

User Manual

Autoclave

Vacuklav[®] 23 B+ Vacuklav[®] 31 B+

as of software version 4.06



Dear doctor,

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

Since 1951, MELAG began as a medium-sized family-run enterprise to specialise in the manufacture of sterilization equipment for medical practices. In the meantime our company has grown into one of the world's leading producers of sterilization equipment. Verification of its success has been the sale of more than 450,000 MELAG units worldwide, attesting to the high quality of our sterilizers, which are exclusively made in Germany.

This autoclave has also been manufactured and tested according to the most stringent quality criteria. Nevertheless, please read the User Manual carefully before the initial start-up of the device. The long-term serviceability and the retention of value of your autoclave depend primarily on the careful preparation of the instruments and the regular maintenance of the device.

MELAG - General Management and employees

For physicians, physician's assistants, and service personnel

Please read this User Manual before you start operation of the autoclave. The instructions contain important safety precautions. Make sure to keep the User Manual near to the autoclave. The instructions are a part of the product.

User Manual of Vacuklav[®]23 B+, Vacuklav[®]31 B+

Valid for Vacuklav[®]23 B+, Vacuklav[®]31 B+
as of software version 4.06

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Subject to technical changes




Foreword

Thank you for deciding to buy this Pro Class MELAG autoclave.

This User Manual describes both the autoclaves Vacuklav[®] 23 B+ and Vacuklav[®] 31 B+. They are identical except for their chamber depth and device depth.

Device name	The device name "autoclave" is used in this User Manual to designate the steam sterilizers Vacuklav [®] 23 B+ and Vacuklav [®] 31 B+.
User Manual	The User Manual contains important safety instructions and information which you need to operate the autoclave. Read these instructions carefully and thoroughly in proper sequence.
Avoid dangers	Please read all the safety instructions attentively before using the autoclave.

About this manual

Symbol	Meaning	Explanation
 Danger!	Risk to health	Indicates a dangerous situation which if not avoided could entail slight to life-threatening injuries.
 Warning!	Observe without fail	Indicates a dangerous situation which if not avoided could entail damage to the instruments, the practice equipment or the autoclave.
	Important information	Indicates important information.

Example of emphasis	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 User Manual.
Figure 1/(5)	Cross-reference	Reference to a detail in a figure – in the example, to Part No. 5 in Figure 1.



Safety instructions

To operate the autoclave, pay attention to the following safety instructions given below and in the individual chapters of this User Manual.

Instruction

Mains cable and power plug

Setting up, installation, commissioning

Preparation and sterilization of textiles and instruments

Program termination

Removal of the items to be sterilized

Maintenance

Carrying the autoclave

Errors

- Do not sterilize any liquids with this autoclave.
- Never damage or change the mains cable or power plug.
- Never operate the autoclave if the mains cable or power plug are damaged.
- Never pull on the mains cable to take it out of the socket. Always take hold of the power plug itself.
- Only have the autoclave set up, installed, and commissioned by people authorised by MELAG.
- Only operate the autoclave in areas which are not subject to explosion hazards.
- The electric connections and connections for feed water and used water may only be completed by a specialist technician.
- Follow the instructions of the textile and instrument manufacturers for preparing and sterilizing textiles and instruments.
- Observe the relevant standards and directives for the preparation and sterilization of textiles and instruments, e.g. →RKI [Robert Koch Institute] and →DGSV [German Society for Sterile Supply].
- Only use wrapping materials and systems which are suitable for steam sterilization according to the manufacturer's information.
- Take heed that when opening the door after terminating a running program, hot water steam can escape out of the chamber, depending on when the program was terminated.
- Depending on the time of the program termination, the load might not be sterile. Observe the clear instructions shown on the →display of the autoclave. If necessary, sterilize the affected →objects after rewrapping.
- Never open the door by force.
- Use a tray lifter to remove the tray. Never touch the →sterilized items, the chamber or the door with unprotected hands. The parts are hot.
- Check the wrapping of the sterilized objects for damage when removing them from the autoclave. If a wrapping is damaged, wrap the object again and re-sterilize it.
- Have the maintenance done only by →authorized persons.
- Two people are necessary to carry the autoclave.
- Use a suitable carrying strap to transport the autoclave.
- If repeated error messages occur while operating the autoclave, turn the device off and notify your specialist dealer.
- Only have the autoclave repaired by →authorized persons.

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Chapter 1 – Performance Specification

In this chapter you learn

- Under which conditions and for which purpose you should use this autoclave
- What benefit you can achieve by using this autoclave
- Which sterilization programs you can use

Proper use

Application area

The autoclave is intended for use in the medical field, e.g. in clinics, and in physician and dental practices.

Sterilization tasks

According to →DIN EN 13060 this autoclave is considered a Class B sterilizer. It is suited as a universal autoclave for demanding sterilization tasks. For instance, you can sterilize narrow-bore instruments and transmission instruments – wrapped or unwrapped – and larger quantities of textiles.



Danger of burning!

Observe the following instructions for using the autoclave:

- Do not sterilize any liquids with this autoclave. It is not approved for the sterilization of liquids.

In case of non-observance, the consequences could be →delayed boiling, damage to the autoclave and burns.



Warning!

- Use the autoclave only for the intended purposes outlined in the related technical documents and only in connection with the devices and components approved by MELAG.
- The sterilization of instruments and textiles with this autoclave, like the foregoing instrument preparation, is only to be done by competent personnel.
- Only use instruments, wrappings and textiles which are suitable for steam sterilization according to the manufacturer's information.

In case of non-observance the consequences can entail damage to the autoclave and/or to the →items to be sterilized.

User benefit

Universal use

The autoclave sterilizes on the basis of the →fractionated pre-vacuum method. This ensures the complete and effective wetting or penetration of the →items to be sterilized with saturated steam. This method makes it possible to sterilize all kinds of loads which occur in a physician's medical practice.

**Large quantities
Low time expenditure
No pause times
Overheating protection**

To generate the sterilization steam, the autoclave uses a →separate steam generator. At program start, steam is generated and conducted into the sterilization chamber. A defined pressure and a prescribed temperature is thereby given. The sterilization chamber is protected from overheating and you can consecutively sterilize large quantities of instruments or textiles very rapidly and achieve excellent drying results.

Automatic pre-heating

The cold chamber is preheated on activation of preheating or can be maintained at a specific temperature between two sterilizations.

	This shortens the program time periods and reduces the formation of condensate to give improved drying results.
<i>Clean feed water according to VDE0510</i>	The autoclave functions according to the feed water one-way system. This means that it uses fresh purified →feed water for every sterilization run. The quality of the feed water is monitored via integrated →conductivity measurement. This prevents stains on instruments and soiling of the autoclave, assuming the instruments have been carefully prepared.
<i>Automatic feed water supply</i>	The →feed water for generating the steam is automatically supplied via an internal water storage tank or a water treatment unit (e.g. MELAdem® 40, MELAdem® 47).
<i>Optimal drying for wrapped items to be sterilized</i>	The drying of the →sterilizing materials is carried out with the post-vacuum method (→vacuum drying). This way you achieve optimal drying results for wrapped objects as well.
<i>Optimized total operating time</i>	The autoclave works with an →electronic parameter control. This way the autoclave optimizes the total operating time of a program depending on the load.
<i>High safety with extensive safety devices</i>	<p>The autoclave verifies pressure and temperature in the sterilization chamber at all times and its door locking system does not permit opening the door when there is overpressure in the chamber.</p> <p>A →process evaluation system is integrated in the electronics of the autoclave. It monitors the process parameters such as temperature, time and pressure during a program. It monitors the parameters with respect to their limit values at activation and control and guarantees a safe and successful sterilization.</p> <p>If one or more parameters are above or fall below the determined limit values, the autoclave outputs a warning or fault messages and, if necessary, aborts the program. In the event of an automatic program abort, observe the information on the display.</p>
<i>Additional function check</i>	<p>With the help of the test programs, you can conduct an additional function check at any time.</p> <p>Use the vacuum test to check the autoclave for leaks in the steam system.</p> <p>With the →Bowie & Dick Test, you can verify the autoclave for sufficient steam penetration of porous sterilizing materials (e.g. textiles).</p> <p>With →Conductivity measurement, you can verify the water quality of the feed water.</p>
<i>Effective batch documentation</i>	<p>The autoclave has an internal log memory which can save up to 40 program cycles. All data of the completed programs are automatically stored here.</p> <p>You can read out the internal log memory immediately after the end of the program, or at a later time.</p>

Overview of sterilization programs

Type tests	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Program type as per →DIN EN 13060	Type B	Type B	Type S	Type B	Type B
→Dynamic pressure test of the sterilization chamber	X	X	X	X	X
→Air leak	X	X	X	X	X
→Empty chamber test	X	X	X	X	X
→Solid load	X	X	X	X	X
→Porous partial load	X			X	X
→Porous full load	X			X	X
→Hollow body B			X		
→Hollow body A	X	X		X	X
→Simple wrapping	X	X		X	X
→Multiple wrapping	X			X	X
Drying →solid load	X	X	X	X	X
Drying →porous load	X			X	X
Sterilization temperature	134°C	134°C	134°C	121°C	134°C
Sterilization pressure	2 bar	2 bar	2 bar	1 bar	2 bar
Sterilization time	5.5 min.	3.5 min.	3.5 min	20.5 min.	20.5 min.
X = Conformity with all applicable sections of the standard →DIN EN 13060					

Chapter 2 – Device Description

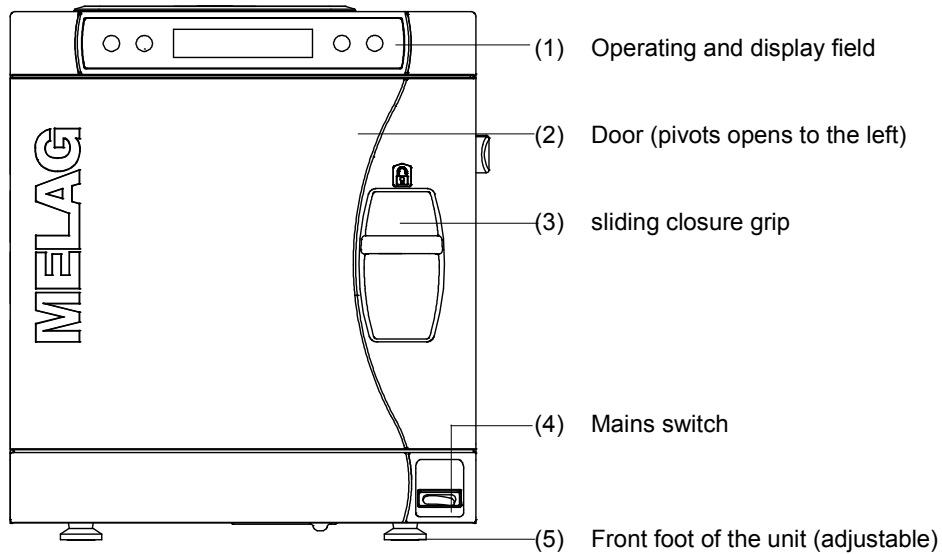
In this chapter you learn

- Which components are included in the standard scope of delivery
- Which components the autoclave contains
- What safety devices the autoclave has
- How the operating elements are designed and how you should use them
- How the menus of the user interface are structured
- What kind of water supply the autoclave needs

