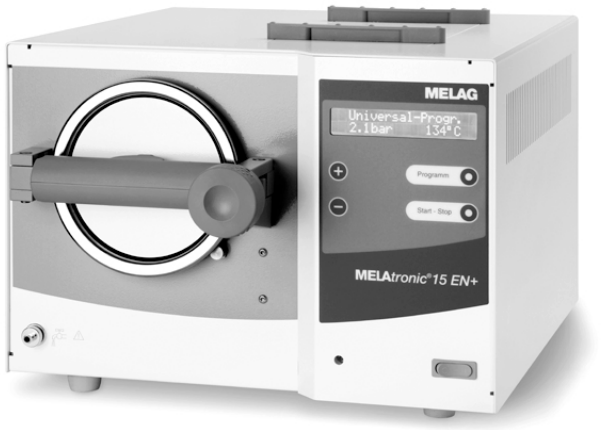
MELAG

User Manual

Autoclave

MELA*tronic*® *15 EN+*

as of software version 5.15



Dear Dr.

We should like to extend our thanks for the expression of trust in our company which you have displayed through the purchase of this MELAG product.

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

You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management systems is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485 and ISO 9001. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE 0197

For doctors, physician's assistants and service personnel

Please read this user manual carefully before commissioning the autoclave. The instructions include important safety information. Please store these operating instructions carefully and in close proximity to your autoclave. It represents a component of the product.

MELAtronic®15 EN+

as of software version 5.15

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Dokument: BA_EN_15EN+_v6.docx / Revision: 6 – 16/1504

Date of update: 07.07.2016

Foreword

Thank you for having chosen this MELAG autoclave.

Device description This manual uses the device description "autoclave“ for the steam sterilizer MELA*tronic 15 EN+*.

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

Hazard avoidance Please read the safety information carefully before using the autoclave.

About this manual

Symbols	***Meaning***	***Explanation***
 **Danger!**	Health hazard	Indicates a dangerous situation, the non-avoidance of which could result in injuries ranging in seriousness from light to life-threatening.
Warning	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 autoclave.
	Important information	Draws your attention to important information.

Accentuation of an example	***Meaning***	***Explanation***
Conductivity measurement	Glossary entry	Words or phrases marked with an arrow are explained in the glossary. The glossary is listed alphabetically. It can be found at the end of this manual.
`Universal-Program`	Software citation	Words or phrases appearing on the display of the autoclave are marked as software citations.
Chapter 6 - Logging	Cross reference	Reference to another text section within this manual.
Figure 1/(5)	Cross reference	Reference to a detail in a figure – in the example, to part no. 5 in figure 1.

Symbols on the autoclave

Symbols on the autoclave	***Meaning***	***Explanation***
	Health hazard	Indicates a hot surface or hot steam which could be emitted from the aperture marked.
	Health hazard	Indicates the necessity to observe the safety instructions contained within the user manual before operating the autoclave.

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.

Symbols on the steam sterilizer

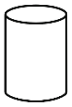
In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the medical device directive. The four-digit number confirms that this is monitored by an approved certification agency.

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

Manufacturer of the medical device

date of manufacture of the medical device

Serial number of the medical device by the manufacturer



Indication of the scale of the chamber volume

Operating temperature of the device

Operating pressure of the device

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

Please read this user manual carefully before commissioning the device. The manual includes important safety information. The functionality and value-retention of this sterilizer depends on the care accorded to it. Please store this user manual carefully and in close proximity to your sterilizer. It represents a component of the product.

This User Manual contains important safety information.

Failure to comply of the safety instructions could result in human and material damage.

The symbol of the struck out waste bin identifies a device that may not be disposed in the domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of. With the designation of an apparatus with this symbol, the manufacturer furthermore declares that he satisfies all requirements of the law concerning the release, redemption and environmentally sound disposal of electric and electronic appliances.

Safety Instructions

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

Appropriate use

- Never use this autoclave to sterilize any fluids.
- Use the autoclave only for the purpose named in the user manual.

Power cable and mains socket

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

Set-up installation and commissioning

- The autoclave should only be set-up, installed and commissioned by MELAG authorized persons.
- Never operate the autoclave in areas exposed to the danger of explosion.
- The connections for electrical provision and water supply and discharge must be set-up by trained personnel.
- Documentation media (computer, CF card reader, etc.) must be placed in such a way that they cannot come into contact with liquids.

Treating and sterilizing textiles and instruments

- Follow the manufacturer instructions of your textile articles and instruments regarding their treatment and sterilization.
- Observe the relevant standards and directives applicable to the treatment and sterilization of textiles and instruments e.g. from the RKI, and DGSV.
- Only ever use packaging material and systems which have been cleared by their manufacturer for steam sterilization (consult the manufacturer's instructions).

Program abort

- Please observe that depending on the time of the program abort, opening the door following a program abort can lead to hot steam leaving the chamber.
- Depending on the time of the program abort, it is possible that the load is unsterile. Observe the clear instructions on the autoclave display. It may be necessary to re-pack and re-sterilize the sterilization material.

Removing the sterilized equipment

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

Maintenance

- Maintenance should only be performed by authorized personnel.

Carrying the autoclave

- The autoclave should always be carried by two people.
- Use the correct carrying strap to carry the autoclave.

Malfunctions

- Upon the incidence of repeated error messages in the autoclave, turn off the autoclave and if necessary, inform your stockist.
- The autoclave may only be serviced by authorized personnel.

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Chapter 1 – Performance Specifications

This chapter informs you as to

- **The purpose and under which conditions you can use this autoclave.**
- **The benefits of using this autoclave**
- **The sterilizing programs which you can use**

Proper Use

Area of application

The autoclave is designed for use in a general medical environment in which the packaging type and instruments used and do not require a class B autoclave.

Sterilization tasks

According to DIN EN 13060, this autoclave is a Class S sterilizer. As a Universal autoclave, it is suitable for the sterilization of unwrapped or single wrapped massive instruments and simple hollow items (hollow body B) and smaller amounts of textiles.

Danger of burns

Please observe the following provisions for the use of the autoclave:

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

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

Warning

- Only ever use the autoclave 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 treatment, the sterilization of instruments and textiles using this autoclave may only be carried out by competent personnel.
- When conducting sterilization procedures, only use instruments, packaging and textiles which the manufacturer has cleared for steam sterilization.

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

User Benefits

Universal use

The autoclave 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 or small amount of textiles quickly and safely.

Short time frame

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

Overheat control
Automatic pre-heating

The sterilization chamber is protected against overheating.
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 autoclave uses both a feed-water circulation system and a feed-water one-way system, using the external condensate container (p. 17, **Connecting the external condensate container**)
When using the feed water circulation system, the autoclave 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 autoclave.

Feed water supply

The feed water supply for steam generation is conducted automatically via an internal storage tank.

Optimal drying for wrapped sterilization material.

The sterilization material is dried using pulsing over-pressure drying. This brings the best drying results even when using wrapped sterilization material.

Optimal total operating time

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

High safety via comprehensive safety features

The autoclave 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 autoclave 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 autoclave 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.
The Bowie & Dick test enables you to check the autoclave for the sufficient steam penetration of porous sterilization material (e.g. textiles).
You can monitor the quality of the feed water using the conductivity measurement.

Effective batch documentation

The autoclave 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.

Overview of the Sterilization programs

Type tests	***Universal-Program***	***Prion-Program***	***Gentle-Program***	***Quick-Program S***
Program type in accordance with DIN EN 13060	Type S	Type S	Type S	Type S
Dynamic pressure test of the sterilization chamber	X	X	X	X
Empty chamber test	X	X	X	X
Massive load unwrapped	X	X	X	X
Massive load single wrapped	X	X	X	---
Porous load single wrapped	X	X	X	---
simple hollow items (Hollow body B)	X	X	X	X
Drying massive load	X	X	X	X
Drying, porous load	X	X	X	---

X = Complies with all applicable sections of the standard DIN EN 13060

Chapter 2 – Device Description

This chapter informs you as to

- **Which components are included in a standard scope of delivery**
- **The constituent components of the autoclave**
- **The safety features of the autoclave**
- **The assembly of the operating elements and how to operate them.**
- **The type of water supply required by the autoclave**

Scope of delivery

Standard scope of delivery

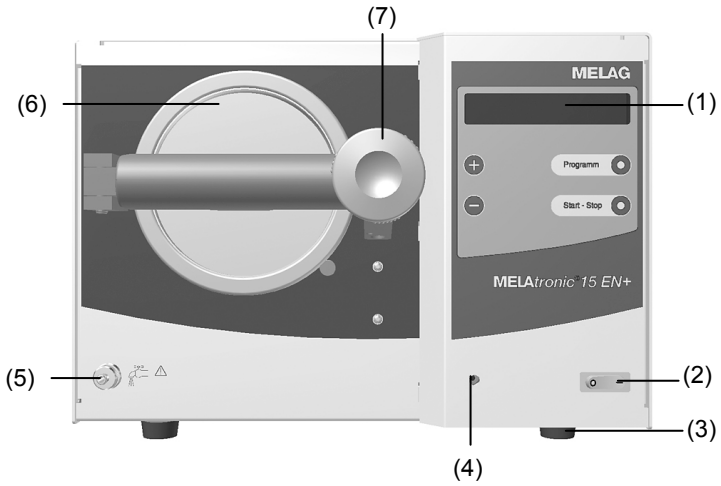
- MELAtronic 15 EN+
- User Manual
- Record of installation and setting up
- Declaration of conformity
- Pressure Device Directive certificate
- Guarantee certificate
- Manufacturer's inspection report
- 1 Mounting for trays
- 1 tray lifter
- 1 hose for emptying the interior water storage tank
- TORX spanner for removing the carrying strap
- 1 chamber filter key
- 2 replacement fuses

Optionally

- Trays
- MELA*flash* CF card printer with CF card and card reader
- MELA*net* Box
- MELA*print* 42 log printer

