log number flashes	Last cycle output: no. 40
4.	To select another number, press the "-" or "+" button until the right number is reached, e.g. here No. 25	Last cycle output: no. 25
5.	Press "Program" button to start the output of the selected log, (or to terminate press "Start-Stop" and return to the "Function" menu)	Please wait Output
6.	If you wish to output further logs then return to Point 4, or...	Last cycle output: no. 25
7.	... to terminate press "Start-Stop" and return to the "Function" menu	Function: Batch output
8.	Press the "Start-Stop" button to return to the initial display	14:27:30 0.02bar 25°C

5.6.3 Display protocol memory

When the output medium is connected and initialized, the protocol memory can be viewed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number "	Function: Last batch number
2.	navigate with button "+" (or "-") until the display shows menu "Function", submenu "Batch output"	Function: Batch output
3.	Press "+" (or "-") button until the display shows the memory status, e.g.:	Allocated: 40 Free: 0
4.	Press the "Start-Stop" to return to the "Function" menu	Function: Batch output
5.	and press "Start-Stop" again to return to the starting display	14:27:12 -0.02bar 25°C

5.6.4 Output all stored logs subsequently

In order to output all stored logs subsequently and independently from the time of the end of a program (an output medium is connected and initialised) proceed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" button. Select "Function" menu, submenu "Last batch number"	Function: Last batch number
	navigate with button "+" (or "-") until the display shows "Function: Batch output"	Function: Batch output
2.	Press "Program" button, Select "Batch output" menu, submenu "Output medium "	Batch output Output medium
3.	Press "+" (or "-") until the submenu "Output all cycles" appears on the display	Output stored cycles
4.	Press "Program" button to start the output of all the stored logs (up to 40!), or to terminate press "Start-Stop" and return to the "Function" menu (Once the output has started termination is only possibly by switching off the power!)	Please wait Output
5.	When the output is complete, the display again shows the submenu :	Outout all cycles
6.	Press the "Start-Stop" button to return to the "Function" menu...	Function: Batch output
7.	...and then press "Start-Stop" again to return to the initial display	14:27:12 0.02bar 25°C

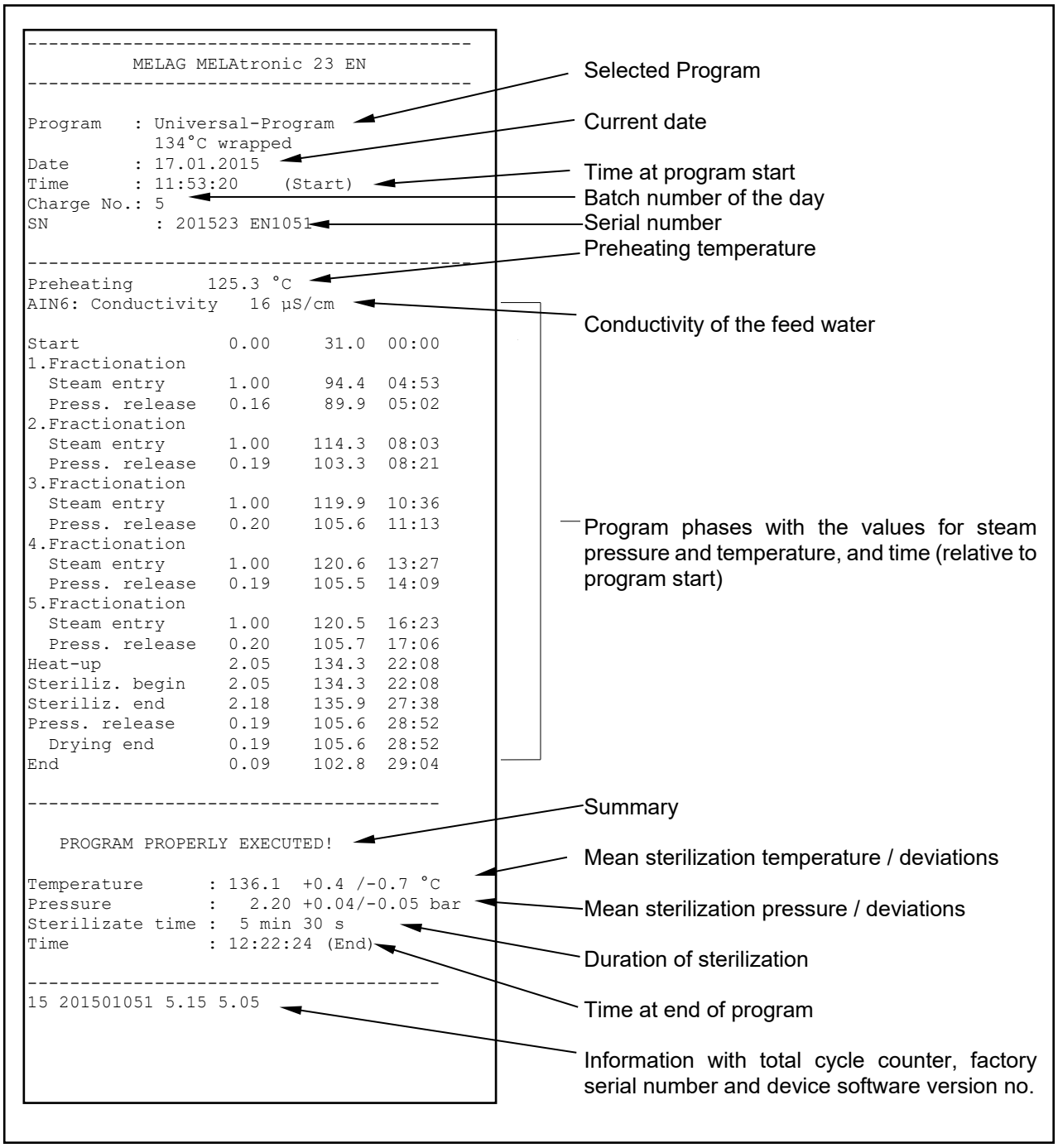
5.6.5 Delete all stored logs

In order to delete all cycle logs (e.g. in the event of the warning message "Protocol memory full", with the option "Immed. output NO", selected (see Section 9.1), then after switching on the steam sterilizer proceed as follows:

Operation		Display message
1.	Hold down "+" button and also press "-", Select "Function" menu, submenu "Last batch number"	Function: Last batch number
2.	Navigate with button "+" (or "-") until the display shows submenu "Batch output"	Function Batch output
3.	Press button "Program", display shows menu "Batch output", submenu "Output medium"	Batch output Output medium
4.	Press "+" (or "-") until the display shows "Delete all cycles".	All cycles delete
5.	Press the "Program" button to delete all logs (or press "Start-Stop" to terminate).	Allocated: 0 Free: 40
6.	Then press "Start-Stop" to return to "Function" menu...	Function: Batch output
7.	...and press "Start-Stop" again to return to the starting display	14:27:12 -0.02bar 25°C

5.7 Read log files correctly

The print-out record contains the following information:



6 Operating pauses

In general, the door should only be leant to during operational pauses in order to reduce wear on the door seal and to avoid premature failure or sticking.
In the event of longer breaks, such as during vacations, the water storage tank should be drained. If the condensate container is connected, the container should be emptied, too.