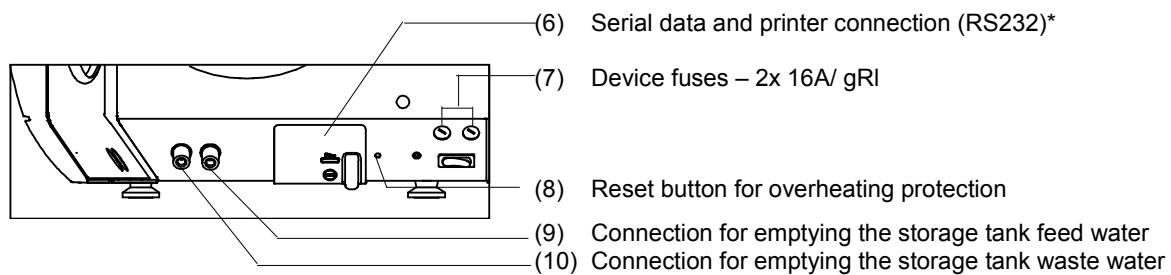
Scope of delivery	
<i>Standard scope of delivery</i>	<ul style="list-style-type: none"> ▪ Vacuklav®23 B+ or Vacuklav®31 B+ ▪ User Manual ▪ Technical Manual ▪ Warranty certificate ▪ Manufacturer's inspection report ▪ Pressure device directive certificate ▪ Record of installation and setting up ▪ 1 Mounting for trays or cassettes ▪ 1 hose for draining the internal storage tank ▪ 1 TORX wrench for removing the carrying strap ▪ 1 lever for emergency unlocking of the door ▪ 1 tank filter key ▪ 2 replacement device fuses on the inside door of the autoclaves
<i>As option</i>	<ul style="list-style-type: none"> ▪ Trays ▪ Tray lifter ▪ Standard tray cassette and lifter ▪ Additional tray mounts ▪ Log printer MELAprint® 42 ▪ MELAflash CF card Printer with CF card and card reader ▪ MELAnet Box

Device views

Front side



Front side below with opened door



*hidden behind the white cover

Back side

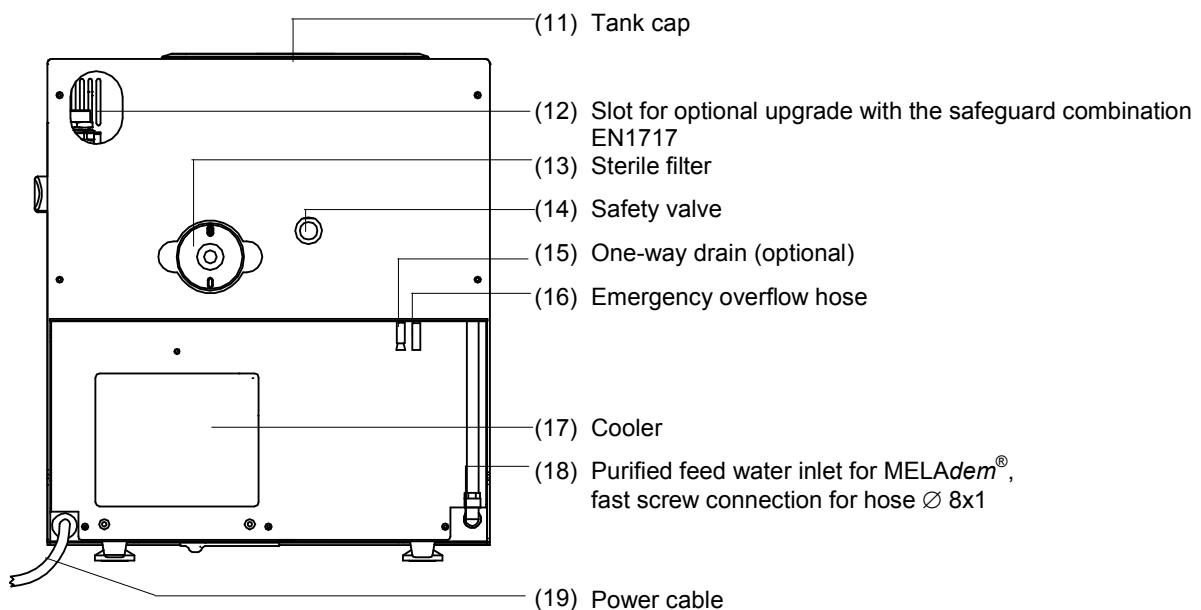


Fig. 1: Device views

Interior view

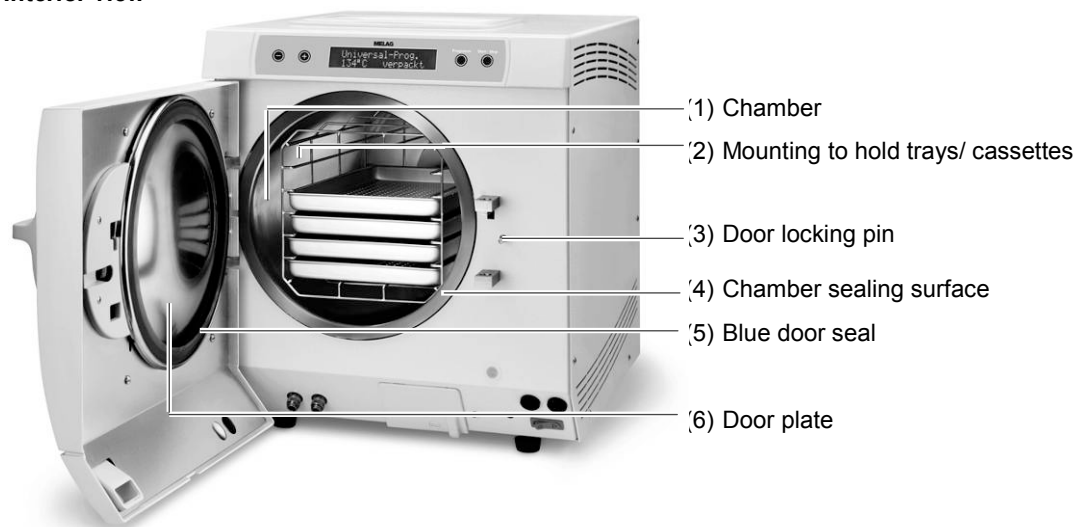


Fig. 2: Interior view

Effective capacity

Device type	Diameter	Depth	Volume
Vacuklav [®] 23 B+	Ø25 cm	45 cm	22 litres
Vacuklav [®] 31 B+	Ø 25 cm	35 cm	18 litres

Mountings for the load

The autoclave is always delivered with a mounting to hold trays or cassettes.

The mounting (A) is standard and can hold either five trays or three standard tray cassettes rotated by 90°.

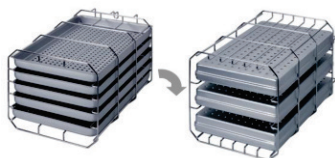


Fig. 3: Mounting A



Fig. 4: Mounting B

The mounting (B) can hold four standard tray cassettes or four trays.

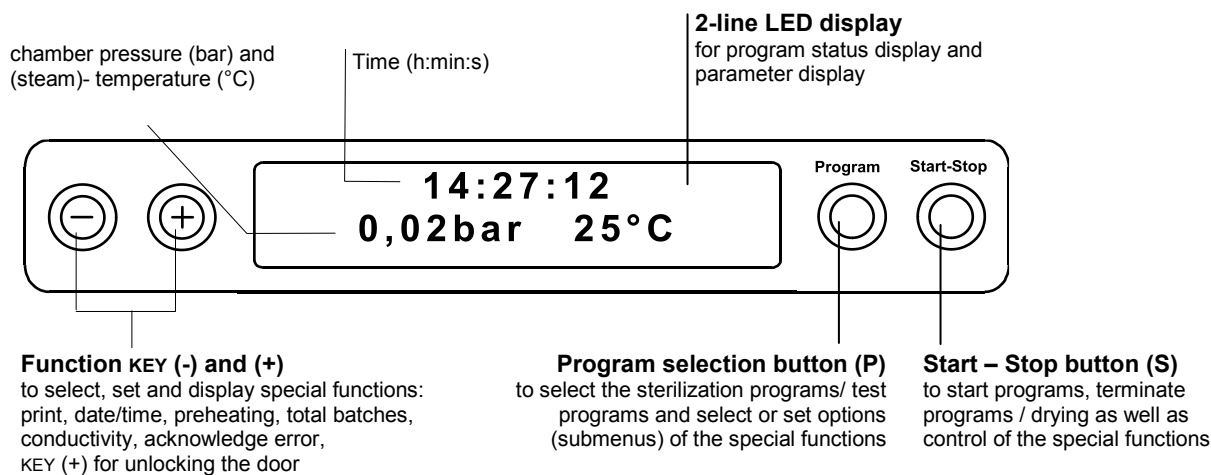


Fig. 5: Mounting D

The mounting (D) can hold two high cassettes (e.g. for implant cassettes) or four trays rotated by 90°.

Control panel

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



Initial state

The display switches to the initial state after every switch-on, where the current time and the chamber pressure in bar and the (steam) temperature in °C is displayed.

Supply with feed water

The autoclave requires →demineralized or →distilled →feed water for steam production according to →VDE 0510. The feed water supply is provided either by an external water storage tank or with a water treatment unit (e.g. MELAdem® 40/ MELAdem® 47). The autoclave automatically sucks in the feed water.

Feed water with internal storage tank

If you employ the internal storage tank for the feed water supply, you must fill it manually from time to time. At the given point in time, the autoclave outputs an appropriate message. Only use water according to →VDE 0510 as →feed water.

Internal storage tank

The internal storage tank holds maximum 5 litres. This quantity of →feed water suffices for up to 7 sterilizations.

Distilling unit MELAdest® 65

With the MELAdest® 65 distilling unit, you can produce →feed water in the practice cost-effectively.

Feed water via water treatment system

A water treatment unit is connected to the domestic water supply. It produces the →feed water required for generating the steam for the autoclave. The purified feed water connection for the autoclave is directly connected to the water treatment unit.

If you use a water treatment unit, then there is always sufficient feed water available. You no longer have to manually fill the water storage tank.

The waste water can either be collected in an internal storage tank and manually emptied or automatically drained via the one-way drain.

***Water treatment units
MELAdem® 40 and
MELAdem® 47***



The water treatment units MELAdem® 40 and MELAdem® 47 produce the optimal purified feed water quality for the autoclave. The selection of the respective unit depends on the number of sterilizations per day and the respective loads. Both MELAG autoclaves can be supplemented with a water treatment unit.

NOTICE:

Please first consult with MELAG if you would like to employ water treatment units of other manufacturers.

Chapter 3 – Initial start-up

In this chapter you learn

- Who may set up, install and start up the autoclave
 - Which prerequisites you must create for setting up, installing and starting up the autoclave
-

Conditions for setting up, installing and starting up

- Only have the autoclave set up, installed, and started up by people →authorized by MELAG.



- According to the currently valid VDE standards, this device is not suitable for use in areas subject to explosion hazards.
- The autoclave is intended for use outside the patient environment. The minimum distance to the treatment area must have a radius of at least 1.5 metres.

Damages to the autoclave and/or injuries can occur in case this precaution is not observed.

Set-up location requirements

Location

Set up the autoclave in a dry and dustproof location. The air humidity should be 30% to 60% and the ambient temperature 16° to 26 °C.