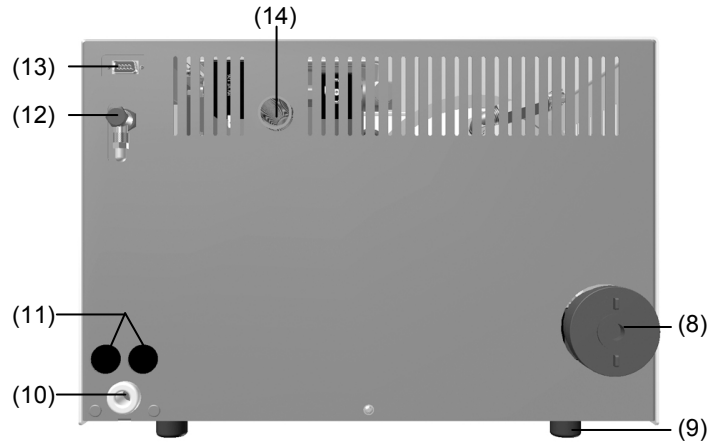
Views of the device

Front



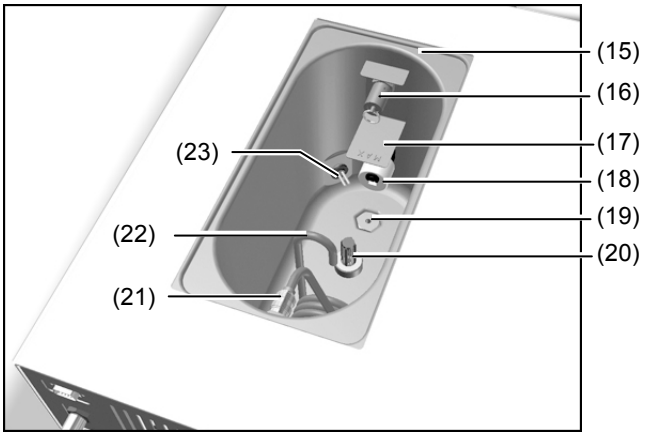
(1) Operating and display panel
(2) Mains switch
(3) Front device foot (adjustable)
(4) Reset key overheating protection
(5) Storage tank drain valve
(6) Door, pivots to the left
(7) Twist grip

Rear



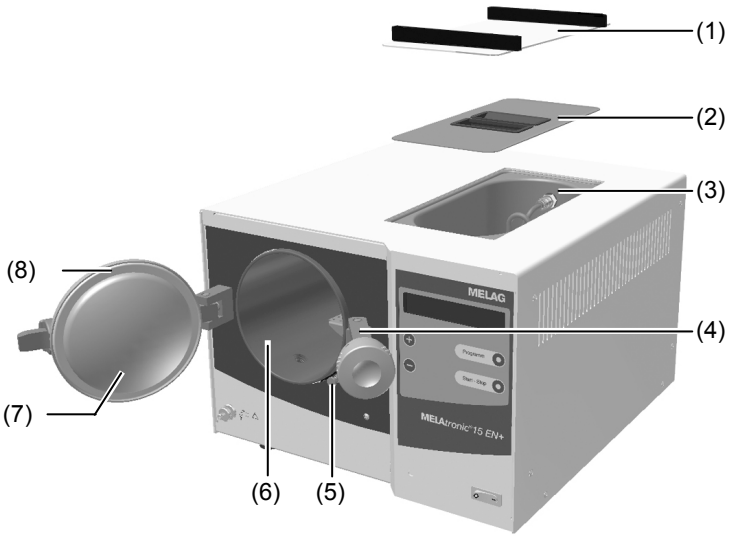
(8) Sterile filter
(9) Device foot, rear
(10) Mains cable
(11) Fuses – 2x 16A/gRL
(12) Connection to external condensate container
(13) Serial data and printer connection (RS232)
(14) Ventilation hose from storage tank

View from above (open)



(15) Internal storage tank
(16) Spring safety valve
(17) MAX mark
(18) Float switch feed water
(19) Discharge outlet (leads to drain valve)
(20) Water intake filter
(21) Quick coupling for connection of the evaporator coil
(22) Evaporator coil
(23) Conductivity sensor

Fig. 1: Views of the device



(1) Upper tank cap with grate
(2) Lower tank cap
(3) Internal storage tank for feed water
(4) Latch
(5) Door contact
(6) Chamber
(7) Door plate
(8) Grey door seal

Fig. 2: View of the interior

Packing space

Device type	*Diameter*	*Depth*	*Volume*
MELA*tronic 15 EN+*	∅ 15 cm	38 cm	7 Litres

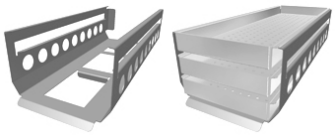


Figure 1: Tray mount

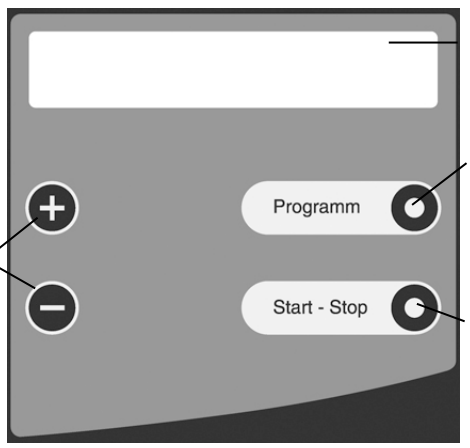
Mounting for the load

The autoclave is always delivered with a mounting for holding trays or cartridges.

- The mounting is standard and can accommodate three trays.

Operating panel

The operating panel consists of a two-line alphanumerical LED display and four membrane keys.



2-line LED display
for program status display and parameter display

Program selection key (P)
to select the sterilization programs/test programs

Function keys (+) and (–)
to select, set and display special functions:print, date/time, pre-heating, total batches, conductivity, acknowledge error, KEY (+) for unlocking door

Start – Stop key (S)
to start programs, terminate programs/drying as well as control of the special functions

Basic state

The display switches to the basic state after every activation of the device. This displays the current time and chamber pressure in bar and the (steam) temperature in °C.

Feed water supply

The autoclave requires demineralised or distilled feed water in accordance with DIN EN 1360 to generate steam. The supply with feed water is effected from the internal storage tank. The autoclave draws in the feed water automatically.

Feed water via the internal storage tank

When using the internal storage tank for the feed water supply, it is necessary to refill it periodically. The autoclave will issue a maintenance message at the relevant time. Only use water as feed water in accordance with DIN EN 13060.

Chapter 3 – Commissioning

This chapter informs you as to

- **Who is permitted to set-up, install and commission the autoclave**
- **The requirements for the set-up, installation and commissioning of the autoclave.**
- **How to switch on the autoclave**

Pre-conditions for the set-up, installation and commissioning

- The autoclave should only be set-up, installed and commissioned by MELAG authorized persons.

Danger

- In accordance with current VDE specifications, the autoclave is unsuitable for operation in areas exposed to the danger of explosion.
- The autoclave is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

Failure to comply with these provisions can result in damage to the autoclave and/or human injury.

Removal from the packaging

Unpacking the autoclave

- Remove the autoclave from the box using the carrying straps.

Removing the carrying straps

- Unscrew the four screws from each side of the housing to remove the blue carrying straps.
- Re-screw these screws without the washers. Store the carrying straps and washers in a safe place.

Requirements of the installation location

Location

Install the autoclave in a dry and dust-protected location. Humidity should amount to between 30 - 60 % and the surrounding temperature 16 - 26°C.

Horizontal position

To ensure malfunction-free operation, the autoclave must be held in a horizontally and vertically level position through extending or retracting the device feet. Check this with a spirit level.

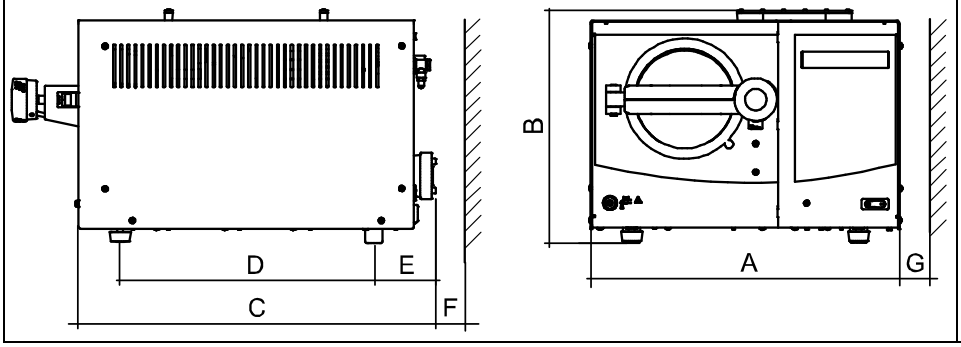
Warning

- Make sure to maintain the prescribed distance between the back, sides and top of the autoclave and the surrounding surfaces.
- As steam can issue from the ventilation hose at the back of the autoclave, it is necessary to ensure that there are no electrical connections on the wall at this location.

Failure to observe these provisions can result the build-up of heat. This could restrict the functionality of the autoclave and result in a reduced life-expectancy of the pressure pump and lengthened program times.

Distance to the surrounding surfaces

The distance between the surrounding surfaces and the sides and the rear of the autoclave must amount to a minimum of 5 cm. The top of the autoclave should be freely-accessible so that the inbuilt storage tank can be filled and good ventilation in ensured. A minimum of 30 cm clearance should be maintained.

Space requirements		
	Width Height Depth	A=44 cm B=33 cm C=50 cm D=36 cm E=8.2 cm F=5 cm G=5 cm

Additional space for an external condensate container (optional)

In addition to the space required for the autoclave, you may also need additional space underneath the autoclave for an external condensate container (HxWxD: 35.6 x 28 x 17.5 cm).

Establishing connections

Danger of injury

- Only allow an electrician to fit the electrical connection.

Failure to observe this provision can result in a short-circuit and/or fire and/or water damage and/or electric shock. This could result in serious injury.

Electrical connection

The mains socket must be freely accessible after installation so that the device can be taken from the electricity supply at any time.

Provide the following electrical connection for the autoclave:

- A 220 -240V circuit (max. voltage range 207-253V) and 50/60 Hz
- 16 A separate fuse – a minimum of the automatic type B
- FI protection 30 mA
- Connected rating 1500 W.

Observe the following safety measures when dealing with the mains cable and plug:

Danger of injury

- Never change, bend or twist the power cable.
- Never remove the plug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Never run the cable over areas in which it could become trapped (e.g. doors or windows).
- Never lead the cable along a source of heat.
- Never use any nails, paper fasteners or similar objects to fix the cable.

Should the cable or plug become damaged, switch off the autoclave. The power cable and plug should only be replaced by authorized personnel.

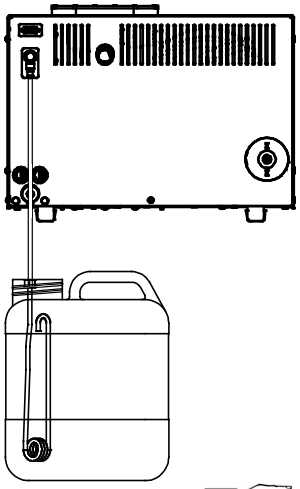
Failure to observe these provisions can result in damage to the cable or plug and/or a fire or an electric shock. This could result in serious injury.