6.1 Sterilization frequency / pauses

After a sterilization cycle, the steam sterilizer can be reloaded and started immediately. However, continuous operation can lead to increased development of water vapour from the aeration rifle at the back of the steam sterilizer housing. This is not harmful for the steam sterilizer provided there is sufficient space around it for ventilation and it is not fully enclosed (e.g. in a cupboard).
In order to reduce formation of water vapour it is advisable to connect the external condensate container.
In case of using the closed-loop system, please observe the max. sterilization cycles per work day, see Section 2.3.5, page 12.

6.2 Decommissioning / Transport

When closing down and transporting the steam sterilizer you should proceed as follows:

- Switch off the power.
- Disconnect from the mains, allow the steam sterilizer to cool down.
- Empty the internal water storage tank.
- Disconnect and empty the condensate container, if connected.
- Fasten the transport ribbons to the steam sterilizer.
- If transporting the steam sterilizer with trays and tray rack assemblies in place, then protect the inside surface of the door by including a sheet of foam or similar material.
- **Notice:** To avoid damage use the original packaging when transporting the steam sterilizer.
- If the appliance may be exposed to frost in transit then follow the relevant service instructions!
- When setting the appliance up for reuse after transport or repairs then proceed in accordance with Section 3.

7 Maintenance

7.1 Cleaning

The **tray rack** and the steam sterilizer **chamber** including the contact area of the door gasket and the door opening should be inspected thoroughly at least once a week for signs of damage or soiling. If necessary, wipe out the steam sterilizer chamber using a **lint-free cloth** and surgical spirits. This involves withdrawing the trays and tray guide assembly. Stubborn spots can be removed using small amounts of a mild commercial steel cleaning agent (pH-levels from 5 to 8). Care must be taken to ensure that cleaning agent does not get into the pipes attached to the steam sterilizer chamber. The cleaning agent must not contain chlorine and should not be alkaline. Do not use abrasive cleaning pads, steel wool, or brushes.
Check the internal storage tank weekly for soiling. Drain off residual water via the drain tap before cleaning as follows:

- Connect the hose for draining the internal storage tank (included in the scope of delivery) to the drain tap of the internal storage tank.
- Position the free end of the hose in a sufficiently dimensioned, empty container.
- **Warning**: Risk of burns - After sterilisation, the water in the internal storage tank is hot. Open the drain tap.

If necessary, clean the tank before filling it with a bottle brush and warm water with a degreaser. Clean the **conductivity sensor** (Fig. 1 Pos. 14) inside the water storage tank with alcohol and rinse the tank with clear water before refilling the storage tank with fresh purified water.
Inspect the door gasket every week for signs of damage and soiling, and if necessary clean it with a mild commercial liquid cleaning agent (pH-levels from 5 to 8) or with surgical spirits. If necessary, the gasket can be removed.
The outer parts of the steam sterilizer can be cleaned with a mild commercial cleaning agent or with surgical spirits.
The **bolt of the door lock** (right side), the threads of the door latch and the door grip and the door hinge (left side) must be regularly lubricated with silicone grease (art. no. 24355), in order to ensure that the door can easily be locked and unlocked, without unnecessary wear.
The steam sterilizer operates with easily accessible filters. The condition of these filters is very important for the proper functioning of the steam sterilizer. Please service the filters as follows:
If you are operating the steam sterilizer with a water-circulation system, then clean the **water supply filter in the water storage tank** (Fig. 1 Pos. 17) once a week. If you are operating your steam sterilizer with a single-use (non-reusable) water system, the water supply filter must be cleaned once a month. To clean the filter, drain the water from the water storage tank and unscrew the coupling ring of the filter. Clean the filter insert, and replace it in the water tank. Secure with the coupling ring. If there are visible defects to the filter (such as tears or holes), then replace the filter.
If you are operating the steam sterilizer with a water-circulation system, then clean the **water supply/pressure-relief filter** in the sterilization chamber once every three (3) months. If you are operating your steam sterilizer with a single-use (non-reusable) water system, then clean the water supply/pressure-relief filter once every six (6) months. To clean these filters, use the filter spanner (wrench) to unscrew the slotted round nut on the cover plate of the heating unit. Take off this cover plate. Now use the right-angle side of the filter spanner to unscrew the water supply/pressure-relief filter. To clean the filter, remove the sieve insert from the filter housing, and clean the insert and the housing. Then re-assemble the filter in the reverse order. If the filter insert is damage, defective, or corroded, replace it.
Once a month, use the filter spanner (wrench) to remove **the flow filter in the sterilization chamber**. Clean the filter and re-install it.

7.2 Instrument reprocessing

MELAG - non-rusting materials
All parts of the steam sterilizer which come into contact with steam are made on non-rusting materials: the pressure chamber and the door of stainless steel, steam pipes of Teflon, and screws and magnet-valves of brass.
Film rust
The use of these materials means that no parts of the steam sterilizer can initiate rust formation. Where rust does attack the steam sterilizer or instruments sterilized in it, tests repeatedly show that this has been brought into the steam sterilizer on instruments (film rust).
Even top-quality stainless steel instruments can form rust if they are not handled properly, e.g. if they are treated with the wrong chemical cleaning or disinfecting agents.