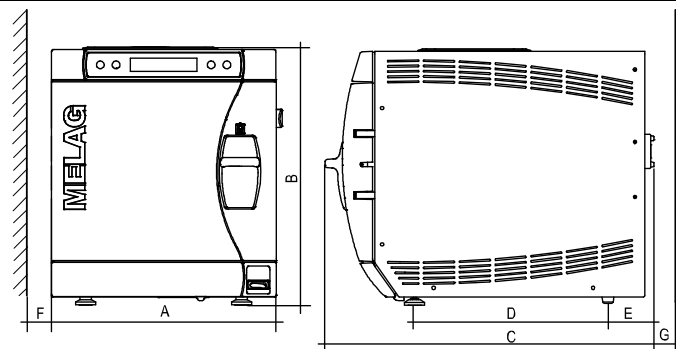


- Without fail, keep the specified distance free to the surrounding surfaces at the sides and above the autoclave.

Non-observance can lead to heat accumulation. This could adversely affect the function of the autoclave and entail the shortening of the vacuum pump's service life and result in extended program times.

Distance to the surrounding surfaces

The distance to the surrounding surfaces must be at least 5 centimetres on both sides and 10 centimetres at the back side. The autoclave should be freely accessible from above, so that the built-in storage tank can be filled and a good ventilation is guaranteed.

Space requirements			Vacuklav® 23 B	Vacuklav® 31 B+
	Width	A= 42.5 cm	A= 42.5 cm	
	Height	B= 48.5 cm	B= 48.5 cm	
	Depth	C= 75.5 cm	C= 63 cm	
		D= 49.5 cm	D= 37 cm	
		E= 8.5 cm	E= 8.5 cm	
		F= 5 cm	F= 5 cm	
		G= 10 cm	G= 10 cm	

maximum acoustic power for Vacuklav® 23 B+ and Vacuklav® 31 B+: < 65db (A)

Additional space for feed water supply



Other than for the autoclave, the water treatment unit for the feed water supply require space.

NOTICE:

In no case may you subject the water storage tank to sunlight. This way you avoid algae formation.
The maximum suction height from the external storage tank is 1.5 metres.

Space requirement for water treatment unit

MELAdem® 40

- can be directly hung on to the autoclave on the side
- The attachment can be next to the autoclave or above or below the autoclave

MELAdem® 47

- Attachment next to the autoclave or above or below the autoclave (e.g. lower cabinet)
- delivered with water storage tank

Water treatment unit	Width	Height	Depth	Diameter
MELAdem® 40	32 cm	35 cm	15 cm	
MELAdem® 47 module housing	39 cm	47 cm	15 cm	
MELAdem® 47 water storage tank		51 cm		Ø 24 cm

Connections required



- The electric connections and connections for feed water and used water may only be completed by a specialist technician.

Non-observance could lead to a short-circuit and/or fire and/or water damage and/or electrical shock. Serious injuries could be the consequence.

Electrical connection

Provide the following electrical connections for the autoclave:

- Electric circuit with 220V - 240 V and 50/60 Hz
- 16 A separate fuse protection – at least Automat Type B
- Protection from leakage current 30 mA

Connected load

as software version 4.07	2100 W for Vacuklav®23 B+ / 31 B+
software version 4.06	2500 W for Vacuklav®23 B+ 2400 W for Vacuklav®23 B+

**NOTICE:**

In order to prevent water damage, MELAG recommends the use of a leak monitor, e.g. water stop valve from MELAG (Art. No. 01056).

Waste-water drain

In order to attach the autoclave to the effluent pipe, you can order an upgrade set (MELAG Art.-No. 26695) from MELAG. The waste water is collected in the water storage tank (waste water side) and flows through the one-way outflow hose into the flush siphon, using the MELAG double-chamber siphon (Art. No. 266359). The drain must be located at least 30 cm beneath the autoclave.

**NOTICE:**

The waste-water hose must be laid dip-free with continuous descent. For waste-water paths which are longer than two metres we recommend a fixed laying of HT (high temperature) piping by a specialised installation firm.



Observe the following precautionary measures when handling the mains cable and power plug:

- Never splice or modify the mains cable.
- Never bend or twist the mains cable.
- Never pull on the mains cable to take it out of the socket. Always take hold of the power plug itself.
- Never place any heavy objects on the mains cable.
- Never run the mains cable over places where it could be squeezed (e.g. doors or windows).
- Do not run the mains cable along a heat source.
- Do not use any nails, staples or similar objects to fixate a cable.

If the mains cable or the power plug is damaged, turn off the autoclave. Mains cables or power plugs may only be replaced by →authorised persons.

If these points are not observed, the cable or plug can be damaged and/or a fire or electrical shock might occur. Serious injuries could be the consequence.

Insert power plug into the socket

Plug the power plug into the socket.

Prerequisites for initial start-up

The following prerequisites must be satisfied for initial start-up:

- The feed water supply must be secured.
- The power supply of the autoclave must be assured.

Record of installation and setting up



NOTICE:

As documentation of proper setting up, installation and setting up as well as for your warranty claim, the record of installation must be filled out by the person responsible and a copy sent to MELAG.

Switch on autoclave

Switch on mains **After switching on**

Turn the mains switch on to power the autoclave (page 10, **Fig. 1/(4)**).

- After switching on the autoclave with the mains switch, the →display shows in alternation to the initial state the message **Unlocking door with button (+)**, if the door is closed.

Directly after having switched on the autoclave and before initial start-up, remove the trays and accessories from the chamber.

- Press the **KEY (+)** to unlock the door. After pressing the key you can open the door

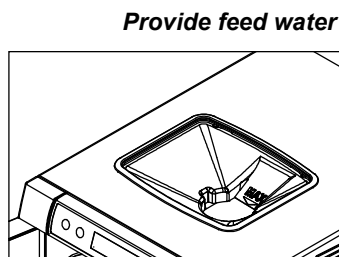
Chapter 4 – Sterilization

In this chapter you learn

- Which prerequisites should be created for a smoothly-running sterilization
 - How to switch between internal and external feed water supply
 - What you should observe when preparing the items to be sterilized
 - How to correctly load the autoclave
 - Which programs you should use for what
 - How you start a program
 - Which stages a program runs through
 - How to cancel a program
 - How to recognise when the sterilization is successfully finished
 - What you can do to improve the drying results
 - What you must consider when removing the items to be sterilized
-

Create prerequisites

Create the prerequisites for a smooth and successful sterilization process as follows:



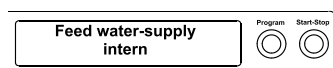
- If you use an internal storage tank for the feed water supply, fill this with feed water of the respective quality (see page 36, **Use qualitatively high-grade water**). You can use the removable funnel insert to conveniently fill fresh feed water into the right chamber of the storage tank up to the MAX mark. Simply remove the filter for cleaning.
- If you employ a water treatment system, e.g. MELAdem® 40, MELAdem® 47, and the water feed is closed, then open it up. If the water storage tank of the MELAdem® 47 is empty, turn the water feed tap on at least one hour before the sterilization..

Switching on

- If the autoclave is still not switched on, switch it at the mains switch (page 10, Fig. 1/(4)). (See as of page 17, **Switch on autoclave**).

Select feed water supply

Depending on whether the feed water should be supplied from the internal storage tank or whether you employ a water treatment unit for the feed water supply, select the appropriate setting on the display.



- Select the setup menu **function** by simultaneous brief pressing of the KEYS (+) and (-). The display shows **Function: Last batch number..**
- Navigate with the KEY (+) or (-), up to the display **Function: Feed water-supply.**
- Press the KEY (P). The currently set option appears on the display, e.g. **Feed water-supply - intern.**
- To set the value to **Feed water-supply - extern**, press the KEY (P) again.

- In order to save the setting and to leave the menu, press the KEY (S).
- By again pressing the Key (S), you completely leave the menu and return to the starting position of the display.

At initial delivery, the **Feed water-supply** is set to **intern**.

Prepare items to be sterilized

A significant prerequisite for safe disinfection and sterilization of →sterilizing materials is the appropriate preparation, i.e. cleaning and maintenance of the sterilizing materials according to the manufacturer's instructions. Furthermore the materials, cleaning agents and processing procedure employed are of significance.



NOTICE:

If possible, sterilize textiles and instruments separately from each other in separate sterilization containers or sterilization packages. This way you achieve improved drying results.

Textiles



Danger!

Observe the following instructions for treating textiles and putting the textiles into sterilization containers:

- Comply with the instructions of the textile manufacturer for treatment and sterilization and observe relevant standards and directives.
- Adjust the folds of the textiles parallel to each other.
- Stack the textiles in the sterilization containers vertically if possible, and not too closely together, so that flow channels can form.
- Retain the vertical stacking method when you pack the textiles in sterilization containers.
- If textile packages do not stay together, wrap the textiles in sterilization paper.
- Sterilize only dry textiles.
- The textiles may have no direct contact to ground and walls of the sterilization chamber, otherwise they absorb →condensate.

In case of non-observance, the steam penetration of the textiles can be obstructed and/or bad drying results can result. Unsterile textiles could be the consequence. This could mean endangering the health of the patient and the practice team.

Instruments**Danger of infection!**

Observe the following instructions for treating used and brand new instruments:

- Follow without fail the instructions of the instruments manufacturer for treatment and sterilization, and observe the relevant standards and directives of your country.
- Clean the instruments very thoroughly, for instance with the help of a thermal disinfectant.
- After disinfection and cleaning, rinse the instruments if possible with →demineralized or →distilled water and subsequently thoroughly dry the instruments with a clean, non-fuzzing cloth.
- Employ only cleaning materials which are suitable for steam sterilization. Ask the manufacturer about the cleaning materials.

In case of non-observance, residual dirt can possibly be loosened up during sterilization in the steam pressure. Residue of the disinfection and cleaning agents lead to corrosion. Increased maintenance requirements and impairment of the function of the autoclaves can be the consequence.

Unsuitable cleaning materials, e.g. water-rejecting cleaning materials or steam-impermeable oils, can result in unsterile instruments. This endangers your health and the health of your patients.

When using the following devices, observe without fail the preparation instructions of the instrument manufacturer:

- Ultrasonic units
- Maintenance appliances for hand pieces and angle pieces
- Cleaning and disinfection devices (e.g. thermal disinfectant)

Load the autoclave

Only if the autoclave is properly loaded can the sterilization be effective and the drying deliver good results.

**NOTICE:**

Use perforated trays, such as the trays from MELAG. Only this way can →condensate run off. If you use closed materials or shell halves to bear the items to be sterilized, you risk bad drying results. Please note that the use of tray insertions made of paper can perhaps likewise lead to worse drying results.

Wrapping**Warning!**

The correct use of suitable wrapping is important for the success of the sterilization.

Employ only packaging materials and -systems (sterile barrier systems), which satisfy the DIN EN ISO 11607-1 Standard.

Closed sterilization - containers

You can employ reusable rigid packaging such as standard tray cassettes or soft packaging such as clear-plastic sterilization packages, paper bags, sterilization paper, textiles, fleece.

Preferably use sterilization containers made of aluminium. Aluminium conducts heat well and thus accelerates drying.



When using closed sterilization containers, observe the following instructions for holding the →sterilizing materials:

- Closed sterilization containers must be equipped at least on one side – possibly below – with perforations or valves.

Non-observance leads to insufficient steam penetration which could make the sterilization ineffective. Furthermore the condensate drainage is prevented, and bad drying results are the consequence. This can ultimately lead to unsterile instruments and thereby to endangering the health of the patient and the practice team.