Connecting the plug to the mains

- Plug the mains plug into the mains socket.

Connecting the external condensate container

External condensate container (optional)



Following frequent use, the water in the storage tank can heat up so that complete condensation on the evaporator coil is no longer possible. This can result in an ejection of steam from the ventilation hose on the rear of the autoclave.

In such a case, we recommend using an external condensate container. The autoclave will then work using the feed water one way system as the feed water used no longer condenses in the storage tank, rather is collected in the external condensate container.

- Unscrew the lock nut on the rear of the autoclave and replace it with the outlet hose (included in the scope of delivery of the condensate container). Screw it tight with the union nut.
- Fill the condensate container with tap water up to the MIN mark. Screw on the cap and position it underneath the autoclave.
- Plug the other end on the outlet hose on the plug-in coupling in the condensate container cap to its fullest extent.
- Remove the evaporator coil from the storage tank by pressing the quick coupling (Fig. 1/(21)) on the pressure release backwards. Retain the evaporator coil in case you need to return it.

NOTE

The water from the external condensate container may not be used for further sterilization.

The condensate container must be fitted underneath the autoclave. The outlet hose must be fitted with a constant incline.

Program modifications

The stages of the autoclave programs fractionating, heating, sterilizing, pressure release, drying and aeration and its parameters pressure, temperature and time, correspond to the usual requirements placed on a practice environment.

Pre-warming

The function "pre-heating“ provides a standard possibility of influencing the course of the program.

Further alterations to the program run are possible in each individual case and will still ensure the effectiveness of the sterilization, but may only be performed by authorized persons. Please consult your stockist or MELAG.

Preconditions for commissioning

The following requirements must be satisfied to commission the autoclave:

- The feed water supply must be switched on.
- The autoclave power supply must be switched on.

Installation and setup protocol

Important

The set-up protocol from the responsible person must be filled out and a copy sent to MELAG as proof of the correct setup, installation and commissioning. This is a constituent part of any guarantee claim.

Switching on the autoclave

Switch on at the mains

Switch on the autoclave at the mains (Fig. 1/(2).

After switching on

- After the autoclave has been switched on at the mains, the display will alternate between the basic state and the message **`Unlocking door with key '+'`** (If the door is locked).
- The trays and accessories must be removed from the chamber directly after the autoclave having been switched on for the first time and before commissioning.
- Press the (+) key to unlock the door. Only now can you open the door.

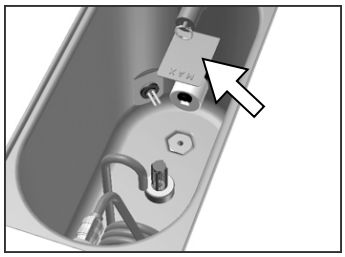
Chapter 4 - Sterilizing

This chapter informs you as to

- **How to fill fresh feed water**
- **What you should be aware of when preparing the sterilization material**
- **How to load the autoclave correctly**
- **Which program serves which purpose**
- **How to start a program**
- **Which phases a program runs through**
- **How to abort a program**
- **How to recognize that sterilization has ended successfully**
- **What you can do to improve the drying outcome**
- **What you must observe when removing the sterilized equipment**

Filling the feed water

Supply from an internal storage tank



Fill the internal storage tank with feed water of the correct quality (see p. 38, **Always use high-quality feed water**).

- Remove the upper and lower tank cap and fill with approx. 3 litres of fresh feed water up to the MAX mark in the storage tank.

NOTE

Ensure that the water level does not rise above the MAX mark.

Warning

- In order to allow the off-flowing steam to condense entirely, to prevent an undesirable steam ejection from the storage tank and to avoid increased feed water consumption, the evaporation coil in the storage tank should always be covered with feed water.

The storage tank should always be filled promptly or in the optimal case, should be drained via the drain valve before refilling.

Switch on

If the autoclave has not yet been activated, switch it on at the mains.

Preparing the sterilization material

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

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

Textiles

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

Danger of infection

- Observe both the textile manufacturer's instructions regarding treatment and sterilization as well as the relevant standards and directives e.g. from the RKI, and DGSV.
- Only ever sterilize dry textiles.
- The textiles must not be permitted to come into direct contact with the floor or walls of the sterilization chamber; otherwise they will become saturated with condensate.
- Observe the maximum load quantities for textiles.

Failure to observe this can prevent the steam penetration of the textiles and/or produce poor drying results. It could also result in unsterile textiles. This could endanger the health of patient and practice members.

Instruments

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

Danger of infection

- Follow both the instrument manufacturer's instructions regarding treatment and sterilization and comply with the relevant standards and directives e.g. from the BGV A1, RKI and DGSV.
- Clean the instruments exceptionally thoroughly e.g. using a washer-disinfector.
- Rinse the instruments after washing and disinfecting, where possible with de-mineralized or distilled water and then dry the instruments with a clean, non-fuzzing cloth.
- Use only those cleaning agents suitable for steam sterilization. Consult the manufacturer of the agents.

Failure to observe these provisions could result in any dirt residue being loosened by the steam pressure during sterilization. Residual disinfection and cleaning fluids result in corrosion. This could result in increased maintenance requirements and a restriction of the autoclave function.

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

When using ultra-sound devices or washing and disinfection devices, please observe the manufacturer's treatment instructions.

Loading the autoclave

Only when correctly loaded is effective sterilization and good drying possible.
The maximum load may never under any circumstances be exceeded.

NOTE

Use perforated trays such as those from MELAG. Only in this way can the condensate drain off. The use of a non-perforated base or half-shell to accept the sterilization material can result in poor drying results. Please note that under certain circumstances, the use of paper tray inserts can lead to poor drying results.

Packaging

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

Warning

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

You can use re-useable ridged packaging systems such as e.g. sterilization containers or soft packaging such as transparent sterilization packaging, paper bags, sterilization paper, textiles or card webbing.

Sealed sterilization container

It is better to use aluminium sterilization containers. Aluminium is a good conductor of heat and thus improves drying.

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

Warning

- Closed sterilization containers must be either perforated or have a valve on at least one side - optimally the bottom.

Failure to observe these points results in insufficient steam penetration, and a possibly unsuccessful sterilization result. It also prevents the drain-off of condensate and produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

MELAG sterilization containers fulfil the requirements of DIN EN 868 for successful sterilization and drying. They have a perforated lid and are fitted with single-use paper filters.

Stacking sterilization containers

Wherever possible, please ensure that sterilization containers are stacked on top of those of identical size, so that the condensate can run down the walls.

Warning

- Ensure that the perforations are not covered when stacking the containers.

Failure to observe these provisions can result in the dripping condensate being unable to drain off to the chamber floor. This would then saturate the sterilization material directly underneath it. This produces poor drying results. This can result in unsterile instruments and thus endanger the health of patient and practice team.

Soft sterilization packaging

Soft sterilization packaging can be used in both sterilization containers and on trays or be sterilized standing, in conjunction with a film bracket. Please observe the following when using soft sterilization packaging e.g. MELA*fol* .

Warning

- Arrange soft sterilization packaging in a perpendicular position and at narrow intervals.
- Do not place multiple soft sterilization packages flat on top of each other on a tray or in a container.
- If the seam seal tears during sterilization, this could be caused by the choice of undersized packaging. Should this be the case, re-pack the instruments and sterilize them again. The packaging should be filled ¾ full and have 3 cm clearance to the seam seal.
- Should the seam seal rip during sterilization, extend the sealing pulse on the sealing device or make a double seam.

Failure to observe these provisions can result in unsterile instruments and thus endanger the health of patient and practice team.

Multiple packaging

The use of multiple packaging is not possible.

Mixed loads

Please observe the following when using mixed loads:

- Always place textiles at the top
- Place the sterilization containers at the bottom
- Unwrapped instruments at the bottom
- Transparent sterilization packages and paper packaging should be loaded on top – with the single exception: When loaded in combination with textiles, they should be loaded at the bottom

Transparent sterilization packaging should be loaded on their edges so that the paper side and film side are in contact. If this is not possible, the paper side should face downwards.

Loading variations	***MELAtronic 15 EN+***	
	Instruments	Textiles
Max no. per single piece	2 kg	150 g
Loading variations with mounting	max. 3 trays, depth 35 cm max. 4 sterilization containers 15K max. 2 sterilization containers 15M max. 1 sterilization containers 15G	
Maximum total	2 kg	150 g

*MELAG mounting, trays and sterilization containers. See appendix **A – accessories**

To observe before every sterilization run

- Control the storage tank for dirt.
- Check that the storage tank is sufficiently full.
- When using the external condensate container, check its fill level and empty it at the correct time.
- Measure conductivity before starting a program (see p. 43, **Displaying the water quality**).

Closing the door

Please observe the following when closing the autoclave door:

- To close the door, move the latch over the closure bar and then secure the door by turning the twist grip firmly.

NOTE

The autoclave must be switched on when closing the door, so that the

locking pin advances. Only in this way can the door be closed fully.

Selecting the program

You can switch between the basic state and the desired program using the program selection switch.

Now select the sterilization program according to how and whether the sterilization material is packed. It is also necessary to take into account the temperature resistance of the sterilization material.

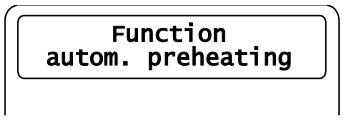
The following table shows which program is to be selected for which sterilization material.