Preparing sterilization material
The example of the formation of film rust shows how important it is to prepare sterilization material properly before sterilization.
Instruments must be disinfected and cleaned immediately after use in accordance with UVV/VBG 103 before sterilization and maintained (e.g. by oiling).
The disinfection must be made similarly strict national codes of practice in a disinfectant and/or cleaning solution at the correct concentration for the correct length of time.
MELAG recommends the use of cleaning aids such as ultrasonic baths, cleaning and maintenance equipment, as well as thermo-disinfecting devices.
It is essential that the instruments are well cleaned in order to avoid dirt and contamination being separated from the load in the steam sterilizer and clogging filters, valves, and nozzles. In particular locks, joints, and hinges must be cleaned thoroughly with a brush before sterilization. No traces of cleaning and disinfecting agents should be allowed to enter into the sterilization chamber of the steam sterilizer, since this can give rise to corrosion! The instruments should be swilled off with demineralized water and then dried off before being loaded in the steam sterilizer. All instruments must be treated in accordance with the manufacturer's instructions in order to ensure their long working life.
Brand-new instruments
The cleaning procedures described above must also be followed before sterilizing brand-new instruments. These often carry small amounts of grease, oil and soiling from the manufacturing process.
PLEASE NOTE: Carefully follow all instructions provided by manufacturers of instruments for the preparation of their products for first-time sterilization and for subsequent sterilizations.

7.3 Rust formation = Drag-in rust

As already explained, the non-rusting materials used in the steam sterilizer cannot cause rust formation in the steam sterilizer!
Where rust forms this is "drag-in rust". This originates from instruments or other metal items carrying traces of rust, even though they are made of stainless steel, or which are made of normal steel but which have a damaged galvanic coating. Often, a single rusty instrument is enough to pass rust on to other instruments or to lead to film rust forming in the steam sterilizer resulting to corrosion damage. Drag-in rust must be removed from the affected instruments or from the steam sterilizer and tray assembly using a mild commercial cleaning agent for stainless steel. (This should not contain of chlorine). Do not use steel wool, a wire brush or other abrasive cleaners! Spots can be removed with a damp, lint-free cloth or a cloth with surgical spirits or alcohol.

7.4 Use qualitatively high-grade feed water

Quality requirements
For steam sterilization it is necessary to use high quality distilled or demineralized water.
The water used should at least comply with the specifications in accordance with the standard EN 13060 listed in the table in Section 12 Appendix.

7.5 Avoid formation of spots on instruments

Formation of spots on instruments
The extent to which spots form on the instruments depends on the quality of the water used to produce the steam.

7.6 Maintenance recommendation

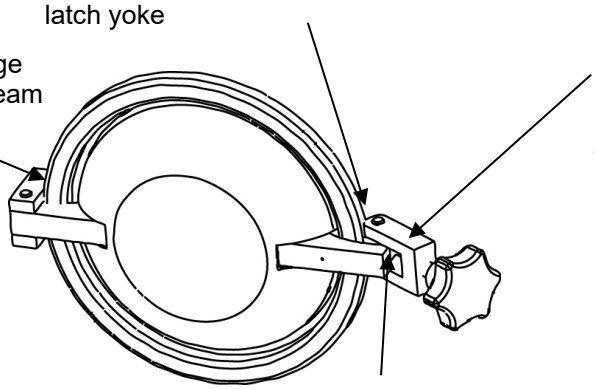
Regular maintenance of the steam sterilizer is important if it is to have a long life and remain in good working order.
MELAG recommends that the steam sterilizer is serviced biennially by a trained technician in accordance with maintenance instructions for this steam sterilizer. The biennial service includes a visual inspection and a test of operational functions. As well as all essential components and electrical elements, parts are also inspected for wear and replaced as necessary.
A maintenance reminder appears on the display every 2 years or after 1000 sterilizations.
Consult your stockist or the MELAG customer service if you have any questions relating to servicing and maintenance.

PLEASE NOTE
National pressure chamber requirements may ask the user of pressure chamber, such as steam sterilizers, to carry out safety inspections. Trained technician can check the download area from our website and find our recommendation in accordance with German requirements. For more information, ask your local authorities.

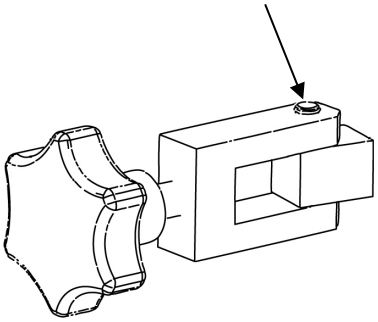
7.7 Caring for the door and door-lock components

In order to prevent premature wear, the threaded spindle of the palm grip hand knob, as well as the hinges of the latch yoke and the door locking beam, must always be kept well greased.
The following drawings indicate trouble that may occur and that may be the result of excessive wear on the door locking system. If any of these difficulties occur, inspection will be necessary by a MELAG Customer Service representative, or by an authorized technician from a stockist.

- Excessive play in the hinge of the latch yoke
- Excessive play in the hinge of the pressure locking beam (the door “hangs”)
- Excessive play in the threaded spindle of the palm grip hand knob (rattling of the spindle in the latch)
- Definite difficulty in turning the threaded spindle

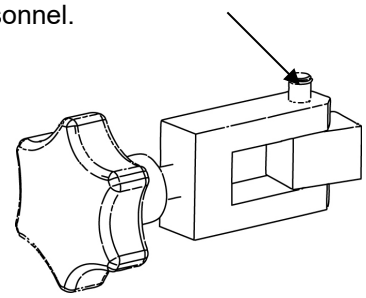


NOTICE:
The hinge bolts must by all means remain inserted completely in the latch and in the hinge yoke of the pressure locking bar (left side).
The bolt must be flush as shown.



- Hard-metal screw-thread insert has been screwed out of the latch.

If this bolt moves up or downward and is no longer flush with the yoke (as shown in proper position in left drawing), do not use the steam sterilizer. It must be repaired by technical customer service personnel.



8 Function test

8.1 Display water quality and temperature of chamber preheating

By repeatedly pressing the "-" button, the preheating temperature of the chamber and the conductivity of the purified feed water used for steam generation can be displayed alternately.

Operation		Display message
1.	Press down the "-" button to display the conductivity of the feed water µS/cm	AIN6: Conductivity 15 µS/cm
	Release the "-" button to return to the basic display (as shown here) or the program status	14:27:12 0.02bar 25°C
	Press the "-" button repeatedly and hold down: Display shows the pre-heating temperature of the chamber.	AIN4: Temp.Preheat. 120°C

8.2 Safety with automatic monitoring

The electronic parameter control means that all relevant parameters are constantly monitored and compared with standard process data, so that error reports can be made immediately. If a program is completed without problems then on its completion there is an "End" message. The print-out contains a corresponding report. The operator of the steam sterilizer can check the progress of the program at any time by means of the values shown on the display (or after its completion by means of the print-out).