The sterilization containers from MELAG satisfy all requirements according to →DIN EN 868 for successful sterilization and drying. They are perforated in the lid and floor and are equipped with disposable paper filters.

Stack sterilization containers



Stack on top of each other, if possible, only sterilization containers of the same size, where the →condensate can run off on the side at the walls.

- When stacking the sterilization containers, take care that the perforations are not covered.

In case of non-observance, the condensate cannot drip off to the vessel bottom. It would soak sterilizing materials lying underneath. The consequence would be bad drying results. This can ultimately lead to unsterile instruments and thereby to endangering the health of the patient and the practice team.

Soft sterilization wrapping



→Soft sterilization packages can be sterilized both in sterilization containers on trays or standing when using a package holder. When using soft sterilization packages such as **MELAfol®**, observe the following instructions:

- Arrange the →soft sterilization packages standing vertically at small intervals to each other.
- Do not place several soft sterilization packages flat on top of each other on a tray or in a container.
- If the welding seam tears open during sterilization, then it might be that the wrapping was too small. If this is the case, re-wrap the instruments and sterilize them once again. The packaging should be filled to ¾ or the spacing for the sealing seam at 3 cm.
- If the welding seam tears open during sterilization, extend the sealing cycle of the package sealing device or weld a double seam.

Non-observance can ultimately lead to unsterile instruments and thereby to endangering the health of the patient and practice team.

Multiple wrapping

The autoclave functions on the →fractionated pre-vacuum method. This permits the use of →multiple wrapping.

Mixed loads

For sterilizing mixed loads, observe the following instructions:

- Always place textiles on the top
- Sterilization containers at the bottom
- Unwrapped instruments at the bottom
- Transparently wrapped sterilization packages and paper packaging on the top – exception: in combination with textiles on the bottom
- The heaviest loads at the bottom
- Stack transparently wrapped sterilization packages if possible edgewise in such a way that alternately paper side lies on paper side and foil side on foil side; if this is not possible, then with the paper side facing downwards.

Loading variants	Vacuklav® 23 B+		Vacuklav® 31 B+	
	Instruments	Textiles	Instruments	Textiles
Greatest weight per single piece	2 kg	1.8 kg	2 kg	1.8 kg
Loading variant mounting A*	max. 5 trays, depth 420 mm max. 6 sterilization containers 15K max. 3 sterilization containers 15M max. 2 sterilization containers 15G max. 6 sterilization containers 17K max. 3 sterilization containers 17M max. 1 sterilization containers 17G max. 3 swab drums 17R max. 1 sterilization container 23G max. 2 sterilization containers 23M max. 2 swab drums 23R max. 2 sterilization containers 28M max. 1 sterilization containers 28G max. 3 standard tray cassettes		max. 5 trays, depth 290 mm max. 3 sterilization containers 15K max. 3 sterilization containers 17K max. 3 swab drums 17R max. 2 swab drums 23R max. 2 sterilization containers 28M max. 1 sterilization container 28G max. 3 standard tray cassettes	
Maximum total weight	5 kg	1.8 kg	5 kg	1.8 kg
*Mountings, trays, sterilization containers, norm-tray cassettes from MELAG, see Appendix A – Accessories				

Close the door

When closing the door of the autoclave, observe the following instructions:

- Close the door with light pressure against the chamber flange and simultaneously press down the sliding-closure grip.

Select program

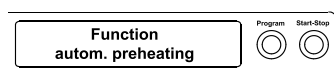
Select by rotating between the initial state and the desired program with the program selection button (P).

Select the sterilization program according to how the →items to be sterilized are wrapped. Furthermore, consider the resistance to high temperature of the items to be sterilized.

The following table shows which program to use for which items to be sterilized.

Programs	Wrapping	Especially suitable for	Sterilization at	Operating time*	Drying	Load 23 B+/31 B+
Universal-Program	→single and →multiple wrapping	→Mixed loads; long, narrow-bore hollow bodies	134 °C	30 min	20 min	5 kg
Quick-Program S	only unwrapped (no textiles)	Simple →solid instruments, transmission instruments; simple hollow bodies	134 °C	15 min	5 min	5 kg
Quick-Program B	→single wrapped and unwrapped (no textiles)	Narrow-bore hollow bodies	134°C	28 min	10 min	single wrapped 1.5 kg
						unwrapped 5 kg
Gentle-Program	→single and →multiple wrapping	Larger quantities of textiles	121 °C	45 min	20 min	Textiles 1.8 kg
		Thermo-instable goods (e.g. plastic, rubber articles) →Mixed loads				Thermo-instable Goods 5 kg
Prion-Program	→single and →multiple wrapping	Instruments where a danger of infection by pathologically-modified proteins is suspected (e.g. Creutzfeld-Jacob, BSE)	134 °C	45 min	20 min	5 kg

* without drying (full load in the Vacuklav® 23 B+ und Vacuklav® 31 B+: 5 kg) and depending on the load and installation conditions (such as the supply voltage)



Select automatic pre-heating

With the automatic pre-heating, the chamber of the autoclave before a program start is kept to the program-specific pre-heating temperature or maintained at this temperature between two program runs.

Prerequisite is that the autoclave remains continuously switched on.

The condensate formation at the chamber wall is reduced and drying is supported. The cycle times shorten.

The automatic pre-heating is activated in the factory settings.

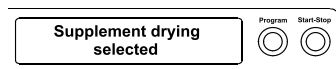
In order to change this setting if desired, proceed as follows:

- Select the **SETUP Menu Function** by brief simultaneous pressing of the KEYS (+) and (-).
The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-), up to the display **Function: autom. Pre-heating** is displayed.
- For confirmation press the KEY (P). The display shows the current preset option, e.g. **Pre-heating Yes**.
- Press the KEY (P) once again, switch the display to **Pre-heating No**. The pre-heating is deactivated.
- In order to end the menu **Function: autom. Pre-heating** and return to the initial state, press the KEY (S) twice.



NOTICE:

MELAG recommends the activation of automatic pre-heating.



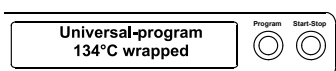
Select additional drying

For difficult drying tasks you can extend the drying time of a program by 50% with the function Additional Drying.

For this proceed as follows:

- When starting the program, Simultaneously press the KEY (S) AND KEY (+).

The display shows **Supplement drying selected**. Then the program sequence begins.



Start program

If you have selected a program with the program selection button, in addition to the selected program the sterilization temperature is displayed and whether the respective program for packaged or unpacked sterilizing materials is suitable.

- Press the KEY (S), in order to start the program.

The autoclave checks the transport of the →feed water and its →conductivity.

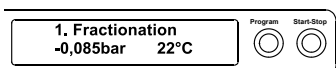
If the Quick-Program S is started, the warning text **Warning only unwrapped instruments** is shown on the display.

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

Program is running

After the start of the program you can track the program steps on the →display. Chamber temperature and pressure as well as the duration until the end of sterilization or the expired drying time is displayed.

Evacuation phase



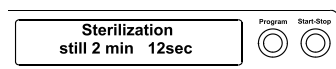
In the Evacuation Phase (fractionation) air is evacuated repeatedly until a program-dependent pressure is reached. This occurs in alternation with the inflow of steam up to a slight overpressure.

Depending on selected program and the current chamber temperature at program start, additional →fractionations are connected.

Heating-up phase

The heating-up phase follows after the evacuation phase. The pressure and the temperature climb with continual steam introduction in the chamber until the sterilization parameters are reached.

Sterilization phase

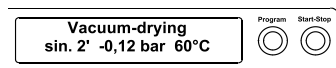


After achieving the sterilization parameters of pressure and temperature, the sterilization phase begins.

In alternation with pressure and temperature the remaining time of the sterilization phase is also displayed.

A pressure discharge with a corresponding display is carried out at the end of the sterilization phase.

Drying phase



The drying phase begins after the pressure discharge.

The chamber is ventilated with simultaneous pressure compensation at the end of the drying cycle.

The regular drying time is 5 minutes for the Quick-Program S, 10 minutes for the Quick-Program B and 20 minutes for the other programs.

Manually terminate program

You manually terminate a running program in any of the phases.



IMPORTANT!

Do not interrupt a running program by disconnecting the power plug! In case of non-observance, an error message of power loss is displayed when the autoclave is switched back on.

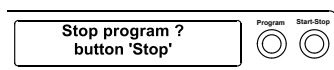


Danger of burning!

- Take heed that when opening the door after terminating a running program, hot water steam can escape out of the chamber, depending on when the program was terminated.
- Use a tray lifter to remove the tray. Never touch the →sterilized items, the chamber or the door with unprotected hands. The parts are hot.
- To remove tray cassettes, use a tray-lifter or gloves. The parts are hot.

In case of non-observance, you can suffer burns.

Manual termination before beginning of drying



If you terminate a program before the beginning of drying, then the →items to be sterilized are still unsterile.

To terminate the program, carry out the following steps:

- Press the KEY (S).
- Confirm the following prompt **Stop program?** Repeatedly press "Stop" with the KEY (S).



NOTICE:

The confirmation prompt is shown for about 5 seconds on the display. If the key is not pressed again, the program continues with the normal process.

Depending on the point in time of the termination, a pressure discharge or ventilation of the instrument is carried out. An appropriate display is shown on the screen.

After the pressure discharge or ventilation is carried out, there is a request for an acknowledgement of the program termination.

The screen alternately displays **Stop End** and **Acknowledge with button ' - '.**

- Press the KEY (-)

The message **Unlocking door with button ' + '.** is displayed in alternation with the previously-selected program.

After pressing the KEY (-) you can open the door.

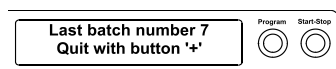
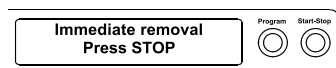
A reference to **Program stopped/ load not sterile** is issued to the logging printout.

In the drying phase you can cancel the program with the KEY (S).

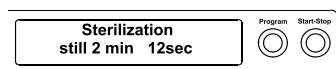
Manual termination during drying

You must then expect insufficient drying, especially for wrapped →sterilized items. Sufficient drying is a prerequisite for sterile storage. Therefore, if possible, always let sterilization programs with wrapped items continue up to the end of the drying phase. In a quick program, sterilized unwrapped instruments dry from their own heat after removal from the autoclave.

In the drying phase, the expired drying time is shown in alternation with



Sterilization phase successfully finished

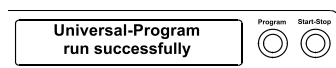


Sterilization not successfully finished

Program abort by the system



Improve drying results



the message **Immed. Removal Press "Stop"** is displayed.

To terminate the program, carry out the following steps:

- Press the KEY (S).
- Confirm the following prompt **Stop program?** Repeatedly press **"Stop"** with the KEY (S).

The termination is confirmed with **Drying stopped** on the display.

NOTICE:

The confirmation prompt is shown for about 5 seconds on the display. If the key is not repeatedly pressed, the program continues with the normal process.

After the ventilation of the chamber with a corresponding display text the message **Universal-Program run successfully** follows in alternation with **Last batch number. xx** and **quit with '+'**.

If a printer or another output medium is connected to the autoclave and the **Immed. Output** is set to **yes**, a reference to **Drying stopped** is issued to the logging printout.

Sterilization phase is finished

You can recognize on the display whether the sterilization phase has successfully completed.