	Universal-Programm	**Schnell-Programm S**	**Schon-Programm**	**Prionen-Programm**
Sterilisiertemperatur	134°C	134°C	121°C	134°C
Sterilisierdruck	2 bar	2 bar	1 bar	2 bar
Sterilisierzeit	5,5 Min.	3,5 Min.	20,5 Min.	20,5 Min.
Betriebszeiten				
Betriebszeit*	21 min	14 min	35 min	36 min
Trocknung	32 min	10 min	33 min	33 min

* without drying (full load with MELA*tronic 15 EN*+ 2 kg) and depending on the load and set-up conditions (e.g. the mains voltage)

Program	***Packaging***	***Especially suitable for***	***Load***
Universal-Program	unwrapped and single wrapped	Mixed loads; long, simple hollow items (hollow body B)	2kg
Quick-Program S	only unwrapped (no textiles)	Simple massive instruments	2kg
Gentle-Program	unwrapped and single wrapped	Textiles; thermo-unstable items (e.g. plastic, rubber, simple hollow items (hollow body B); massive instruments	Textiles 150 g
			Thermo-unstable items 2 kg
Prion-Program	unwrapped and single wrapped	Instruments under suspicion of carrying the danger of infection through abnormally altered proteins (e.g. Creutzfeld-Jacob, BSE), simple hollow items (hollow body B).	2kg

Selecting automatic pre-heating



The automatic pre-heating function heats the autoclave chamber to a program-specific pre-heated temperature before the program start, or holds this temperature between two program runs.
The precondition is that the autoclave remains continually activated.
This reduces the build-up of condensate on the chamber wall and assists the drying. This produces shortened cycle times.
Automatic pre-heating is activated as standard.
To alter this setting proceed as follows:

- Press the (+) und (-) keys simultaneously and quickly to select the

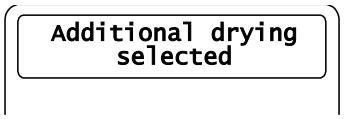
setup menu, **Function**. The display shows **Function: Last batch number.**

- Navigate using the (+) or (-) keys until the display shows **Function: autom. preheating**.
- To confirm, press the (P) key. The display shows the option currently set, e.g. **pre-heating YES**.
- Pressing the (P) key again makes the display switch to **preheating NO**. The pre-heating function has been deactivated.
- To end the menu **Function: autom. preheating** and to return to the basic state, press the (S) key twice.

NOTE

MELAG recommends activating the function automatic pre-heating.

Selecting additional drying

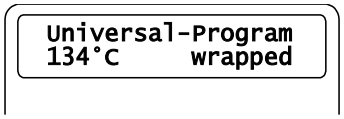


The function additional drying extends the drying time by 50%. This is suitable for difficult drying tasks.
To do so, proceed as follows:

- Press the keys (S) and (+) simultaneously upon starting the program.

The display shows **Additional drying selected.**
The program run will now begin.

Starting the program



After having selected a program via the program selection key, the display will show both the selected program and sterilization temperature as well as whether the program is suitable for wrapped or unwrapped sterilization material.

- Press the (S) key to start the program.

The autoclave checks the feed water supply and its conductivity.

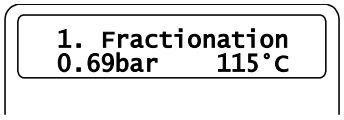
If the Quick-Program S has been started, the warning **Attention, only unwrapped instruments** appears on the display.

- If the load contains exclusively unwrapped instruments, press the (S) key again to confirm and to start the program.

Program run

After starting the program, you can follow the program run in the display. It shows the chamber temperature and pressure as well as the time until the end of sterilization / the drying time which has passed.

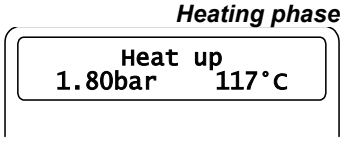
Ventilation phase



During the ventilation phase, the fractionated flow procedure removes air from the chamber and pumps saturated steam in the chamber with pulsing, repeated steam input and removal.

Depending on the program selected and the current chamber temperature upon program start, further fractionations can also follow.

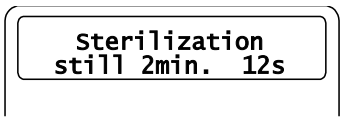
Heating phase



The heating phase follows the ventilation phase. The continued steam admittance into the chamber leads to an increase in pressure and temperature which continues until the sterilization parameters have been reached.

Sterilization phase

After the sterilization parameters pressure and temperature have been met, the sterilization phase begins.

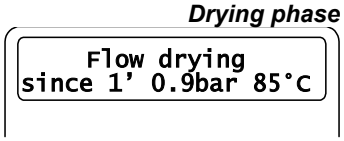


In addition to alternate display of pressure and temperature, the display also indicates the time left in the sterilization phase.

Pressure release

Pressure is released after the end of the sterilization time. Pressure and temperature fall.

Drying phase



The drying phase begins after the pressure release.
The regular drying time for the Quick-Program S: 10 minutes. For the Universal-Program: 32 minutes. For the Gentle- and Prion-Program: 33 minutes.

Manual program abort

You can abort a current program in all phases.

Important

Never abort a program by switching off at the mains. Failure to observe this provision will result in an error message on the display indicating a power outage after the autoclave has been switched back on.

Danger of burns

- Please observe that depending on the time of the program abort, opening the door following a program abort can lead to hot steam leaving the chamber.
- Use a tray lifter to remove the tray.
  Never touch the sterilized equipment, the chamber or the door with bare hands. The components are hot.
- When removing the tray cassettes, always use either a tray lifter or gloves. The components are hot.

Failure to observe this requirement can result in burns.

Manual abortion before the drying begins

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

If you abort the program before the overpressure has been reached, we recommend performing the first sterilization run as an empty run i.e. without a load.

A program abort requires the following steps:

- Press the (S) key
- Confirm the following safety question **`Stop program?`** By pressing the (S) key repeatedly.

NOTE

The safety question will be shown on the display for approx. 5 seconds. If the key is not pressed repeatedly, the program will continue with the usual program run.

Depending on the time, pressure will be released.
A corresponding display text appears on the display.
After pressure release, you will be asked to clear the program abort.

The display will alternate between **`Stop/end`** and **`Acknowledge with key '-'.`**

- Press the (-) key.

The display alternates between displaying the message **`Unlocking`**

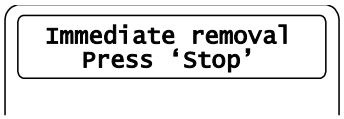
door with '+' key and the program previously selected.

You can open the door after pressing the (+) key.

The log records the note “program aborted / load not sterilized“.

Manual abort during drying

You can abort the program during the drying phase without the autoclave registering an error.
You then need to expect insufficient drying, especially in the case of wrapped sterilized equipment. Sterile storage requires sufficient drying. To ensure this, please allow programs with wrapped sterilized equipment to continue to the end of the drying phase.
Unwrapped instruments sterilized in a Quick-Program dry after being removed from their own warmth.

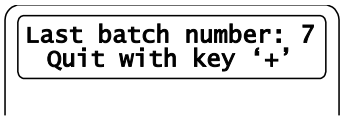


During the drying phase, the drying time which has elapsed is displayed, alternating with the message **Immediate removal, Press 'Stop'**.
A program abort requires the following steps:

- Press the (S) key
- Confirm the following safety question **Stop program?** Press the **'Stop' key** together with the (S) key repeatedly.

The display confirms the abort with **Drying stopped.**

NOTE
The safety question will be shown on the display for approx. 5 seconds. If the key is not pressed repeatedly, the program will continue with the usual program run.



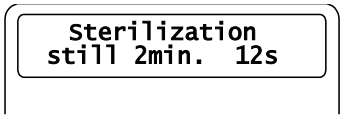
After ventilation of the chamber with the corresponding display text, the message **Universal-Program run successfully** is displayed in alternation with **Last batch number xx** and **Quit with key '+'**.

If a printer or other output media is connected to the autoclave, and the option **Immediate ioutput** is set to **Yes**, the warning **Drying stopped** is issued on the log.

Sterilization phase is finished

Sterilization phase successfully ended

The display enables you to see whether the sterilization phase has already been completed successfully.



The time left in the sterilization phase is shown in the display in alternation with the pressure and temperature.

Sterilization not successfully ended

The sterilization phase is unsuccessful if the operator or the system (responding to an error) aborts the program run.

System abort

A system abort returns the chamber to a pressure less state.

NOTE
If the program abort is brought about by the operator, a warning message is displayed. If the program is aborted by the system, an error message will be displayed.

Drying phase

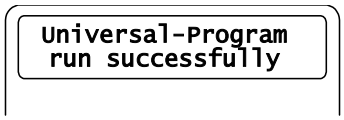
The autoclave provides excellent drying of the sterilization material. If difficult-to-dry items require better drying, you can undertake the following steps to improve drying:

Improving drying results

- Load the autoclave properly. e.g. stand the transparent and paper sterilization packaging upright.

Observe the contents of the section **Loading the autoclave** on page 20. Use a film bracket if necessary.

Program is finished



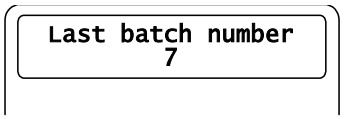
Once the program has come to an end, the chamber pressure is adapted to the surrounding pressure. When the program has ended successfully, the corresponding message will be issued on the display.

Immediate print

Activating the function immediate print outputs the log of the program run on the selected output medium (see page 29, **Chapter 5 - Logging**).

Displaying the batch number

Display the last batch number



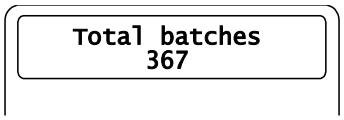
The last batch number of the day is shown on the display after every program run.

You can also arrange for the batch number to be displayed. To do so:

- Press the (+) und (-) keys simultaneously to select the setup menu **`Function.`** The display shows **`Function: last batch number`**.
- Press the (P) key to display the current daily batch number.

To return to the basic state, press the (S) key twice.

Displaying the total batch counter



You can arrange the display of the number of the batches previously recorded.

- Press the (+) und (-) keys simultaneously to select the setup menu **`Function.`** The display shows **`Function: Last batch number`**
- Navigate using the (+) or (-) keys until the display shows **`Total batches.`**
- Press the (P) key.

The display shows the current total number of batches.

- To return to the basic state, press the (S) key twice.

Removing the sterilized equipment

Danger of burns

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

- Never use force to open the door. This could damage the autoclave and/or result in the emission of hot steam.
- Use a tray jack to remove the tray.
- Never touch the sterilized equipment, the chamber or the door with bare hands. The components are hot.

Failure to observe this requirement can result in burns.

Danger of infection

- Check the packaging on the sterilized equipment for damage when removing it from the autoclave.
- Should the packaging be damaged, re-pack the sterilization material and re-sterilize it.

Failure to observe these specifications could result in unsterile instruments and could endanger the health of your patients and practice team.

Opening the door

Once the program has ended, you will be requested to **`Clear with '+'`**. Press the (+) key After hearing the click of the door being unlocked, you can open the door and remove the sterilized equipment.
If the output media are connected and **`Immediate output yes`** is selected, log output will follow automatically (see p. 31, **Automatic immediate log output**).

Danger of burns

Please observe the following regarding the door:

- The door plate in particular can be hot during and after a program run. Never touch the door plate directly. Touch only the twist grip to open the door.