9 Malfunctions

If the steam sterilizer does not seem to be working properly (e.g. poor drying, warnings, or error reports) then follow these instructions in order to exclude possible operational errors. Following these instructions continue to work with the steam sterilizer. If the malfunction occurs repeatedly then contact our dealer, and authorised MELAG customer service or contact MELAG directly. You should describe the problem precisely and include the works number of your appliance.
All messages with current descriptions can be found in the Troubleshooting portal on the MELAG website (https://www.melag.com/en/service/troubleshooting).

9.1 Warning messages

For the following warning messages, please observe the comments made and restart the program in question. If the warning occurs repeatedly please consult your stockist.

Warning message	Cause / Remedy
ATTENTION! **Door open** **No Start possible** **Acknowledge with button "-"**	Door not closed properly • Turn the door grip down until contact is made (display should then show "Door closed")!
ATTENTION! **No feed water** **Feed water refill** **No Start possible** **Acknowledge with button "-"**	This message appears when there is too less of feed water in the water storage tank • Check the level of water in the tank, and refill to max. with distilled or demineralized water of the appropriate quality
Feed water quality bad **Feed water check supply**	Conductivity of the demineralized or distilled water is above the first limit value, a start is possible by pressing the "Start" button once more: • Empty water from the water storage tank, clean tank with distilled / demineralized water and refill to the MAX- mark with purified water to specifications

Warning message	Cause / Remedy
Feed water quality insufficient **No start possible** **Acknowledge with button "-"**	Conductivity of the demineralized or distilled water is above the second limit value, a start of a sterilization cycle is no more possible: • Empty water from the water storage tank, clean tank with distilled / demineralized water and refill to the MAX- mark with purified water to specifications
Output medium is not ready	Communication with the output medium via the serial interface has been interrupted. This message appears when a log cannot be printed out. It is displayed for 20 seconds. If the output medium becomes operational during this period the cycle log prints out: • The steam sterilizer may be operated without an output medium. Check under the "Function" menu → "Batch output - Output medium" menu that the option "No Output medium" has been selected. (see Section 5.6.1) • Check the cable connection between the log printer/ MELAflash CF card printer and the steam sterilizer. • Check the power supply to the log printer. In the MELAprint 42/44 the red light should indicate 'power on' • The printer may be "Offline". Select "online" (MELAprint 42/44: press "SEL" button, green LED "SEL" should indicate)
Protocol memory full	The internal protocol memory is full (40 cycles recorded), an output medium is registered, and in the "Batch output" menu the option "Immed. output / NO" is selected. The message is displayed when a program is started. Pressing the "Start / Stop" button again deleted the message and the program starts: • You can continue operations simply by pressing the "Start / Stop" button twice when you start a program. • Select "Immed. output/ YES" (see Section 5.6.1) • Delete stored records (See Section 5.6.5), if necessary output all stored cycle logs first (see Section 5.6.3) • In the "Batch output - Output medium" menu, select the "No output medium" option (see Section 5.5)
Execute service	The service message is activated after a certain number of loads or a set operating period, when a service is due. The message appears before the start of every program. If you press the "Start / Stop" button again the message is deleted and the program starts. 1. You can continue operations, by simply pressing the "Start / Stop" button twice when you start a program. 2. Have a service carried out as recommended by an authorised MELAG servicing company or your stockist. The cycle counter for servicing is resetted during the service.
ATTENTION! Battery empty	The monitoring of the voltage of the battery on the main board is too low. The battery must be exchanged by a MELAG authorized service depot.

9.2 Malfunction messages

Errors are generally reported by an "Error" on the display with the number of the error and its short name.
Error reports may occur without a program start (when the power is switched on or soon after), or during a program.
If errors are reported during a program, then in addition to the error report the program will also be stopped. This may be accompanied by the equalisation of the pressure in the steam sterilizer, and in this case the error message will alternate with the messages "Pressure release", or "Ventilation", and "End".
After the termination, the display will alternately show the error message and "Acknowledge with button "-". Until you have quit the error message the steam sterilizer door cannot be opened. If a program has been prematurely terminated in this way the steam sterilizer load must always be regarded as being **not sterilized.**
We recommend that you unload the steam sterilizer, carry out a sterilization cycle without any load (the drying may be impaired for this first cycle) and then reload the steam sterilizer and repeat the interrupted operation cycle.
If an output medium is connected and "Immed. output YES" is selected, a log will automatically be printed out at the end of the termination.
The log output shows the full name of the error, and if a program has been interrupted before completion it will also show "Load not sterile". The following list gives error reports, the cause and possible remedies.

Error message	Cause / Remedy
Malfunction 2: Steam generator	The monitored time was exceeded not only for the heating-up phases during air removal by sub-atmospheric pulsing, but also for achieving the required sterilization pressure. Causes of this error may be any of the following: • Maximum loading amounts were exceeded. • Reduced heating output, since the mains voltage was too low. Please check the electrical power supply from the building. Try to see if the device works properly when connected to another electrical circuit. • Loss of water as a result of leaks, or from collection of water in porous materials. Do not allow water to collect in the objects to be sterilized: be sure to turn bowls, cups, glasses, and the like upside down **so that their openings are downward**. Cassettes perforated on once side must be turned **so that their perforated side faces downward**. **Important: It is not allowed to use cassettes that are completely closed.** • It is not allowed to sterilize without using tray racks. • After the above possible causes have been eliminated, press the reset button on the device: • **Important: After pressing the reset button, perform a sterilization cycle in the Quick-Program S with completely empty sterilization chamber.** If the problem continues, notify your specialist MELAG dealer.
Malfunction 4: Pressure release	The monitoring time for the ventilation of the pressure chamber was exceeded: • Check that the pressure releases at the rear of the chamber are not blocked • If this occurs repeatedly, inform your stockist. Evaporator coil is not connected to the quick coupling in the storage tank: **Warning**! Risk of burns - Only connect the evaporator coil to a switched-off and cooled-down device: • Switch off the device and let it cool down completely over several hours. • Switch on the device. The display shows the current chamber temperature and the chamber pressure. When