The remaining time of the sterilization phase is displayed in alternation with the specification of the pressure and temperature.

The sterilization is not successful if it was terminated by the operator or aborted by the system in the event of an error.

At a system abort, the system puts the chamber into a pressureless state.

NOTICE:

If the program is terminated by the operator, a warning text appears. If the program is aborted by the system, an error message is displayed.

Drying phase

The autoclave does an excellent job of drying the items to be sterilized. In the event of difficult drying tasks it might however be necessary to take the following measures to further improve drying:

- Load the autoclave correctly for drying. Place items wrapped in sterilized clear plastic or paper upwards like filing cards. Observe Section **Load the autoclave** on page 20. Possibly employ the package holder.
- Activate the function **Supplement Drying**. Observe the Section **Select additional drying** on page 24.

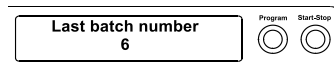
Program is finished

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

Immediate printout

The report of the completed program is issued to the selected output medium for activated immediate output (see page 29, **Chapter 5 – Logging**).

Display last batch number



Display batch number

After every completed program you automatically see on the display the last batch number of the day. This is also shown if the program was terminated by the operator or aborted by the system.

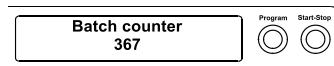
You can also allow the display of the last batch number whenever necessary:

- Select the **SETUP Menu Function** by short simultaneous pressing of the KEYS (+) and (-). The display shows **Function: Last batch number**.
- Press the KEY (P) to display the current batch number of the day.

In order to reach the starting position again, press the KEY (S) twice.

You can allow the display of the number of total →batches.

Display total batch number



- Select the **SETUP Menu Function** by short simultaneous pressing of the KEYS (+) and (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-), up to the display where the submenu **Batch counter** is shown.
- Press the KEY (P).

You see the current counter reading of the total batch number on the display

- In order to reach the starting position again, press the KEY (S) twice.



Danger of burning!

Remove sterilized items

After the end of a program observe the following instructions for removing the →sterilized items:

- Never open the door by force. The autoclave could be damaged and/or hot steam could escape.
- Use a tray lifter to remove the tray.
- Never touch the →sterilized items, the chamber or the door with unprotected hands. The parts are hot.

In case of non-observance, you can suffer burns.



Danger

- Check the wrapping of the sterilized objects for damage when removing them from the autoclave.
- If a wrapping is damaged, wrap the object again and re-sterilize it.

Non-observance can result in unsterile instruments. This endangers the health of the patient and the practice team.

Open door

After the end of a program, the request **Quit with button '+'** is displayed. Press the KEY (+) to unlock the door. After unlocking the door audible, you can open the door and remove the sterilized items.

For connected output medium and **Immediate Output Yes** a logging printout is additionally carried out (see page 33, **Automatic immediate log output**).

Condensate residues on the sterilized items

If you remove the →sterilized items from the autoclave directly after the end of the program, it can happen that slight quantities of condensate moisture are found on the sterilized items.

Smaller quantities of water which may be are found on the upper side of the paper bags and clear plastic sterilization packages are unobjectionable if they dry out within 30 minutes after removal from the autoclave.

Storage of sterilized items

Exclusively employ packaging which complies to standards for the sterilized materials. Do not store sterilized items in the preparation room. For the storage of the sterilized items, observe the criteria mentioned below.

Storage conditions

- Sealed against dust e.g. in a closed instrument cabinet
- Protected from damage on smooth surfaces
- Protected from excessive fluctuations in temperature
- Protected from moisture (e.g. alcohol, disinfectant)

Storage duration in accordance with the type of package wrapping

Storage time

The maximum storage life depends on the packaging and the storage conditions. For →sterilized items which have been wrapped in compliance with the standards (dust-protected storage is assumed) – this time period is up to six months.

Chapter 5 – Logging

In this chapter you learn

- **Why and how you document batches**
- **Which output media you can employ for the batch documentation in which way**
- **How to read the logs correctly**
- **How to set the date and time at the autoclave**

Batch documentation

The batch documentation is indispensable as documentation for the successfully completed sterilization process and as an obligatory measure of quality assurance (→Medical Devices Operator Ordinance). The data, such as type of program as well as →batch and process parameters of the completed programs, are stored in an internal log memory of the autoclave.

For the batch documentation you can transfer the internal log memory readout and the data onto diverse output media. This can take place immediately after every completed program or subsequently, e.g. at the end of a work day in the practice.

Capacity of the internal log memory

The capacity of the internal storage suffices for about 40 logs. If the internal log memory is full, when starting the next program the respectively oldest report is automatically overwritten.

If you have connected a printer and additionally the option **immediate output** is set to **No** (see also Page 33, **Automatic immediate log output**), a confirmation prompt appears before the saved record is overwritten. For additional information on connecting the printer, see page 30, **Connect printer**.

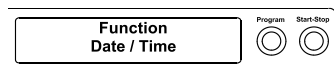
Output media

You can store the logs of the completed programs on the following output media and archive them accordingly.

- Log printer MELAprint® 42
- MELAflash CF card Printer on CF card
- Computer, e.g. with software MELAwIn® / MELAview®
- MELAnet Box
- Modem

State on initial delivery

No option for the output of the logs is set in the initial delivery state of the autoclave. You can read below how to output the logs on the cited media.

Observe time re-settings**Set date and time**

Date and time of the autoclave must be correctly set for proper batch documentation. Observe the time re-settings in autumn and spring ("daylight saving time"), since this is not reset automatically. Set date and time as described below:

- Select the SETUP Menu **Function** by short simultaneous pressing of the KEYS (+) and (-).

The display shows **Function: Last batch number**.

- Navigate with the KEY (+) or (-) in the Menu **Function**, up to the display **Function: date/ time** are displayed.
- Press the KEY (P) in order to confirm. The current hour is displayed.
- Select between the following setting possibilities with the KEY (+) or (-): Hour, minute, second
Day, month, year
- In order to adjust the **hour** parameter, press the KEY (P) for the confirmation.

The current value on the display blinks.

- The value can be increased or reduced with the KEYS (+) and (-).
- In order to store the value, confirm with the KEY (P).

The current preset value on the display no longer blinks

In order to adjust the other parameters, proceed analogously.

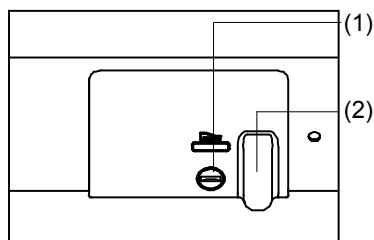
- After finishing the settings, press the KEY (S) in to leave the menu

On the display, the **Function: Date/Time** are again displayed

By pressing the key (S) again you leave the menu completely and the display again shows its starting position.

**Use printer as output medium**

If you want to employ the log printer MELAprint[®] 42 as the output medium, connect it to the autoclave as follows:

Data connection from the autoclave**Connect printer**

Open the white cover of the serial data- and printer connection (see page 10, Fig. 1/ (6)):

- Turn a coin by a quarter-revolution inserted in the locking slot (1) on the white cover.
- Take cover off and fold the interior metal casing to the left.
- Press the metal casing somewhat downwards until it engages and no longer can automatically flip back.
- Connect the cables of the log printer to the printer connection at the autoclave.

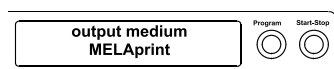
If the printer or a computer is continually connected to the autoclave, the data connection cable of the log printer is laid in the cable ducts (2), the metal casing retracted and the cover is closed again. This provides a comfortable external cable connection to the printer.

Close the log printer MELAprint[®] 42 according to the pertinent operating manual.

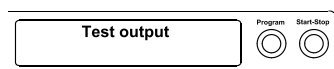
Initialisation of the log printer

In order to be able to print out logs on the connected log printer, you must initialise MELAprint[®] 42 once by making the following setting at the

MELAp rint[®] 42



Test outputs on the log printer MELAp rint[®] 42



autoclave:

- If the autoclave is still not switched on, switch it on.
- Wait until the display shows the basic settings (page 12, **Control Panel**)
- Select the **SETUP Menu Function** by short simultaneous pressing of the **KEYS (+) and (-)**.
The display shows **Function: Last batch number**.
- Navigate with the **KEY (+) or (-)** until the display **Function: Batch output** is shown.
- Press the **KEY (P)** to select the submenu **Batch output - Output medium**.
- Press the **KEY (P)** again. The display shows **Output medium - No Output medium**, in case no printer was yet selected.
- Navigate with the **KEY (+) or (-)**, until the display shows as output medium **MELAp rint**.
- For confirmation press the **KEY (P)**. The display changes back to the menu **Batch output - Output medium**.
- Press the **KEY (S)**, in order to confirm and return to the menu **Function: Batch output**.
- After renewed pressing of the **KEY (S)** the display again shows the initial state.

In order to verify the functional reliability of the log printer MELAp rint[®] 42 and its communication with the autoclave, a test output can be carried out:

- Select the **SETUP Menu Function** by short simultaneous pressing of the **keys (+) and (-)**.
The display shows **Function: Last batch number**.
- Navigate with the **KEY (+) or (-)** until on the display **Function: Batch output** is shown.
- Press the **KEY (P)** to select the submenu **Batch output - Output medium** is displayed and press the **KEY (P)** for confirmation.
- Navigate with the **KEY (+) or (-)** until the display **Test output** is shown.
- In order to start the output, press the **KEY (P)**.
An appropriate display with **Test output** appears.
- In order to break cancel the test output or leave the menu after finished printout, press the **KEY (S)**. The display shows **Function: Batch output**.
- By again pressing the **KEY (S)**, you completely leave the menu and return to the starting position of the display.



MELAflash as output medium

The MELAflash CF card Printer serves for storage of sterilization logs on the MELAflash CF card. The readout of the logs from the CF card to the practice computer is carried out with the MELAflash card reader.

Additionally you can use the software MELAvi[®] for processing the logged data.

TIP

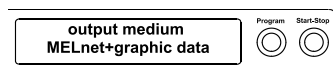
You can download a current version of the software on the internet page of MELAG on www.MELAG.de in the download area.

Connect the MELAflash CF card Printer with the serial interface like the log printer MELApri[®]42 (see page 30). and set at the autoclave as output medium **MELAf1ash** in the SETUP Menu.

You will find detailed information in the operating manual for the MELAflash CF card Printer itself.

NOTICE:

Naturally you can also allow the MELAflash CF card Printer to be connected permanently to the autoclave like the log printer MELApri[®]42.



MELAnet Box as output medium

The MELAnet Box enables the connection of the autoclave with a real ethernet interface to the computer network of the practice or clinic.

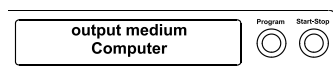
The logs which are created during a program run can be saved by means of a →FTP server or over →TCP via the MELAnet Box on the computer.

In the MELAnet Box there runs a small webserver program, which displays status information of the connected autoclave and settings for the MELAnet Box via a webbrowser. Thus you can allow the display of the current progress of a program cycle or current measured values.

Connect the MELAnet Box with the serial interface like the log printer MELApri[®]42 (see page 30) and set at the autoclave as output medium **MELAnet** in the SETUP Menu **Function**.

You will find detailed information in the operating manual for the MELAnet Box itself.