Failure to observe these requirements can result in burns.

Residual condensate on the sterilized equipment

If you remove the sterilized equipment from the autoclave directly after the end of the program, it is possible that the instruments can be partially damp.
According to DIN 58953, part 7, small amounts of water on the surface of the paper bags and transparent sterilization packaging are harmless as long as they are dried 30 minutes after removal.

Storing sterile instruments

Use only standard-conform packaging for the sterilized equipment. Do not store the sterilized instruments in the treatment room. Observe the provisions of DIN 58953, part 7 and the following criteria when storing sterilized equipment:

Storage conditions

- Protected against dust e.g. in a closed instrument cupboard
- Protected from damage to their shiny surfaces
- Protected from significant temperature differences
- Protected from fluid (e.g. alcohol, disinfection fluids)

The possible length of storage depends on the type of packaging

Storage time

The maximum storage time is dependent on the packaging and the storage conditions. For standard-conform packaged sterilized equipment (protected from dust) it can amount up to six months.

Chapter 5 - Logging

This chapter informs you as to

- **How and why to document batches**
- **Which output media you can use for batch documentation**
- **How to read logs correctly**
- **How to set the date and time on the autoclave**

Batch documentation

The batch documentation acts as proof of the successful conclusion of the sterilization process and represents an obligatory part of quality assurance.
The autoclave internal log memory saves such data as the program type, batch and process parameters of the programme completed.

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

Capacity of the internal log memory

The capacity of the internal log memory is sufficient for 40 logs.
If the internal log memory is full, the oldest log will be overwritten automatically at the beginning of the next program.

If a printer is connected and the option **`Immediate output "No"`** is set (see also page 31, **Automatic immediate log output**), a safety question will be displayed before the log is overwritten. For further information, see page 30, **connecting a printer**.

Output media

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

- MELA*print* 42 log printer
- MELA*flash* CF card printer on a CF-Card
- Computer with the software MELAtrace/MELAview*
- MELA*net* Box

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

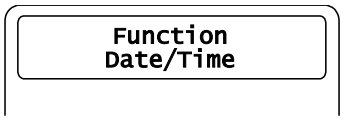
State of delivery

In its state of delivery, an option for log issue is not set on the autoclave. The following sections inform you as to how to issue logs on the specified media.

Setting the date and time

Accounting for the clock change

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



- Select the setup menu **`Function`** by pressing the (+) and (-) keys quickly and simultaneously.
  The display shows **`Function: last batch number`**.
- Navigate in the **`Function`** menu using the (+) or (-) keys until the display shows **`Function: Date/Time`**.
- Press the (P) key to confirm. The current hour is displayed.
- Choose one of the following setting possibilities using the (+) or (-)

keys: hours, minutes, seconds, day, month, year.
- To adjust the **Hours** parameter, press the (P) key to confirm.

The current value flashes on the display.

- You can increase or reduce the value using the (+) and (-) keys.
- To save the value, confirm with the (P) key.

The current value set no longer flashes on the display.

To alter the other parameters, proceed in a similar fashion.

- After ending the settings, press the (S) key to leave the menu.

The display shows **Function: Date/Time** once again.

Repeated pressing of the (S) key enables you to leave the menu and the display returns to its basic state.

Initializing the log printer MELAprint 42

Use printer as output medium

Should you wish to use the log printer MELA*print* 42 as an output medium, connect it to the autoclave as follows:

- Attach the log printer connection cable to the serial connection (RS232 interface) on the rear of the autoclave (see Fig. 1/(13)).
- Connect the power supply in accordance with the appropriate operating instructions.

In order to print logs with the log printer connected, you need to perform the following on-off settings in order to initialize the MELA*print* 42.

- If the autoclave has not yet been activated, switch it on.
- Wait until the display shows the basic position (page 13, **Operating panel**).
- Select the setup menu **Function** by pressing the (+) and (-) keys quickly and simultaneously. The display shows **Function: last batch number**.
- Navigate in the **Function** menu using the (+) or (-) keys until the display shows **Function: log output**.
- Press the (P) key to select the sub-menu **Log output – output medium**.
- Press the (P) key again. The display shows **Log output – no output medium**, if a printer has not been selected.
- Navigate using the (+) or (-) keys until the display shows **MELAprint** as the output medium.
- To confirm, press the (P) key. The display returns to the menu **Log output – output medium**.
- Press the (S) key to return to the setup menu **Function: log output**.
- After repeated pressing of the (S) key, the display returns to its basic state.

Test issue on the log printer MELAprint 42

You can perform a test issue to check the functionality of the log printer MELA*print* 42 and its communication with the autoclave.

- Select the setup menu **Function** by pressing the (+) and (-) keys quickly and simultaneously.
  The display shows **Function: last batch number**.
- Navigate using the (+) or (-) keys until the display shows **Function: log output**.
- Press the (P) key to select the sub-menu **Log output – output medium**.
- Press the (P) key to confirm.
- Navigate using the (+) or (-) keys until the display shows **Test output**.
- To start the print-out, press the (P) key.

Test output

The display shows **Output**.

- To abort the test issue or to leave the menu once the issue has occurred, press the (S) key. The display shows **Function: log output**.

Repeated pressing of the (S) key enables you to leave the menu entirely and return to the display basic state.

NOTICE

For further information of the protocol printer (for example for the duration of for he log prinouts) please refer to the respective operating instructions.

Use MELA*flash* as output medium

The MELA*flash* CF-Card printer saves the logs on the MELA*flash* CF-Card. The logs can be read out from the CF card on the practice computer using a MELA*flash* card reader.

You can also use the software MELA*trace*/MELA*view* to read out the log data.

The MELA*flash* CF card printer is connected via the serial interface just as with the log printer MELA*print* 42 (see p. 30). Set the issue media as **MELAflash**. In the autoclave set-up menu **Function**. You can obtain more detailed information in the MELA*flash* CF card printer operating instructions.

Use MELA*net* Box as output medium

Output medium
MELAnet+graphic data

The MELA*net* Box allows you to connect a MELAG autoclave to the practice or clinic computer network via an Ethernet interface. The logs generated by an autoclave during the programme run can be saved via the MELA*net* Box using an FTP server.
The MELA*net* Box also supports a small web server program which displays the status information of the autoclave connected and the settings of the MELA*net* Box via a web browser.
You can use it to display the current progress of a program run or current measurement values.
You can attach the MELA*net* Box and the log printer MELA*print* 42 via a serial interface. In the autoclave setup menu, **Function,** set **MELAnet** as the output medium. You can obtain more detailed information in the MELA*net* Box operating instructions.

Use the computer as output medium

Initializing the computer

In order to be able to use a computer as an output medium, the computer must be connected to the autoclave via the series interface. You can use the software MELA*trace*/MELA*view* to read out the logs.

Output medium
Computer

To register the computer on the autoclave, proceed as described on page 30, **Use printer as output medium**.
Ensure that the output medium **Computer** is selected in the setup menu **Function**.

Automatic immediate log output

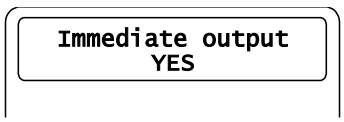
If you want to issue the associated text and graphic logs automatically after the end of a program on an output medium, use the function **Immediate output - yes**.

This is not set on the autoclave in its state of delivery.

Requirements for automatic immediate log issue after the end of a program

The following requirements must be fulfilled in order to issue logs immediately after the end of a program.

- The output media computer, the log printer MELA*print* 42 or MELA*flash* CF card printer must be connected and initialized.



The options for immediate log issue upon program end are to be set in the following way:

- Switch on the autoclave at the mains.
- Select the setup menu **`Function`** by pressing the (+) and (-) keys quickly and simultaneously. The display shows **`Function: last batch no.`**.
- Navigate using the (+) or (-) keys until the display shows **`Function: log output`** and then press the (P) key.
- Navigate using the (+) or (-) keys until the display shows the sub-menu **`Immediate output YES/NO`**.
- Press the (P) key, to switch between **`Immediate output NO/YES`**.
- To issue logs immediately, **`Immediate output YES`** must be set.
- Press the (S) key to save the settings and to leave the menu. The display shows **`Function: log output`**.
- Pressing the (S) key once again enables you to leave the menu and return to the display basic state.

NOTE

If immediate issue is not possible, for example, because the output medium activated is not connected, a warning will appear. MELAG recommends using the immediate log issue function.

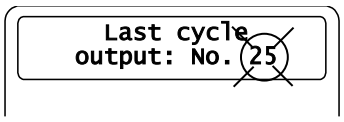
Subsequent log issue

It is possible to issue logs subsequently and independently of the time of the end of the program. You can choose whether all or only the saved logs (up to 40) are to be printed. Use the output media connected for this task e.g. the log printer.

Printing selected logs

To print the subsequently selected logs of a particular program proceed as follows:

- Select the setup menu Function by pressing the (+) or (-) keys quickly and simultaneously. The display shows **`Function: last batch number`**.
- Navigate using the (+) or (-) keys until the display shows **`Function: log output`** and then press the (P) key.
- The menu **`Log output – output medium`** is displayed.
- Navigate using the (+) or (-) keys until the display shows **`Output last cycle: No.40`** (as example No. 40).
- Press the (P) key. The current log number flashes.
- To issue a log or another cycle, navigate to the desired number using the (+) or (-) keys until you have reached the following number e.g. In this case, 25.



- Press the (P) key in order to start the selected program. The display shows **`Output.`**

After a successful issue, the display returns to its previous setting **`Output last cycle: No.25`**.

Repeat the last three steps in order to issue further logs.

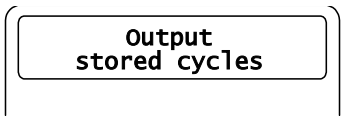
- Press the (S) key to leave the sub-menu without issuing the log.
- Press the (S) key to leave the menu after having issued the log. The display shows the menu **`Function: log output`**.

Repeated pressing of the (S) key enables you to leave the menu entirely and return to the display basic state.

Printing all saved logs

Proceed as follows to issue all the saved logs subsequently:

- Select the setup menu **`Function`** by pressing the (+) or (-) keys quickly and simultaneously.
  The display shows **`Function: last batch number`**.
- Navigate using the (+) or (-) keys until the display shows **`Function: log output`** and then press the (P) key.
- Navigate using the (+) or (-) keys until the display shows **`Output stored cycles.`**



- Press the (P) key in order to start the selected program. The display shows **`Output`**.
- Following a successful issue, the display shows **`Output stored cycles`**.
- Press the (S) key to leave the sub-menu without issuing the log..