	the pressure has dropped below 0.15 bar, the door is unlocked and can be opened to plug in the evaporator coil. • Connect the evaporator coil to the provided quick coupling.
Malfunction 8: Time base	Maximum difference between the program duration and the internal clock exceeded: • If this occurs repeatedly, inform your stockist.
Malfunction 9: Door open	Door not closed properly ▪ Turn the door grip down until contact is made (display should then show "Door closed")! • If this occurs repeatedly, inform your stockist.
Malfunction 10: Overh. steam gener.	The capillary tube level regulator is open at the start of the program (error report immediately after start), or the monitoring time until refilling with demineralized or distilled water during the program (until the end of sterilization) is exceeded: • Check the horizontal levelling of the steam sterilizer. • Clean the filter inside the water storage tank • Clean the filters inside the sterilization chamber • After termination of a program and immediate restart of a program this malfunction may occur. Wait for 2 minutes and start the sterilization cycle once more. If this occurs repeatedly, inform your stockist:
Malfunction 18: Sensor defect: No	The internal testing of the sensors for temperature, pressure or conductivity showed an excessive deviation, the error can be reported on switching on the appliance or in the course of a program: • If this occurs repeatedly, inform your stockist.
Malfunction 21: Preheating	The pre-heating has not reached the necessary temperature within the specified time limit: • If this occurs repeatedly select the option "Automatic preheating No" and inform your stockist (see Section 4.7)
Malfunction 22: Overh. Preheating	The maximum preheating temperature was exceeded: • If this occurs repeatedly start the steam sterilizer without preheating and inform your stockist.
Malfunction 23: Current	The monitoring time for the pressure release in the outflow process for the fractionating was exceeded: • Check that the flow filter in the chamber (at the bottom directly behind the door) is not blocked • If this occurs repeatedly, inform your stockist
Malfunction 26: A/D-Converter	The limit deviation for internal analog / digital signal conversion has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 32: Power loss	After starting the program there was a loss of power. The error report is received when the electricity supply is restored: Check the mains power supply installation, if no errors can be found, inform the service agent.
Malfunction 33: Pressure loss	The time limit for the steam generator to reach the necessary pressure has been exceeded: • If this occurs repeatedly, inform your stockist.
Malfunction 34: Sterilization TU	The minimum sterilization temperature has not been reached: ▪ Reduce the size of the load. • Check the filter inside the chamber (In front on the left side behind the door) if it is dirt or clogged. • If this occurs repeatedly, inform your stockist.

Malfunction message	Cause / Remedy
Malfunction 35: Sterilization TO	The maximum sterilization temperature has been exceeded: • If this occurs repeatedly, inform your stockist
Malfunction 36: Sterilization PU	Sterilization pressure falls below the minimum level: ▪ Reduce the size of the load. • If this occurs repeatedly, inform your stockist
Malfunction 37: Sterilization PO	The maximum sterilization pressure has been exceeded: • If this occurs repeatedly, inform your stockist.
Malfunction 38: Sterilization TD	The difference between measured and theoretical temperature is too large: • If this occurs repeatedly, inform your stockist.

9.3 Reaction to warnings / error messages

The steam sterilizer has a number of safety features and an extensive integrated control and monitoring system, in order to ensure the greatest possible level of safety for the sterilization process, and to eliminate risks for the patients and operators.
Various aspects of the operation of the steam sterilizer, such as pressure and temperature sensors are automatically checked when the steam sterilizer is switched on.
The quantity and quality of the feed water is checked before each program start.
A successful program start is followed in the next stages by the monitoring of all parameters of relevance for the sterilization. If any limit values for the individual program phases are exceeded then there is a malfunction message and the program is automatically interrupted.
In addition to messages, warnings or malfunction reports on the display, if a printer is connected then a print-out will provide details of the type of malfunction and when it occurred.
If any such warning message occurs then you should consult Section 9, which provides detailed advice and possible operational errors.

9.4 No display on the screen

After switching on the steam sterilizer, the display should show the initial setting.
If there is no display: Check:

1. Is the power cable plugged into the mains?
2. Is the mains supply OK? (if necessary check with another appliance).
3. Exchange the two power fuses (Fig. 1, Pos. 10) on the back of the steam sterilizer as following: Disconnect the power cable and remove the screw cap over the fuses using a screwdriver or a coin. Exchange the fuses (two reserve fuses are delivered with the steam sterilizer) then replace the screw cap and reconnect the steam sterilizer to the power supply. If there is still no display when the steam sterilizer is switched on, or if the display blacks out repeatedly, please inform your stockist. If you exchange the fuses, order two new spare fuses through your dealer (art. No. 57592).

9.5 Door lock blocked

The steam sterilizer is equipped with an electric door-locking function. This function will disable the twist handle of the door lock during the sterilization program, and after occurrence of any malfunction (until the malfunction has been acknowledged by the operator). This door-locking function is also effective if no power is supplied: This means than the twist handle will also be blocked if necessary, even after the steam sterilizer has been switched off. After the power switch is turned back on, and at the end of a program, the system will automatically pull the door locking bolt (Fig. 1 Pos. 20) to the rear – which will release the twist handle.
In certain positions of the twist door handle, the door locking bolt may jam and it cannot be pulled to the rear. The operator will notice this when a quiet hum or buzzing sound can be heard. This is not a malfunction. To release the locking bolt, simply turn the twist handle slightly.

If the locking bolt repeatedly blocks the twist handle, then report this fault to your stockist or authorized service personnel.

9.6 Leaks in the door

If – after the start of the program, and upon beginning of pressure build-up – leaks in the door occur and steam discharges from the door area, then proceed as follows: Check the door gasket and the collar of the sterilization chamber for dirt and debris. Clean if necessary. If the door gasket is visibly damaged, replace it. Before starting a program, be sure to turn the door handle tightly and securely lock the steam sterilizer – regardless of the display (even if “Door closed” appears).
If you cannot stop the leak by the above measures, then report this fault to your stockist or authorized technician.

9.7 Too large feed water consumption

The steam sterilizer can be operated in a mode with a circulatory flow system. This means that an external condensate container has not been connected. Any loss of water in this mode will be the result of evaporation losses by incomplete condensation in the water storage tank. This loss is caused by very frequent use of the steam sterilizer, and the resulting heating of the water.
When the external condensate tank is connected, the steam sterilizer operates with a single-use (non-reusable) water system. This means that the water used for each sterilization cycle is not condensed and returned to the water storage tank, but is collected in an external condensate container. In this case, the consumption of water will depend on the program and the loading of the steam sterilizer.
If your steam sterilizer is consuming considerably more water than the amounts given in the attached appendix, first check to make sure that the steam sterilizer has been set up perfectly level (horizontal). If the steam sterilizer is level, and if it still uses excessive amounts of water on a long-term basis, then report this fault to your stockist or authorized technician.