Initialisation of the computer



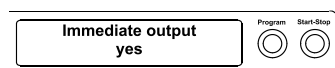
Computer as output medium

In order to be able to employ a computer as output medium, the computer must be connected with the serial interface to the autoclave. Additionally the software MELAvi[®] can be installed for the log readout.

In order to register the computer at the autoclave, proceed as described on page 30, **Initialisation of the Log Printer**.

Observe that for the output medium in the SETUP Menu **Function** you must set at the autoclave as output medium **Computer**.

Prerequisite for automatic immediate output of the logs after the end of the program



Automatic immediate log output

If you immediately would like to output the associated report automatically on an output medium after the end of a program, use the function **Immediate output Yes**. This is not preset in the initial delivery state.

The following prerequisites must be satisfied for the immediate log output after the end of a program:

- As output medium the computer, the log printer MELAprint® 42 or another output medium must be connected and initiated.

This sets the option for an immediate output of the logs after the end of the program:

- Switch the autoclave on with the power switch.
- Select the **SETUP Menu Function** by short simultaneous pressing of the KEYS (+) and (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-) until on the display **Function: Batch output** is shown and press the KEY (P).
- Navigate with the KEY (+) or (-) until on the display the submenu **Immediate output Yes/No** is shown.
- Press the KEY (P), in order to switch between **Immediate output No** and **Immediate output Yes**.
- In order to output logs immediately, **Immediate printout Yes** must be set.

In order to save the setting and to leave the menu again, press the KEY (S). The display shows **Function: Batch output**.

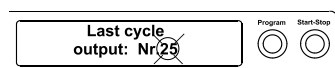
- By again pressing the KEY (S), you leave the menu completely and return back to the initial state.



NOTICE:

If it is not possible to output a log report for the immediate output because for example the activated output medium is not connected, a warning message appears. MELAG recommends that you employ the immediate output of logs.

Print selected logs



Output the logs subsequently

You also have the option of outputting the logs subsequently and independently from the time of the end of the program. You can select whether selected or all saved logs (up to 40 logs) should be printed. For this, use the connected output medium, e.g. the log printer. In order to subsequently print selected logs of certain programs, proceed as follows:

- Select the **SETUP Menu Function** by short simultaneous pressing of the keys (+) or (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-) until on the display **Function: Batch output** is shown and press the KEY (P).
- The Menu **Batch output – Output medium** is displayed.
- Navigate with the KEY (+) or (-) until the display **Last cycle output: No. 40** is shown (as example No. 40).
- Press the KEY (P). The current report number blinks.
- In order to output a log of another cycle, navigate with the KEYS (+) or

(-) up to the desired number, here e.g. 25.

- Press the KEY (P) in order to start the output of the selected program. The display shows **Output**.

After finished printout, the display changes again to its previous setting **Last cycle output: No. 25**.

- In order to output additional logs, repeat the last three steps.
- In order to leave the submenu without outputting, press the KEY (S).
- In order to leave the menu after the output, press the KEY (S). The display shows the menu **Function: Batch output**.
- By again pressing the KEY (S), you completely leave the menu and return back to the basic position of the display.

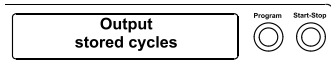
Print all saved logs

In order to subsequently output all saved logs, proceed as follows:

- Select the SETUP Menu **Function** by short simultaneous pressing of the keys (+) or (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-) until on the display **Function: Batch output** is shown and press the KEY (P).
- Navigate with the KEY (+) or (-), until the display **Output stored cycles** is displayed.
- Press the KEY (P) in order to start the printout of the selected program. The display shows **Output**.

After finishing the output the display again shows **Output stored cycles**.

- In case you would like to leave the submenu without printing, press the KEY (S).



NOTICE:

A termination **during** the output on the log printer is only possible by disconnecting the instrument at the mains switch or interrupting the power supply of the printer.

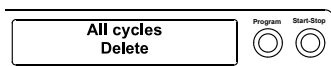
- In order to leave the menu, likewise press the KEY (S). The display shows the setup menu **Function: Batch output**.
- By again pressing the KEY (S), you completely leave the menu and return to the starting position of the display.

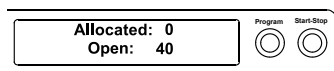
Delete stored logs

In order e.g. to suppress the warning text **Protocol memory full** for preset option **Immediate output No**, the saved logs can be manually deleted.

In the following example you can read how you can delete all saved logs.

- Select the SETUP Menu **Function** by short simultaneous pressing of the keys (+) and (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-) until on the display **Function: Batch output** is shown and press the KEY (P).
- Navigate with the KEY (+) or (-) until on the display **All cycles delete** is shown.
- Press the KEY (P) in order to delete all logs now.
- In order to cancel the submenu without deleting, press the KEY (S).
- In order to leave the menu after deletion, press the KEY (P). The display shows **Function: Batch output**.
- By again pressing the KEY (S), you completely leave the menu and return to the starting position of the display.





Display protocol memory

With a connected and initialised printer or another output medium you can verify how many logs are already saved in the log memory of the autoclave.

Proceed as follows:

- Select the SETUP Menu **Function** by short simultaneous pressing of the KEYS (+) and (-). The display shows **Function: Last batch number**.
- Navigate with the KEY (+) or (-) until on the display **Function: Batch output** is shown and press the KEY (P).
- Navigate with the KEY (+) or (-), up to the display for the Storage Occupancy (see left Display Figure) are shown.
- In order to leave the menu again, press the KEY (S) twice.

Read log files correctly

Header

The head of the program listing includes the general fundamental information for the completed program such as for example current date, the selected program, the daily batch number and the autoclave type.

Values of the program steps

During the program the program sequence phases are recorded with the accompanying values for steam pressure, temperature and time (relative to the program start).

Summary

The summary states whether the program was successfully concluded. Furthermore the values of the required sterilization time, the sterilization temperature and the pressure including its maximum deviations are displayed.

<pre> ----- MELAG Vacuklav 31-B ----- Program : Universal program 134°C wrapped Date 07.10.2007 Time 21:34:07 (Start) Batch No.: 100 Preheating 80.9 °C AIN6:Conductivity 7 µS/ cm Program step Press. Temp. Time bar °C min. Start 0.01 26.3 00:00 1. Fractionation Evacuation -0.92 26.3 02:26 Steam entry 0.40 105.2 06:13 2. Fractionation Evacuation -0.82 65.6 06:11 Steam entry 0.41 109.4 09:29 3. Fractionation Evacuation -0.82 59.9 10:57 Steam entry 0.41 109.4 12:42 Heat-up 2.04 134.1 14:52 Steriliz. begin 2.04 134.1 14:52 Steriliz. end 2.18 135.7 20:22 Press. release 0.20 105.2 21:03 Vacuum-drying Drying begin -0.34 92.6 21:12 Drying pressure -0.92 52.9 23:10 Drying pressure -0.93 67.8 25:10 Drying pressure -0.93 69.3 27:10 Drying pressure -0.93 66.7 29:10 Drying pressure -0.93 64.3 31:10 Drying pressure -0.93 62.3 33:10 Drying pressure -0.93 60.8 35:10 Drying pressure -0.93 59.6 37:10 Drying pressure -0.93 58.5 39:10 Drying pressure -0.93 57.8 41:10 Drying end -0.83 58.0 41:12 Ventilate -0.26 60.4 41:23 End 0.00 61.5 41:35 ----- Program properly executed! Temperature : 135.7 +0.3 /-0.3 °C Pressure : 2.17 +0.03/-0.03 bar Sterilize time: 5 min 30 s Time : 22:15:42 (End) ===== 67 200703066 4.06 4.06 CRC: 0xB3C5 V1.30A </pre>	<p>Header</p> <p>Started program</p> <p>Current date time at program start daily batch number</p> <p>Preheating temperature →conductivity of the →feed water</p> <p>Values of the program steps</p> <p>Program sequence phases with the accompanying values for pressure, temperature and time (relative to the program start)</p> <p>Summary</p> <p>Control message</p> <p>Mean sterilization temperature with max. deviations Mean sterilization pressure with max. deviations Sterilization time maintained Time at the end of the program</p> <p>Information with total-cycle counter, factory serial number and instrument software version no.</p>
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Chapter 6 – Maintenance

In this chapter you learn

- How to clean the autoclave and which cleaning agents are suitable
- How to avoid the formation of spots
- How to exchange the door seal
- What to observe in autoclave maintenance

Weekly inspection of chamber, door seal, mounting, chamber sealing surface

In case of contaminations

Door seal



Cleaning

Examine the chamber including door seal and chamber sealing surface and the mounting for loading (page 20, **Load the Autoclave**) once weekly for contaminants, deposits or damage.

If you determine any contaminations, draw the existing trays or cassettes and the associated mounting forwards out of the chamber. Clean the contaminated parts.

The door seal must not be greased or oiled. It should be kept clean and dry.

When cleaning the chamber, the loading mounting, the chamber sealing surface and the door seal, observe the following:

- Switch the autoclave off before cleaning and pull the power plug from the wall socket.
- Make sure that the chamber is not hot.
- Use a soft and lint-free cloth.
- Use chlorine- and vinegar-free cleaning agents.
- First drench the cloth with cleaning alcohol or methylated alcohol and try to wipe off the contamination.
- In case of persistent soiling of the chamber, mounting or chamber sealing surface, employ only a mild →stainless steel cleaning agent with a pH value between 5 and 8.
- Employ neutral liquid cleaning agents to clean the door seal.
- No cleaning agents may get into the piping system which exits the autoclave chamber.
- Do not use any rough objects such as pot cleaners made of metal or steel brushes.

In case of non-observance the cleaned surface could become scratched or damaged and the sealing surfaces not tight. This would promote dirt deposits and corrosion in the sterilization chamber.

Housing parts

Clean the housing parts with neutral liquid cleaners or methylated alcohol.

Internal storage tank for feed water

If you provide the feed water supply manually via the internal storage tank, check for soiling when you refill the feed water. If necessary, clean the tank with a cloth and fresh feed water before refilling.

**Notice:**

Make sure to wipe up and remove any soiling or impurities from the tank with a cloth without leaving any residues. If dirt particles are only detached but not actually removed, they can get into the dirt particle filter integrated into the drain hose while emptying the wastewater tank.

Non-observance could impair the service life of the dirt particle filter and make it necessary to exchange the filter at short notice.

Clean the left side of the water storage tank (waste water) every two weeks.

The both chambers are emptied as follows:

- Attach the drain hose on a quick-fitting connection (left of the waste-water tank, to the right of the feed-water tank), until this perceptibly engages
- Drain off the water into a container with at least 5 litres holding capacity.

To remove the drain hose again, press the grey release knob at the quick-fitting connection. The hose detaches itself automatically from the connection.



Warning!

Please observe the following when removing the quick-fitting connection:

- When draining the storage chambers, stand to the side of the connection
- Be sure to hold the hose tight with the other hand while pressing on the grey release button of the quick-fitting connection in order to arrest the spring tension of the connection.

Non-observance can lead to injuries.

- Repeat the procedure for the other chamber if necessary.

Avoid formation of spots

Formation of spots due to improperly cleaned instruments

Only if you correctly clean the instruments before sterilization can you avoid the detachment of residues resulting from loading or instrument preparation under steam pressure during the sterilization. Detached dirt residues (e.g. residues of disinfectants) can clog the filter, nozzles and valves of the autoclave and deposit as stains, spots or discolorations on the instruments and in the chamber (see page 19, **Prepare items to be sterilized**).