NOTE

Interrupting the print-out is only possible by switching off the device at the mains or cutting the electricity supply to the printer.

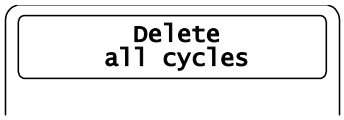
- Press the (S) key to leave the menu. The display shows the setup menu **`Function: Log output`**.

Repeated pressing of the (S) key enables you to leave the menu entirely and return to the display basic state.

Deleting the saved logs

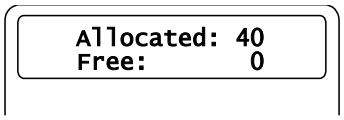
Delete the saved logs manually to suppress warning messages, e.g. **`Log memory full`** with the option **`Immediate output`** set.
The following example shows how to delete all the logs saved.

- Select the setup menu **`Function`** by pressing the (+) and (-) keys quickly and simultaneously.
  The display shows **`Function: last batch number`**
- Navigate using the (+) or (-) keys until the display shows **`Function: log output`** and then press the (P) key.
- Navigate using the (+) or (-) keys until the display shows **`Delete all cycles.`**



- Press the (P) key to delete all logs.
- To cancel the sub-menu without deleting, press the (S) key.
- Press the (P) key to leave the menu after having deleted it. The display shows **`Function: log output`**.
- Repeated pressing of the (S) key enables you to leave the menu entirely and return to the display basic state.

Displaying the log memory



If a printer or other output medium is connected and initialized, you can check how many logs have already been saved in the autoclave log memory.

Proceed as follows:

- Select the setup menu **`Function`** by pressing the (+) and (-) keys quickly and simultaneously.
  The display shows **`Function: last batch number`**.
- Navigate using the (+) or (-) keys until the display shows **`Function: log output`** and then press the (P) key.
- Navigate using the (+) or (-) keys until the display shows the number of logs saved (see image of display).
- Press the (S) key twice to leave the menu.

Reading logs correctly

Head

The head of the program log comprises the general basic information regarding the program run. This includes date, the program selected, the daily batch number and the autoclave type.

Program step values The phases of the program run are recorded whilst it runs and the values for steam pressure, temperature and time (related to the program start) are recorded.

Summary The summary indicates whether the program has been completed successfully. The values of the sterilization time recorded, the sterilization temperature and the pressure (including the maximum deviation) are also displayed.

```
----------------------------------------
          MELAG MELAtronic15 EN
----------------------------------------
Program    : Universal-Program
             134°C wrapped
Date: 19.03.2010
Time: 10:34:21    (Start)
Batch Nr.:  2
SN         : 201415EN+4560


Pre-heating       131.2 °C
AIN6: Conductivity      7 µS/cm

Program step     Pressure   Temp.    Time
                    bar      °C       min

Start               0.00     70.7   00:00
1.Fractionation
  Steam entry       1.00     97.0   02:40
  Pressure release  0.17     94.5   02:49
2.Fractionation
  Steam entry       1.00    113.8   04:29
  Pressure release  0.19    104.8   04:49
3.Fractionation
  Steam entry       1.00    120.1   06:24
  Pressure release  0.20    106.0   06:55
4.Fractionation
  Steam entry       1.01    120.5   08:33
  Pressure release  0.19    105.7   09:10
5.Fractionation
  Steam entry       1.00    120.5   10:50
  Pressure release  0.19    105.8   11:29
Heat up             2.05    134.2   15:04
Steriliz. Begin     2.05    134.2   15:04
Steriliz. End       2.19    136.1   20:34
Pressure release    0.14    107.0   21:32
Flow drying
  Drying begin      0.14    107.0   21:32
  Flow drying       0.14    107.0   21:32
  Drying pump       0.72    106.2   21:44
  Drying end        0.73     86.3   52:45
End                 0.00     85.5   53:15
----------------------------------------

        PROGRAM PROPERLY EXECUTED


Temperature 136.2  +0.4 /-0.4 °C
Pressure:   2.21 +0.04/-0.04 bar
Sterilization time:  5 min 30 s
Time: 11:27:37 (end)
--------------------------------------

17 201404560 5.15 5.05 CRC
```

Head

Program started

Current day
Time of program start
Daily batch number
Serial number

Pre-heating temperature
→Feed water →Conductivity

Program step values

Program stage phases with the associated values for steam pressure, steam temperature and time (relative to the program start).

Summary

Control message

Median sterilization temperature with max. deviations
Median sterilization temperature with max. deviations
Sterilization time maintained
Time upon program end

Information with total batch counter, factory number and device software number version no.

Figure 2: Example of a program log for a successful Universal-Program

Chapter 6 - Maintenance

This chapter informs you as to

- **How to clean the autoclave and which cleaning fluids are suitable for the task**
- **How to avoid stains**
- **What you need to observe in maintaining the autoclave**

Cleaning

Weekly check of chamber, door seal, mounting and chamber sealing face

Investigate the chamber, door seal and mounting for the load (see page 20, **Loading the autoclave**) once a week for impurities, deposits or damage.

Upon impurities

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

Warning

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

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

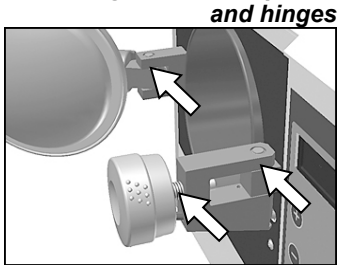
Failure to observe these provisions could result in the surfaces becoming scratched and the seal face developing leaks. This creates conditions favourable to dirt deposits and corrosion in the sterilization chamber.

Housing

Clean the housing elements with a neutral fluid cleaner or spirit.

Greasing the thread spindle and hinges

To prevent premature wear and tear, the twist grip thread spindles and hinges of the locking prong and pressure bar must always be well greased.



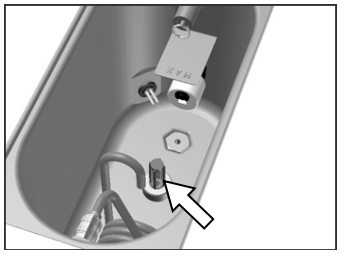
Weekly control of the internal storage tank

Check the internal storage tank every week for soiling. If necessary, clean the tank before filling it with a bottle brush and warm water with a degreaser.
Residual water should be drained off via the drain valve before cleaning.

Changing the feed water

When using the feed water circulation system the feed water must be changed at least once a week.

Cleaning the water intake filter



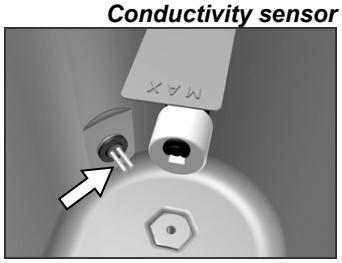
When using the feed water circulation system, you should clean the water intake filter in the storage tank on a weekly basis. When using a one-way system with an external condensate container, this should be performed monthly.

In order to clean the filter, proceed as follows:

- Empty the internal storage tank via the drain valve  (see Fig. 1/(5)).
- Unscrew the union nut and remove the filter upwards.
- Clean the filter under running water and control it for damage such as tears or holes.
- If the filter is without fault, replace it and fasten with the union nut.

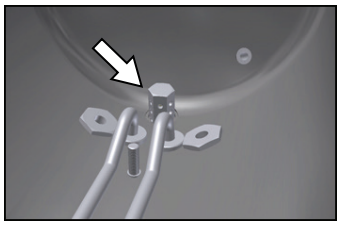
Otherwise, the filter should be replaced.

Conductivity sensor



Clean the conductivity sensor in the storage tank using alcohol and then clean the storage tank with water. Refill with fresh feed water.

Cleaning the feed water / pressure release filter in the chamber



When operating with a feed water circulation system, clean the chamber filter every three months. Operation with a one-way system requires cleaning every half year.
In order to clean the reservoir, proceed as follows:

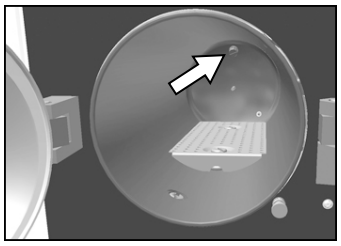
- Use the filter key to unscrew the cover plate screws in the chamber and remove the cover plate.
- Remove the filter in the chamber floor using the cropped side of the filter key.
- Clean the filter under running water and check it for damage such as tears or wear.
- Clean the clips in the chamber floor and replace the filter as long as it is in working order.
- Replace the cover plate in the chamber and tighten.

If the filter is damaged or worn, replace it.

Warning

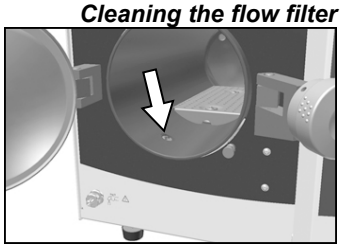
- **Never confuse it with the “pressure pump” filter.**

Cleaning the "pressure pump" filter.



When operating with a feed water circulation system, clean the chamber filter every three months. Operation with a one-way system requires cleaning every half year. Do so by unscrewing the filter and rinsing under running water.
Warning! Do not confuse it with the water intake filter.

Cleaning the flow filter



Clean the flow filter on a monthly basis by removing the filter with the filter key included within the scope of delivery and rinsing it under running water.

Avoiding the development of stains

Stain development following inappropriately cleaned instruments

Only after cleaning instruments properly prior to sterilization is it possible to avoid residue from the load or the instrument treatment from being released during sterilization. Loosened dirt residue (e.g. from disinfectants) can clog the autoclave filter, nozzles and valves and deposit themselves on the instruments and chamber as deposits and stains (see page 19, **Preparing the sterilization material**).

Stain development from extraneous rust

All steam-conducting parts of the autoclave consist of non-rusting material. This rules out the possibility of stain or rust development being caused by the autoclave. The development of rust is always extraneous rust. Incorrect instrument treatment can result in the accretion of rust even on stainless steel instruments of leading manufacturers. Often, an instrument which drops rust can suffice to cause the development of rust on another instrument or in the autoclave.
Remove foreign rust from the instruments using chlorine-free stainless steel cleaning fluid (see page 36, **Cleaning**) or send the damaged instrument to the manufacturer.

Stain development arising from poor-quality feed water

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

Always use high-quality feed water

Warning

When using feed water for steam sterilization, please observe the following:

- Only use demineralized or distilled water in accordance with DIN EN 13060, appendix C.