9.8 Bad drying results

Good drying depends only on the correct operation of the steam sterilizer, but also on the way the steam sterilizer is loaded. If drying is not satisfactory:

1. Open the door after a sterilization cycle slightly so the load can be dried effectively with the activated preheating function.
2. Check that the steam sterilizer has been set up correctly so that condensate can flow out of the chamber.
3. Check that the condensation outflow is not blocked by dropped, instruments, filter paper, etc. on the floor of the pressure chamber.
4. Check that the maximum load has not been exceeded, that the steam sterilizer has been loaded properly (no direct contact with the walls of the pressure chamber), and that the appropriate tray-rack assembly has been used (see Section 4.3).
5. If none of these measures help to reduce water consumption, please inform your stockist.

10 Technical data

Dimensions	MELAtronic 23 EN
Outside dimensions (B x H x T)	52 x 38 x 59 cm
Diameter sterilization chamber	23 cm
Depth sterilization chamber	45 cm
Volume sterilization chamber	18.7 l
Weight (without load/water)	32 kg
Floor loading (normal operation)	39 kg
Floor loading (hydraulic pressure test)	51 kg
External supplies	
Power supply	220-240 V AC* / 50/60 Hz[1]
Rating	1600 W / 7 A
Degree of air pollution (in accordance with EN 61010-1)	2
Overvoltage category (in accordance with EN 61010-1)	II
Feed water	demineralized water according to EN 13060, Appendix C
Maximum loads	
Instruments	4 kg (unwrapped), 2 kg (wrapped)
Process parameters	
Energy consumption in Stand-By	230 Wh
Installation location	Interior of a building
Noise emission	sound pressure level @1 m clearance, < 58 db (A)
Surrounding temperature	5-40 °C (recommended max. 25 °C)
Altitude	until 2000 m
Relative humidity	max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative humidity at 40 °C
Heat emission	2.5 MJ[2]
Universal-Program 2.1 bar / 134 °C	
Energy consumption	450 Wh
Feed water (one-way)	450 ml
Program running time, maximum load*	34 min
Sterilisation time	5.5 min
Sterilization temperature range	+ 4 / - 0 K
Quick-Program S 2.1 bar / 134 °C	
Energy consumption min./max.	360 Wh
Feed water min./max.	340 ml
Program running time, maximum load	24 min
Sterilisation time	3.5 min
Sterilization temperature range	+ 4 / - 0 K
Gentle-Program 1.1 bar / 121 °C	
Energy consumption min/max.	470 Wh
Feed water min./max.	500 ml
Program running time, maximum load*	50 min
Sterilisation time	20.5 min
Sterilization temperature range	+ 4 / - 0 K

[1] observe the max. voltage range 207-253 V

[2] total heat discharged in one hour to the surrounding air

Prion-Program 2.1 bar / 134 °C	
Energy consumption min./max.	550 Wh
Feed water min./max.	480 ml
Program running time, maximum load*	49 min
Sterilisation time	20.5 min
Sterilization temperature range	+ 4 / - 0 K

The above mentioned values for energy and water consumption and for the program running times are average values and can differ in depending on the installation conditions in the practice (power supply/voltage/room temperature/loading of the steam sterilizer).

11 Accessories and spare parts

Article	*art. no.*
Accessories	
Tray Mount “A”	40248
Stopper for mount	ME22322
Tray handle	28885
Key for filter	15551
PVC-drain hose for aqua dest	30301
TORX driver TX20 for housing screws	48420
Tray	00230
Sterilization container 17K with 100 paper filters	01171
Sterilization container 23M with 100 paper filters	01231
Sterilization container 23G with 100 paper filters	01232
Package holder	22420
Condensate container	00356
MELAflash CF-Card-Printer	01039
MELAprint 44	01044
Spare parts	
Grease for door locks	24355
Door gasket	34150
Filter in chamber type 15/17/23	38150
Filter with sieve insert	34010
Filter for feed water	25070
Mains fuse16 A	57592

12 Appendix

Performance of the sterilization programs according to EN 13060

	Sterilization programs			
	Universal-Program	Prion-Program	Gentle-Program	Quick-Program S
Type acc. to EN 13060	S	S	S	S
Type tests (executed according to EN 13060)				
Dynamic Pressure test of the chamber	**X**	**X**	**X**	-
Empty chamber	**X**	**X**	**X**	**X**
Massive load unwrapped	**X**	**X**	**X**	**X**
Massive load single wrapped	**X**	**X**	**X**	-
Simple hollow items, unwrapped	**X**	**X**	**X**	**X**

Program modifications

The standard programs are designed to meet most practical operational needs (pulsed flow, heating, sterilization, pressure release, drying, and ventilation) and to display the parameters of most interest (pressure, temperature, time).
The operator is responsible for ensuring that the steam sterilizer is not overloaded, and that the load is arranged properly to ensure good drying.
The standard option “autom. Preheating” serves to influence the program progress.
Any further program modification to suit specific individual requirements should only be carried out by authorised personnel, after consultation with your dealer or with the experts at MELAG.

Technical tables

Nominal value tolerances

Universal-Program			Prion-Pr.		Gentle-Pr.		Quick-S		◄ same meaning as in Universal-Pr	
Step	Press P	Tolerance	P	Tol.	P	Tol.	P	Tol.	All values in mbar	
1. F.	2000	+ 50/- 30	◄	◄	◄	◄	◄	◄	Steam entry	Fractionation
	1200	+ 30/- 50	◄	◄	◄	◄	◄	◄	Steam flow off	
2. F.	2000	+ 50/- 30	◄	◄	◄	◄	◄	◄	Steam entry	
	1200	+ 30/- 50	◄	◄	◄	◄	◄	◄	Steam flow off	
3. F.	2000	+ 50/- 30	◄	◄	◄	◄	◄	◄	Steam entry	
	1200	+ 30/- 50	◄	◄	◄	◄	---	---	Steam flow off	
4. F.	2000	+ 50/- 30	◄	◄	◄	◄	---	---	Steam entry	
	1200	+ 30/- 50	◄	◄	◄	◄	---	---	Steam flow off	
5. F.	2000	+ 50/- 30	◄	◄	◄	◄	◄	◄	Steam entry	
	1200	+ 30/- 50	◄	◄	◄	◄	---	---	Steam flow off	
	3050	+ 70/- 30	◄	◄	2060	◄	◄	◄	Heat up	
	3050	+ 70/- 30	◄	◄	2060	◄	◄	◄	Sterilization start	
	3200	+ 90/- 90	◄	◄	2200	◄	◄	◄	Sterilization	
	1200	+ 30/- 50	◄	◄	◄	◄	◄	◄	Pressure release	

Empty chamber test

The coldest point (see ●) in the sterilization chamber during the empty chamber test is located near the door.

The hottest point (see ▲) in the sterilization chamber during the empty chamber test is located in the upper left corner of the tray rack at the rear end of the chamber.