Formation of spots due to third-party rust

All steam-conducting parts of the autoclave are made of non-rusting materials. This excludes the formation of rust caused by the autoclave. Should rust stains occur, then we are dealing with third-party rust. If the instruments have been incorrectly prepared, rust can form even on stainless steel instruments of leading manufacturers. Often a single rust-producing instrument already suffices for third-party rust to form on the other instruments or in the autoclave.

Remove third-party rust from the instruments with a chlorine-free →stainless steel cleaning agent (see page 37, **Cleaning**) or send the damaged instruments to the manufacturer for reconditioning.

Formation of spots due to inadequate quality of the feed water

The extent of the formation of spots on the instruments also depends on the quality of the →feed water employed for steam production.



Use qualitatively high-grade feed water

Observe the following when using →feed water for the steam sterilization:

- Use only →demineralized or distilled water according to →DIN EN 13060, Appendix C (VDE 0510).

In case of non-observance, stains or damage on the instruments can arise and the functional readiness of the autoclave can be adversely affected.

Water according to VDE 0510

You can also use distilled or demineralized water from do-it-yourself markets, pharmacies or service stations as →feed water, if the →VDE 0510 is explicitly noted on the label of the packaging.



NOTICE:

→Feed water which you can inexpensively produce with the osmosis processes with MELAdem[®] 40 or with the ions exchanger MELAdem[®] 47 or by distillation with MELAdest[®] 65, satisfies the requirements on the feed water.



Exchange the door seal

If the door seal shrinks or is wavy, it is necessary to exchange the door seal.

The consequence can be poorly sealed areas which can lead to the leakage of steam or cause a too high leakage rate in the vacuum test.

Open the door of the autoclave and take the old door seal out. The door seal is only inserted in the groove of the door plate (page 11, Fig. 2/(5)).

Set the new door seal (Art.-No. 58510) in the groove in such a way, that the **wider sealing surface shows toward the chamber side**.



IMPORTANT!

Observe without fail the different widths of the sealing surface. Only with correct seating in the groove is a proper closing of the door guaranteed and the chamber tight.



Maintenance

- Have maintenance carried out only by trained field service technicians or technicians of the specialist trade. Turn to your specialist dealers or MELAG customer service in your vicinity.
- Comply with the predetermined maintenance intervals.

Malfunctions at the autoclave can occur on continuation of operation despite the servicing message.

***For retention of value and
functional reliability***

Maintenance intervals



Regular maintenance is indispensable for the retention of value and the reliable practice operation of the autoclave.

During maintenance, all functional and safety-relevant components and electrical facilities are checked, and replaced if necessary. The maintenance is carried out according to the maintenance instructions which are relevant for this autoclave.

Regularly allow for maintenance after each 1000 program cycles or two 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

In this chapter you learn

- How quickly you can start sterilization programs in sequence
- What you must observe for longer operating pauses
- How to put the autoclave out of operation, transport it and re-start it

Sterilization frequency

No pause times required

Pause times between individual programs are not required, since the →sterilization chamber is permanently maintained at the required temperature.

After the expiration or termination of the drying time and removal of the →items to be sterilized, you can immediately re-load the autoclave and start a program.

Pause times

Longer operating pauses

Switch the autoclave off for longer operating pauses, e.g. overnight or on the weekend, and leave the door ajar. The door seal is relieved and protected from premature wear. Furthermore it prevents the sticking of the door seal.

Close, if available, the water feed of the water treatment unit.

After operating pauses which last longer than two weeks, carry out a vacuum test and thereafter an empty sterilization with the Quick Program (see page 43, **Chapter 8 – Function test**)

The following situations can occur after longer pauses:

Event	Possible cause	What you can do
→conductivity too high	Bad feed water	Change the →feed water or the mixed-bed-resin pellets for a MELAdem® unit.
Door cannot be opened	Door seal is sticking to the sealing surface	Switch the autoclave on and pull vigorously at the door to open it.

Function test after pauses

After pauses, carry out the tests described in **Chapter 8 – Functional Tests**, depending on the pause duration.

Shut-down

If you would like to shut down the autoclave (put it out of operation) for a longer period of time, for instance because of holidays or a planned transport, proceed as follows:

- Switch the autoclave off at the mains switch.
- Pull the power plug from the wall socket.
- Empty both chambers of the storage tank
- Close, if available, the water feed of the water treatment unit.

Transport



Observe the following when carrying the autoclave:

- Two people are necessary to carry the autoclave.
- Use a suitable carrying strap to transport the autoclave.

Observe that the spacing between the underside of the housing floor plate of the autoclave and the footprint is small.

In case of non-observance spine damage and contusions can result.



Observe the following when transporting the autoclave, e.g. when moving or shipping the autoclave or for the transport within the practice:

- Empty both chambers of the storage tank
- When using a water treatment unit, close the water feed and removal the hose connections at the rear of the device.
- If you would like to leave the mounting and the trays or cassettes in the chamber during transport, protect the surface of the door plate. Lay a piece of foam plastic or bubble wrap between the door plate and mounting.
- Close the door of the autoclave before you move the device.

In case of non-observance, damages to the autoclave and errors can occur.

Re-startup after change of locality

At re-startup of the autoclave after a change of locality, proceed as for an initial start-up (see page 14, **Chapter 3 – Initial start-up**)

Chapter 8 – Function test

In this chapter you learn

- How the autoclave automatically carries out the function test
 - Which possibilities you have for the manual function test
 - Which function tests should be conducted in daily operation
 - Why and how you should conduct a vacuum test
 - Why and how you should conduct a Bowie & Dick test
 - How you carry out batch-related tests
 - How you display the water quality
-

Process evaluation and monitoring system

Automatic function test

The interaction of the sterilization-relevant parameters of pressure, temperature and time are continually automatically monitored by the electronic parameter control.

The →process evaluation system of the autoclave compares the process parameters with each other during the program and monitors them with respect to their limit values.

The monitoring system of the autoclave checks the device components with regard to their functional reliability and their plausible interaction. If the parameters exceed defined limit values, the autoclave outputs warning messages or error messages. If necessary, it aborts the program with a corresponding notice.

If the program was successfully concluded, an appropriate message is issued on the →display.

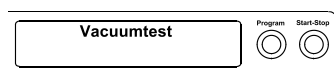
Manual function test

You can track the program sequence based on the values shown on the →display. Furthermore on the basis of logs made for every program, you can logically reconstruct whether a program was successful (see page 29, Chapter 5 – Logging)

Testing in daily operation

Vacuum test

**Weekly in routine operation,
at initial start-up, after
pauses longer than two
weeks and in case of error**



- Conduct a vacuum test in the following situations:
- Once weekly in routine operations
- At initial start-up
- After longer operating pauses
- In case of a respective error (e.g. in the vacuum system)

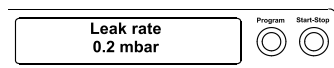
The test serves to determine leaks in the autoclave.
The leakage rate is determined.

Conduct the vacuum test with a cold and dry autoclave as follows:

- Switch the device on at the mains switch. The display switches into its initial state.
- Press the KEY (P) until the menu **Vacuum test** is shown in the display.
- Close the door.
- Press the KEY (S), in order to start the vacuum test.

The chamber is →evacuated until the pressure for the vacuum test is achieved. An equilibration time of five minutes and a measurement time of ten minutes follow. The rise in pressure in the chamber is measured within the measurement time.

The evacuation pressure and the equilibration time or measurement time are shown on the display.



After the expiration of the measurement time, the chamber is ventilated (appropriate display message).

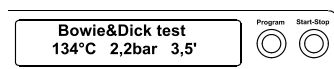
Subsequently the message with specification of the leakage rate is shown on the →display. If the leakage rate is too high, i.e. above 1.3 mbar, an appropriate message appears on the display.

Besides the display shows in alternation with the current batch number of the day and **Quit with button '+'**. After pressing the KEY (+) you can open the door.



NOTICE:

For connected log printer or another output medium and the setting **Immediate output Yes** logging is carried out with simultaneous printout.



Bowie & Dick test

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

Diverse test systems are offered by specialist dealers for the →Bowie & Dick test. Conduct the test according to the manufacturer's instructions of the test system.

Start the program Bowie & Dick test as follows:

- Switch the device on at the mains switch. The display switches into its initial state.
- Select the Bowie & Dick test with the KEY (P).
- Press the KEY (S) to start the Bowie & Dick test.
- After successful completion of the program the display shows in alternation with the current batch number of the day and **Quit with button '+'**. After pressing the KEY (+) you can open the door.

Batch-related tests

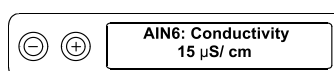
Helix test body system MELAcontrol® / PRO

The test body system MELAcontrol®/PRO is an indicator and batch monitoring system which satisfies the standard →DIN EN 867-5. It consists of a test specimen, the helix, and an indicator strip.

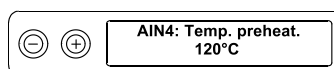
If you sterilize instruments of the category "Critical B", the MELAcontrol®/PRO test specimen should be included as a batch control for every sterilization cycle.

Independent of this you can at all times conduct a steam penetration test with the MELAcontrol®/PRO in the universal program.

The proper use of the Helix test body as directed can nevertheless result in a discoloration of the plastic surface. However, this discoloration has no influence on the functional capability of the Helix test body.



Pre-heating temperature of the chamber



Display water quality

You can at all times have the display of water quality shown on the switched on the autoclave, also during a running program.

To do this keep the KEY (-) pressed until the display shows the →Conductivity. The conductivity is stated in µS/ cm.

As soon as you release the KEY (-) the display returns to its previous status (e.g. initial state).

If you press the KEY (-) twice shortly and the second time keep it pressed, the pre-heating temperature of the chamber is shown instead of the →Conductivity.

Chapter 9 – Errors

In this chapter you learn

- Which type of messages exist
 - What you should do in case of errors
 - What you can do before calling the Hotline
 - What you can do if no display appears
 - What you can do when the feed water consumption is too high
 - What you can do if there are bad drying results
-

A warning is not an error

Not all messages which appear on the →display are error messages.

Warning messages

Warning messages are displayed when necessary. Warning messages are not error messages. They help to ensure smooth operation and to recognize undesirable conditions. Observe these warning messages promptly in order to avoid errors.

Error message

Error messages are displayed if safe operation or sterilization security is not guaranteed.

These can appear on the →display shortly after switching on the autoclave or while a program is running.

The program is aborted if a malfunction occurs during a program run.



- If a program is aborted during the sterilization phase, the load is unsterile. Repackage and repeat the sterilization for the respective →items to be sterilized.

Non-observance endangers the health of your patients and the practice team.

The error message is then shown on the display. in alternation with the current program phase (**Pressure release, Ventilation or End**) After the program abort or termination, the error message is shown on the display in alternation with the message **acknowledge with button** ' - ' and **stop/End**. In order to delete the error message, press the KEY (-).

Before you call

Follow the operating procedures shown in connection with a warning text or an error message on the →display of the autoclave. You will find the most important events in the following table. Possible causes and appropriate operating instructions are listed for the events.

If you do not find the event in the table below or your efforts do not lead to success, turn to your specialist dealer or the →authorised MELAG customer service centre in your vicinity. In order to help you, keep the serial number of your autoclave and a detailed fault description of the fault report ready.