Failure to observe this provision can result in the formation of stains on the instruments and impaired functionality.

Changing the fuse

In the unlikely case of the device fuses activating (see Fig. 1/(11)) change them as follows:

- Switch off the autoclave at the mains and remove the plug from the socket.
- Unscrew and remove both caps on the fuse holder on the rear of the autoclave with a screwdriver or coin.
- Remove the defective replacement fuses and insert the new fuses securely in their holder.
- Re-screw the caps of the fuse holder and reconnect the autoclave to the mains.

Maintenance

Warning

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

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

Value retention and operability

Regular maintenance is vital to ensure reliable operation and value retention of the autoclave.
All function and safety-relevant components and electrical units are checked during maintenance and replaced where necessary. Maintenance is performed in accordance with the maintenance handbook pertinent to this autoclave.

Maintenance intervals

Maintenance should be performed after every 1000 program cycles or 2 years.

NOTE

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

Chapter 7 – Operating Pauses

This chapter informs you as to

- **How quickly you can begin consecutive programs**
- **What you need to observe with longer operating pauses**
- **How to decommission, transport and then recommission the device**

Frequency of sterilization

No pause times required

The standard mode of operation is the circulation system. This means that the evaporated feed water is condensed during fractionating and drawn back via the evaporator coil to the internal storage tank during pressure release. This mode of operation allows between 2-3 sterilization runs per working day.

If used more often, the evaporated water cannot condense entirely as the water in the storage tank is also subject to warming.

The excess steam then escapes via the ventilation hose on the rear of the autoclave.

To minimize steam generation, we recommend holding a longer pause between two batches.

Pause times

Longer operating pauses

When making longer operating pauses, e.g. over night or a weekend, you should switch off the autoclave and only push the door to. This relieves pressure on the door seal and protects it from premature wear and tear. This also prevents the door seal from sticking.

The following situations can occur after longer pauses:

Incident	***Possible cause***	***What you can do***
Conductivity too high	Poor feed water	Change the feed water in the internal storage tank
You cannot open the door	The door seal sticks to the seal face	Switch on the autoclave and pull strongly on the door.

Functional check after pauses

After pauses, perform the checks described in **Chapter 8 – Functional Checks** depending on the length of pause.

Decommissioning

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

- Switch off the autoclave at the mains.
- Remove the plug from the socket.
- Empty the internal storage tank.
- Remove the outlet hose to the external condensate container if you have used it.

Transport

Danger of injury

Please observe the following whilst carrying the autoclave:

- The autoclave should always be carried by two people.
- Use the correct carrying strap to carry the autoclave.
- Please observe that the distance between the bottom of the housing base plate and the setup surface is low.

Failure to observe these provisions could result in injury to the spine and/or pinching.

Warning

Please observe the following during transport, e.g. in the course of moving or despatch, or for transport within the practice:

- Empty the internal storage tank and remove the outlet hose to the external condensate container if you have used it.
- If the danger of frost is given, empty the feed pump in accordance with the service instructions (only by a service technician).
- Should you wish to leave the mountings and trays in the chamber during transport, protect the surface of the door plate. To do so, place some foam or bubble wrap between the door plate and mounting.

Close the autoclave door before moving it.

Failure to observe these provisions can result in damage to the autoclave and malfunction.

Recommissioning after relocation

When recommissioning after a move, proceed as with the first commissioning (see page 15, **Chapter 3 – Commissioning**).

Chapter 8 – Functional Checks

This chapter informs you as to

- **How the autoclave conducts the functional check automatically**
- **What forms of manual functional check are available**
- **Which functional checks you should perform in daily operation**
- **How to display the water quality**

Automatic functional checks

Process evaluation and monitoring systems

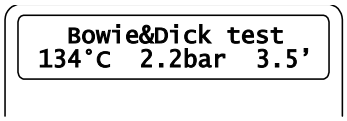
The electronic parameter control subjects the interaction of the sterilization-relevant parameters pressure, temperature and time to constant automatic monitoring.
The autoclave process evaluation system compares the process parameters during the program with each other and monitors them in terms of their threshold values.
The autoclave monitoring system checks the device components for their functionality and their plausible interaction. Should the parameters exceed pre-set threshold values, the autoclave emits warning messages or error messages. If necessary, it interrupts the program with appropriate information.
When the program has ended successfully, the corresponding message will be issued on the display.

Manual functional checks

You can follow the program run on the display via the values displayed there. You can also use the logs recorded for every program to determine the success of a program (see page 29, **Chapter 5 - Logging**).

Checks in daily operation

Bowie & Dick test



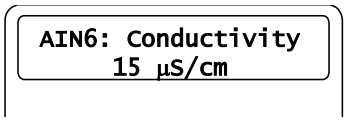
The Bowie & Dick test serves as proof of the steam penetration of porous materials such as textiles.

Specialist stockists provide various test systems for the Bowie & Dick-test. Perform the test according to the test-system manufacturer information.

How to start Bowie & Dick test program:

- Switch on the device at the mains switch. The display switches to its basic state.
- Select the Bowie & Dick test using the (P) key.
- Press the (S) key to start the Bowie & Dick test.
- Following a successful test program, the current daily batch number is displayed, alternating with the message **`Quit with key '+'.`**
- You can open the door after pressing the (+) key.

Displaying the water quality



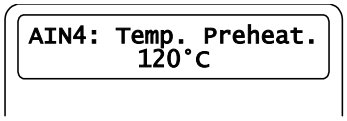
You can access the water quality on the display at any time during a current program when the autoclave is switched on.

To achieve an optimally exact measurement, the conductivity should be measured before the first sterilization at the beginning of the working day, whilst the device is still cold.

To do so, hold the (-) key depressed until the display shows the conductivity. The conductivity is displayed in µS/cm.

As soon as you have released the (-) key, the display returns to its previous state (e.g. basic state).

Pre-heating temperature of the chamber



After having pressed the (-) key shortly twice, hold depressed the second time. Instead of displaying the conductivity, you will see the chamber pre-heating temperature.

Chapter 9 – Malfunctions

This chapter informs you as to

- **The different types of messages**
- **How to react to malfunctions**
- **What you can do before contacting the hotline**
- **What you can do when the display is empty**
- **What to do when the feed water consumption is too high**
- **What to do upon bad drying results**

Warning messages

Not all messages on the display are error messages.
Warning messages are displayed when necessary. Warning messages are not error messages. They help to ensure malfunction-free operation and to recognize undesirable situations. Observe these warnings early in order to avoid malfunctions.

Error message

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

Malfunction message

Malfunction messages are issued on the display together with the malfunction number.

Malfunction messages can be issued without a program start (with the activation of the power switch or with a time-delay) and after the program start during a program run.

If a malfunction emerges during a program run, the program is aborted and pressure will be let off automatically.

Danger of infection

- Aborting a program before the drying phase means that the load is unsterile. If necessary, repack the load and repeat the sterilization for the sterilization material affected.

Failure to observe these provisions can endanger the health of your patients and practice team.

The error messages will be displayed in alternation with the current program phase (**`Pressure release`**, **`Ventilation`** or **`End`**). Following the program abort, the error message is displayed in alternation with the message **`Quit with key '-'`** and **`Stop end`**. To delete the error message, press the (-) key.

Before you call

Ensure that you have complied with all instructions relating to a warning or error message issued by the display of the autoclave. The following table contains a summary of the most important events. The events contain possible causes and the corresponding operator information.
Should you be unable to find the relevant event, or your efforts do not redress the problem, you can contact your nearest stockist or authorized

MELAG customer service provider. To enable us to give the best possible service, please have your autoclave serial number and a detailed description of the error contained in the error message to hand.

Warning	***Possible cause***	***What you can do***
Warning: door open / No start possible	Door contact is not closed upon start	Secure the door using the twist grip
Warning: No feed water / Refill feed water - No start possible	Insufficient feed water in the internal storage tank	Check the fill level of the feed water in the internal storage tank; if necessary, fill the feed water up to the MAX mark.
Feed water quality bad/ Check feed water quality	Feed water conductivity too high	**Start through repeated depressing of the (S) key still possible** Drain the storage tank using the drain valve,  clean, rinse with fresh feed water and fill to the MAX mark with feed water of the corresponding quality.
Feed water quality insufficient/No start possible	Feed water conductivity too high	**Start no longer possible:** See warning message: Poor quality of feed water
Warning: Replace sterile filter	The sterile filter is soiled or torn; Min./Max. pressure upon air drying is exceeded / undercut:	Change the sterile filter (MELAG Art. No. 20160). **NOTE** The message comes at the end of the program and in the last line of the log print-out.
Output medium is not ready	The autoclave is operating without an output medium, but one has been registered. The output medium has not been connected properly The electricity supply to the printer has been interrupted The printer is “offline“	In the menu log issue, set the option **`no output medium`** (see **Initializing the log printer MELAprint 42**). Check the correct connection of the data cable to the autoclave and the output medium. Check the electricity supply. The red LED “P“ on the log printer MELA*print* 42 must be illuminated. Set the printer to “online“ (press the “SEL“ key on the MELA*print* 42, the “SEL“ LED must illuminate green).
Log memory full	The device-internal log memory is full (max. 40 logs possible)	The message is displayed upon program start. Repeated pressing of the (S) key cancels the message and the program starts: the oldest log is deleted.

Warning	*Possible cause*	*What you can do*
	An output medium has been registered and the option **Immediate output – NO** has been set in the **Log output** menu	Set the autoclave to **Immediate output YES**; Delete the printer memory, if necessary; print all the saved logs beforehand. Unregister the output medium in the **Log output** menu and set the option **No output medium**.
Carry out maintenance	The maintenance message has been activated and the device has reached the pre-set number of charges	The message is displayed upon every program start. Repeated pressing of the (S) key removes the message and the program starts. Retain the message. Press the (S) key twice. Arrange for maintenance to be performed by the MELAG customer services / your specialist stockist customer services. **NOTE** The maintenance counter is to be reset by customer services.
Warning: Battery empty	Monitoring of the internal battery voltage has returned too low a value.	The battery is to be changed by MELAG customer services/your specialist stockist customer services.