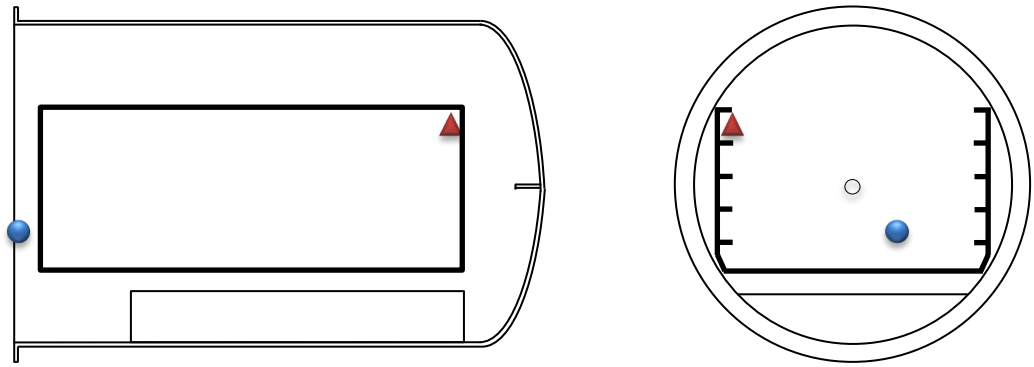


Fig. 4: Empty chamber test

Pressure-time charts

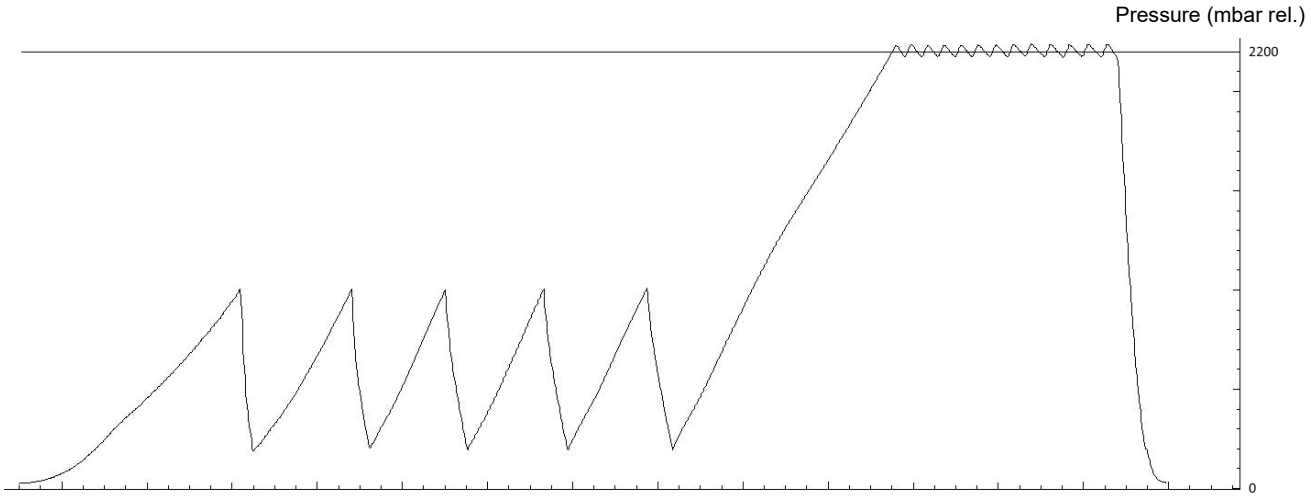


Fig. 5: Universal-Program, 134 °C and 2.1 bar

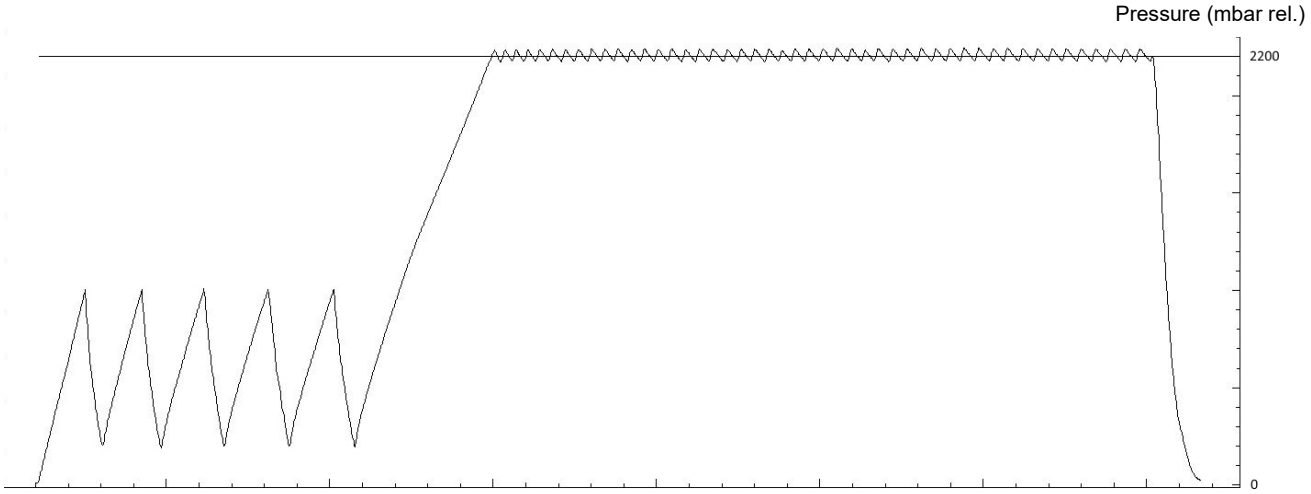


Fig. 6: Prion-Program, 134 °C and 2.1 bar

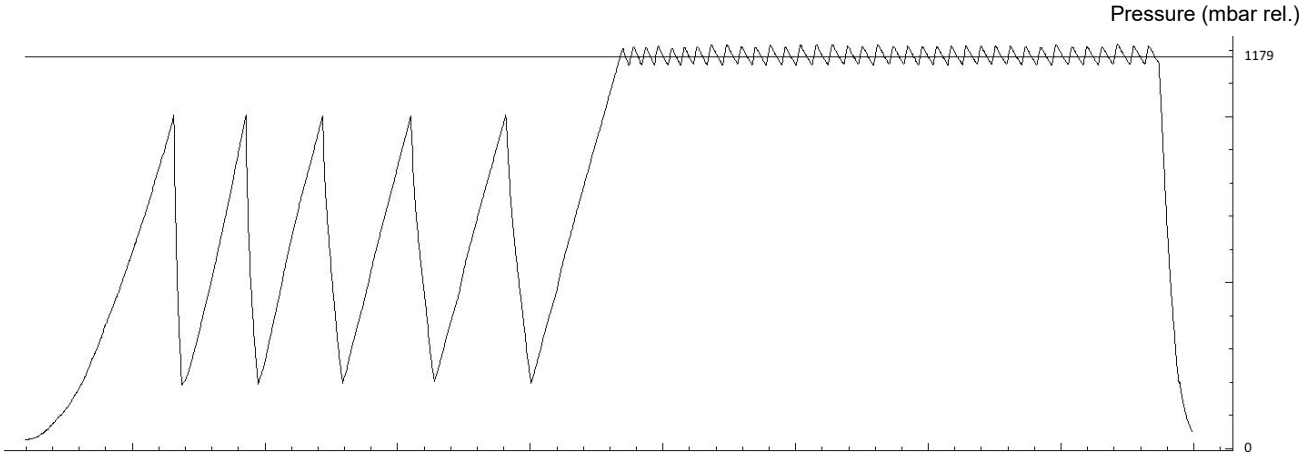


Fig.7: Gentle-Program, 121 °C and 1.1 bar

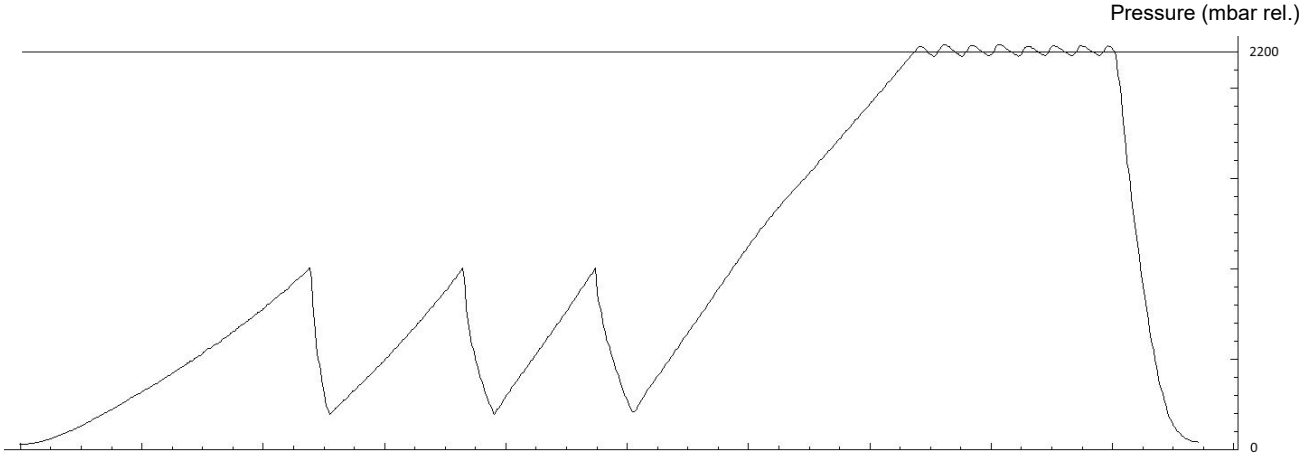


Fig.8: Quick-Program, 134 °C and 2.1 bar

Feed water quality

Specifications for water quality in accordance with the EN 13060

Evaporation residue	≤	10	mg/l
Silicon oxide, SiO_2	≤	1	mg/l
Iron	≤	0.2	mg/l
Cadmium	≤	0.005	mg/l
Lead	≤	0.05	mg/l
Other heavy metals	≤	0.1	mg/l
Chlorides (Cl)	≤	2	mg/l
Phosphates (P_2O_5)	≤	0.5	mg/l
Conductivity at 20°C	≤	15	µS/cm*)
pH (degree of acidity)	5 until 7		
Appearance	Colourless; clean; without sediment		
Hardness (Σ of ions of alkaline earth)	≤	0.02	mmol/l

*) µS/cm = Micro Siemens per centimetre

Glossary

aqua dem
demineralized water

aqua dest
distilled water

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

Authorized personnel
medical stockists, depot technicians or MELAG-specified customer services trained by MELAG

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

CF-Card
compact Flash card; a memory card for digital data in compact form; CF is a standardized term, i.e. these memory cards can be used in every device with a CF 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 steam upon cooling and thereby separated from the steam

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

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
also called aqua dem; water without the minerals usually found in normal spring or tap water; is produced though ion exchange of normal tap water. Used here as feed water.

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 microorganisms, is produced from normal tap water or pre-cleaned water through the process of distillation (evaporation and subsequent condensation). Used here as →feed water

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

DIN 58953
standard – sterilisation, sterile equipment supply

EN 13060
standard – Small steam sterilizers

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

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

Evacuation
creation of a vacuum in a chamber

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

Fractionated flow procedure
over-pressure procedure in which the change between pressure inlet and removal removes air from the chamber and the sterilization material

FTP (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.

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

Initialization
creating a specific starting situation of the software upon starting

Massive
without hollows or cavities, compact, sealed closed

Massive load – verification of a massive load
serves to prove that the necessary sterilization conditions are reached within the entire load with the values set in the control. The load must represent the max amount of massive instruments which requires a sterilizer designed in accordance with EN 13060 in order to be able to sterilize them. [EN 13060]

Mixed load
wrapped and unwrapped sterilization material within a single load

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

Porous
permeable for fluids and air e.g. textiles

Porous full load – test of porous full load
serves to prove that with the values set in the control, the necessary sterilization conditions are reached within an entire load filled with the maximum mass of porous items for which the sterilizer is designed in accordance with EN 13060 [EN 13060]

Process evaluation system
also known as the self-monitoring system – observes itself, takes effect during the program, compares the various sensors.

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

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

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

Standard conform
satisfies all relevant standards

Sterile barrier system
a closed minimum packaging which prevents the entrance of microorganisms e.g. through sealing bags, sealed and re-usable containers and folded sterilization towels etc.

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

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

Sterilizing material
unsterile, sterilizable material which is still to be sterilized.

Stainless steel cleaning medium
e.g. Sidol

Single wrapped
wrapped once e.g. film shrink-wrapped instruments – in opposition to: Multiple packaging

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

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

VDE
Verband der Elektrotechnik, Elektronik und Informationstechnik e.V. (Alliance of the Electronics, Electrotechnical and IT Industry)