Error message	*Possible cause*	*What you can do*
Error 2: Steam generator	Autoclave is overloaded	Maintain correct loading amounts (see p. 20, **Loading the autoclave**).
	Reduced heat production, as the mains voltage is too low	Check the on-site electrical connection. Try operating the device on a different electrical circuit.
	Loss of water following a leak or water retention and/or collection	Avoid water accretion in the sterilization material. Bowls, bakers and glasses should have the opening pointing upwards.
		Cassettes perforated on one side should have the perforations facing downwards.
		Press the overheat protection reset key. Then perform an empty run in the Quick-Program S.
		Upon repeated occurrence, inform your stockist.
Error 4: Pressure release	The pressure-release filter in the chamber is blocked	Unscrew the pressure-release filter (in the rear of the chamber floor) and check for blockage.
	With a condensate container: Kinked hose	Check the hose for kinks.
		Upon repeated occurrence, inform your stockist.
Error 8: Time basis	The maximum difference between the program run time and the internal computer clock has been exceeded	Upon repeated occurrence, inform your stockist
Error 9: Door open!	The door twist grip was not closed tightly enough before the program start. The door contact has opened during a program	Screw the twist grip tightly shut. Correct display message: **`Door locked`**.
		Upon repeated occurrence, inform your stockist.
Error 10: Overheated Steam generator	The capillary tube regulator “level control“ is open during program start (error message directly after the start) or during a program run (by the end of sterilization) if the monitoring time is exceeded until the time at which the capillary tube regulator is reset (by re-filling feed water).	This error message can be generated following a program abort and direct re-start. Repeat after a two minute pause.
		Upon repeated occurrence, inform your stockist.
Error 14: No feed water		See warning message **`Attention no feed water`**. This error message appears after a program has been started.
Error 18: Sensor: …input …	The internal device check of the temperature, pressure or conductivity sensors produced too great a deviation. The message can appear when the device is switched on or during a program run.	Upon repeated occurrence, inform your stockist.
Error 21: Pre-heating	The monitoring time between activation of the pre-heating and the temperature being reached has been exceeded	Upon repeated occurrance, set the option **`Automatic pre-heating NO`** (see 23, **Selecting automatic pre-heating**) and inform your stockist.

Error message	*Possible cause*	*What you can do*
Error 22: Overheated Pre-heating	The maximum pre-heating temperature has been exceeded	Upon repeated occurrance, set the option **`Automatic pre-heating NO`** and inform your stockist.
Error 23: Flow	The monitoring time for pressure reduction in the outflow process has been exceeded during fractionating The flow filter is soiled	Check the flow filter located in the chamber floor (immediately behind the door). Upon repeated occurrence, inform your stockist.
Error 26: A/D conversion	The maximum permissible deviation of the internal computer signal preparation (A/D conversion) was exceeded	Upon repeated occurrence, inform your stockist.
Error 32: Power loss	The operating voltage outage after a program start	The error message is issued after the operating voltage is restored. Check all on-site installations. If you are unable to locate a fault, inform MELAG customer services.
Error 33: Pressure loss	The maximum runtime of the steam generator for achieving control pressure was exceeded	Upon repeated occurrence, inform your stockist.
Error 34: Sterilization TU1	Minimum permissible sterilization temperature has been undercut (temperature sensor 1)	Operate autoclave with smaller load. Control the door seal for wear, change if necessary. Upon repeated occurrence, inform your stockist.
Error 35: Sterilization TO1	Maximum permissible sterilization temperature has been exceeded (temperature sensor 1)	Upon repeated occurrence, inform your stockist.
Error 36: Sterilization PU	Minimum sterilization pressure has been undercut	Operate autoclave with smaller load. Control the door seal for wear, change if necessary. Upon repeated occurrence, inform your stockist.
Error 37: Sterilization PO	Maximum permissible sterilization pressure has been exceeded	Upon repeated occurrence, inform your stockist.
Error 38: Sterilization TD1	Maximum permissible difference between theoretical temperature, calculated from the printer sensor signal and the temperature measured at temperature sensor 1 has been exceeded	Upon repeated occurrence, inform your stockist.
Error 41: Flow drying	The flow filter is soiled	Check the flow filter located in the chamber floor (immediately behind the door). Upon repeated occurrence, inform your stockist.
Error 42: Drying pressure pump	The sterile filter is soiled	Check the sterile filter, replace if necessary. Upon repeated occurrence, inform your stockist.

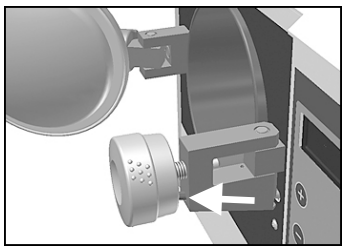
Empty display

The autoclave display remains empty after being switched on.

What you can do

- Check whether the mains plug has been inserted correctly in the socket.
- Check the mains voltage at the socket.
- If necessary, replace both device fuses on the rear of the autoclave (see Fig. 1/(11)).

The door lock is jammed



Depending on the position of the twist grip, it is possible that the locking pin can become stuck fast, so that it cannot be pulled back automatically as per normal.

Turning the twist grip lightly releases it.

Please observe that the door can only be opened when the autoclave is switched on.

Leaks in the door

If steam should emerge from the door area upon program start, proceeds as follows:

Check the door seal and the chamber flange for soiling and clean if necessary.

If the door seal is recognizably damaged, it should be replaced.

Should this occur repeatedly, inform your stockist technician or MELAG customer services.

NOTE

To avoid leaks, always screw the door tight before starting a program, independently of the display message "door closed".

Too high feed water consumption

Operation in a circulation system

If you do not have an external condensate container (i.e. the autoclave is being operated in circulation system), incomplete condensation leads to increased water consumption.
A possible cause for incomplete condensation is frequent sterilization, as the water in the storage tank is subject to repeated warming.

Operation in a one-way system

If the autoclave is operated in a feed water one-way operation, feed water consumption is dependent on the program and load.

What you can do

- Check for the level set-up of the autoclave.
- The base of the chamber must be free. Remove any instruments, filter paper or other objects which have fallen onto the chamber floor. The condensate reflux may be blocked.

Bad drying results

In addition to an orderly device function, the drying depends to a large extent on the correct set-up and loading of the autoclave.

What you can do

- Check for the level set-up of the autoclave.

- The base of the chamber must be free. Remove any instruments, filter paper or other objects which have fallen onto the chamber floor. Ensure that the autoclave is loaded correctly (see page 20, **Loading the autoclave**).
- The chamber filter is blocked. Check and clean this where necessary.
- Do not overload the autoclave. Please ensure that there are no textiles in direct contact with the chamber wall and floor.
- Activate the pre-heating function (see p. **Selecting automatic pre-heating**).

Technical Data

Model name	MELA*tronic 15 EN+*
Device dimensions (WxHxD)	44 x 33 x 50 cm (depths without grip)
Chamber (Ø x D)	15 x 38 cm
Volume (chamber)	7 Litres
Volume (storage tank)	3 Litres
Weight (empty)	22 kg
Electrical connection	220-240V*[1], 50/60Hz, 6,5A 1500W
Device fuse	2 x 16A gRL
Heat emission	2,9 MJ[2]
Noise emission	Sound pressure level @1m clearance, < 65db (A)
Altitude	up to 2000 m
Surrounding temperature	5 – 40 °C
Relative humidity	Max. amount to 80% at 31 °C, decreasing in a linear fashion up to a relative humidity of 50% at 40 °C.
Installation category	II
Feed water quality	Demineralized water in accordance with DIN EN 1360, Appendix C
Max. load	***Instruments*** 2 kg unwrapped instruments, 1 kg single wrapped instruments ***Textiles*** 150 g unwrapped and wrapped textiles
Energy consumption during a program	Universal-Program 250 Wh Quick-Program S: 200 Wh Gentle-Program: 300 Wh Prion-Program: 350 Wh
Energy use standby	130 Wh
Degree of soiling	Category 2
Degree of protection (following IEC 60529)	IP20
CE mark	CE 0197, CE 0035

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

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

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

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

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

CF-Card
compact Flash card; a memory card for digital data 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.

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

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.

Contamination
here: The impurification of the sterilizer load through undesirable outside or damaging materials

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

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

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

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

DIN EN 868-8
standard – packaging materials and systems for medical products requiring sterilization

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

DIN EN ISO 11607-1
standard – materials requirements, Sterile barrier systems and packaging systems; this standard represents the result of the harmonization of EN 868 part 1 and the international standard DIN EN ISO 11607

DIN EN 13060
standard – Small steam sterilizers

Display
display panel on electronic devices for communicating information. Here: Operator panel graphical display

Dynamic Sterilization steam test
serves to prove that the rate of pressure variations during a sterilization cycle does not exceed a particular value which could result in the damage of the packaging material.[DIN EN 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.
[DIN EN 13060] the shortest period, which expands explosively.

Evacuation
creation of a vacuum in a vessel

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

Flow drying
drying in which the dampness of the chamber is removed using mechanically generated air flow, usually using heat

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 autoclave 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.

Hollow body B
→simple hollow items

Initialization
creating a specific starting situation of the software upon starting

Integrated steam penetration
the steam generator is located directly in the autoclave– and not in a separate unit space as with a large autoclave.

LED
Light Emitting Diode: Semi-conductor diode which illuminates upon current flow. LEDs are predominantly used in device status displays e.g. upon hard drive access.

Lubricant
Instrument oil or instrument milk

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 DIN EN 13060 in order to be able to sterilize them. [DIN 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 small components
made of materials which are able to absorb fluids

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 DIN EN 13060 [DIN EN 13060]

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

Pulsating over-pressure drying
drying during which the change between air intake and discharge removes the dampness in the sterilization chamber and on the sterilizing material.

RKI
Robert Koch Institute

Self-Monitoring-System
→Process evaluation system

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

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

Software
non-material component of IT systems e.g. a computer program

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)

Appendix A - Accessories

	Article	*Ordering number**
Tray mount	Mount for 3 trays	40018
Sterilization container with a single-use paper filter in accordance with DIN EN 868-8	15K depth / width / height in cm: 18 / 12 / 4,5	01151
	15M depth / width / height in cm: 35 / 12 / 4,5	01152
	15G depth / width / height in cm: 35 / 12 / 8	01153
Trays	Tray (WxD) 12 x 35 cm	00150
For the documentation	MELA*flash* CF card printer with CF card and card reader	01039
	MELA*print* 42 log printer	01042
	MELA*net* Box	40296
Other	External condensate container	00356
	MELAjet Sprühpistole	27300
Spare parts	Device fuses 16A /gRL	57592
	Sterile filter	20160
	Filter for feed water	25070
	Stopper for sterile filter	74050
	Filter with sieve insert	34010
	Filter drying	70390
	Filter in chamber	38150
	Door gasket	32150
	Key for filter	15551
	Grease for door locks	24355

*All articles listed are available via your specialist stockist