Warning message	Possible causes	What you can do
Warning: Door open / No start possible	Door switch is not closed on start	Push the sliding closure grip downwards until the stop. Correct display: Door closed .
Warning: No feed water/ Refill feed water – No start possible	Only if feed water supply from internal storage tank: Not enough feed water in the internal storage tank	 Check feed water level in the internal storage tank check, if necessary refill feed water.
Warning: No feed water/ Check feed water supply	The warning message appears after program start. The built-in flow monitor doesn't close	Feed water supply from internal storage tank: If the message appears repeatedly, have the unit checked by the MELAG customer service. Feed water supply from MELAdem® 40 Check water treatment unit, possibly open inflow to the unit. If the message appears repeatedly, have the unit checked by the MELAG customer service. Feed water-supply from MELdem® 47 Check water treatment unit, possibly open inflow to the unit. When the pressure reservoir is empty about 1 h after restart and the message is repeated, have the water treatment unit checked by the MELAG customer service. Notice! At the first start-up or re-start-up, this message can occur once since the piping system is still not completely filled: restart.
Feed water quality bad/ exchange cartridge/ module	Conductivity of the feed water too high Conductivity $\geq 40 \mu\text{S}$ Mixed-bed resin pellets consumed	Still possible to start by repeatedly pressing the KEY (S): Feed water-supply off MELAdem® 40: Switch the mixed-bed resin pellets (Art. No. 61026), see Operating Manual for the water treatment unit MELAdem® 40.

Warning message	Possible causes	What you can do
	<p>Mixed-bed resin pellets in the after ion exchanger (3rd cartridge) consumed</p> <p>Mixed-bed resin pellets in reverse osmosis facility consumed</p>	<p>MELAdem® 47 :</p> <p>Switch mixed-bed resin pellets (Art. No. 37470), see Operating Manual for the water treatment unit MELAdem® 47 and examine the unit</p> <p>On repeated occurrence, have maintenance carried out by MELAG customer service or service of the specialist trade. Possibly the pre- and activated carbon filter must be exchanged in addition.</p> <p>For another water treatment unit:</p> <p>Exchange module/ resin cartridge according to the operating manual of the manufacturer</p> <p>On repeated occurrence, carry out maintenance.</p> <p>NOTICE: Initiate program start after completion of the above-mentioned work. On the first start after maintenance of the water treatment unit, this warning text can appear once again since the inlet hose/ measuring cell are still not completely flushed with fresh water.</p>
Feed water quality insufficient/ No start possible	<p>Conductivity of the feed water too high</p> <p>Conductivity $\geq 65 \mu\text{S}$</p>	<p>Start no longer possible:</p> <p>See warning message: Feed water quality bad/ switch cartridge/ module</p>
Please wait Preheating chamber	Message is displayed during program start phase. The autoclave has not reached the starting temperature yet.	The autoclave starts automatically after reaching the starting temperature.
Warning/ Exchange sterile filter	<p>Min. / Max. pressure on ventilation drying is too low/ high</p> <p>Sterile filter polluted or torn</p>	<p>Exchange sterile filter (Art. No. 20160)</p> <p>NOTICE: Message comes at the end of the program and in last row on logging printouts.</p>
Output medium is not ready	<p>The autoclave is operated without output medium although a output medium is registered</p> <p>Output medium is not correctly connected</p> <p>Electric power supply of the printer is interrupted</p> <p>Printer is "offline"</p>	<p>Select the option in the menu Batch output No output medium (see page 30, Initialization of the log printer)</p> <p>Correct connection of the data cable to the autoclave and test at the output medium.</p> <p>Ensure electric power supply, the red LED "P" at the log printer MELAprint®42 must light red</p> <p>Set printer to "online" (press key "SEL" at the MELAprint®42, LED "SEL" must light green)</p>
Protocol memory full	The device-internal log memory is allocated (max. 40 logs possible).	<p>The message is shown at the start of a program.</p> <p>Repeatedly press the KEY (S) to delete the message, and the program starts. The oldest log is then deleted.</p>

Warning message	Possible causes	What you can do
	An output medium is registered and in the menu Batch output the option Immediate output No is set.	<p>Set autoclave to Immediate output Yes (see page 33, Automatic immediate log output)</p> <p>Delete protocol memory (see Delete stored logfiles, possibly output all stored logs beforehand (see page 34, Print all saved logs)</p> <p>Log off the output medium in the menu batch output output medium and set the option no output medium.</p>
Please carry out maintenance	The maintenance message is activated, the device has reached the prescribed batch number	<p>The message is shown at program start.</p> <p>Repeatedly press the KEY (S) to delete the message, and the program starts.</p> <p>Retain the message: press the (S) key twice to start</p> <p>Carry out maintenance with MELAG customer service or service of the specialist trade</p> <p>NOTICE: Service counter is reset by the customer service</p>
Test not successful Leakage rate: 3.2	<p>The leakage rate determined by the vacuum test lies above the maximum permissible value of 1.3 mbar.</p> <p>Door seal, chamber flange is contaminated</p> <p>Door seal wrongly inserted</p>	<p>Check door seal and chamber flange for cleanliness, possibly clean</p> <p>Check door seal for damage, possibly exchange, see page 11</p> <p>Repeat vacuum test with completely cold device</p> <p>Check door seal for correct seating</p> <p>Repeat vacuum test with completely cold device</p>
Warning! Battery empty	The monitoring of the device's internal battery voltage has determined a too low voltage value.	The battery must be exchanged by MELAG customer service or service of the specialist trade

Error message	Possible causes	What you can do
Error 1: Vacuum system	Door seal, sealing surface at the chamber is polluted or defective Door seal wrongly inserted	Check door seal and sealing surface at the chamber for contamination and clean it; Check door seal for defects, possibly exchange, see page 11 Check door seal for correct seating Check the correct set-up of the autoclave. Check the autoclave for fallen instruments, filter paper etc. which might be lying on the chamber floor
Error 2: Steam generator	autoclave is overloaded Decreased heating power, since supply voltage too low	Pay attention to the correct loading quantities (see page 20, Load autoclave) Check building-side electrical installation, operate device on a trial basis on another electric circuit. If problem persists, notify specialist dealers
Error 4: Pressure release	Pressure release filter is soiled	Check whether the pressure-release filter is clogged (in chamber bottom in the rear area). Beforehand, unscrew the filter. On repeated occurrence notify your specialist dealer
Error 6: Ventilation	The sterile filter is soiled, appropriate warning text appears beforehand	Exchange sterile filter
Error 8: Time-base	Maximum difference between the program cycle time and the internal computer clock is exceeded	On repeated occurrence notify your specialist dealer
Error 9: Door open!	The locking sliding handle was pushed upwards during a running program	Push the sliding closure grip downwards until the stop. Correct display: Door closed On repeated occurrence notify your specialist dealer
Error 10: Overheat Steam generator	Capillary tube regulator "level control" is opened at program start (error message immediately after start) or during a program run (until the end of the sterilization) the monitoring time until the capillary tube regulator is switched back (with water feed from feed water) is exceeded	After program termination and immediate start, this error message can be repeated after a pause time of two minutes On repeated occurrence notify your specialist dealer
Error 12: Door locking	Locking pin of the door is stiff	Check the smooth running of the door locking pin On repeated occurrence notify your specialist dealer

Error message	Possible causes	What you can do
Error 14: No feed water		see warning text Warning no feed water , however this error appears <u>after</u> the start of a program
Error 18: Sensor: ...Input: ...	The device-internal inspection of the sensors for temperature, pressure or conductivity resulted in a too large deviation, the message can occur when the device is switched on or during a program	On repeated occurrence notify your specialist dealer
Error 21: Preheating	The monitoring time from switching on the pre-heating until the achievement of the respective pre-heating temperature was exceeded	On repeated occurrence select option Automatic pre-heating No (see page 23) and notify specialist dealers
Error 22: Overheat Preheating	The maximum preheating temperature was exceeded	On repeated occurrence select option Automatic pre-heating No (see page 23, Select automatic pre-heating) and notify specialist dealers
Error 26: A/D converting	The maximum admissible deviation of the computer-internal signal conditioning (A/D converting) was exceeded	On repeated occurrence notify your specialist dealer
Error 27: Temp.Sens. def 1.2	The maximum admissible deviation between the two temperature sensors for the steam temperature was exceeded	On repeated occurrence notify your specialist dealer
Error 31: System leak	During the program vacuum test the permitted pressure maximum was exceeded (very large leak) after achieving the evacuation pressure	Repeat vacuum test, if renewed error message, notify specialist dealers
Error 32: Power loss / Sterilize sterile filter	<p>The loss of the operating voltage occurred after the start of a program</p> <p>Disconnection of the autoclave during a running program</p>	<p>The error message occurs after the operating voltage is again available</p> <p>Check building-side installation, If no defects are detectable, notify MELAG customer service</p> <p>In the event of power failure after a program has been started in overpressure, an additional request appears to sterilize the sterile filter, since this has become damp and is possibly contaminated with microbes.</p> <p>Exchange sterile filter at the back side of the autoclave, sterilize the filter in the Quick Program, after the expiration of the program, plug in the filter again</p> <p>Only terminate a running program with KEY (S) (see also page 25, Manually terminate program)</p>

Error message	Possible causes	What you can do
Error 33: Pressure drop	The maximum switch-on time of the steam generator for achieving the control pressure was exceeded	On repeated occurrence notify your specialist dealer
Error 34: Sterilization TU1	Shortfall of the minimum permissible sterilization temperature (temperature sensor 1)	Operate device with smaller load, possibly carry out vacuum test Check door seal for wear On repeated occurrence notify your specialist dealer
Error 35: Sterilization TO1	Exceeding the maximum permissible sterilization temperature (temperature sensor 1)	Carry out vacuum test On repeated occurrence notify your specialist dealer
Error 36: Sterilization PU	Shortfall of the minimum sterilization pressure	Operate device with smaller load, possibly carry out vacuum test Check door seal for wear On repeated occurrence notify your specialist dealer
Error 37: Sterilization PO	Exceeding the maximum permissible sterilization pressure	On repeated occurrence notify your specialist dealer
Error 38: Sterilization TD1	Maximum permitted difference between theoretical temperature, quoted from the pressure signal, and the temperature measured at the temperature sensor 1 was exceeded	On repeated occurrence notify your specialist dealer
Error 51: Sterilization TU2	Shortfall of minimum permissible sterilization temperature (temperature sensor 2)	Operate device with smaller load, possibly carry out Vacuum test. Check door seal for wear. On repeated occurrence notify your specialist dealer. Also see Error 34
Error 52: Sterilization TO2	Exceeding the maximum permissible sterilization temperature (temperature sensor 2)	Carry out vacuum test On repeated occurrence notify your specialist dealer. Also see Error 35
Error 53: Sterilization TD2	Maximum permitted difference between theoretical temperature, quoted from the pressure signal, and the temperature measured at the temperature sensor 2 was exceeded	On repeated occurrence notify your specialist dealer. Also see Error 38

No display on the screen

After switching on the autoclave the display remains empty.

What you can do

- Check whether the power plug is correctly in the socket.
- Check the supply voltage at the socket.
- If necessary, switch the device fuses at the lower front of the autoclave (see page 10, Fig. 1/(7)) off. Follow the instructions in the technical manual in **Exchange device fuses**.

Too large feed water consumption

The feed water consumption is dependent upon the program and the loading of the autoclave.

What you can do

- Check the correct set-up of the autoclave.
- The floor of the vessel must be free. Where applicable, remove fallen instruments, filter paper, etc.

Bad drying results

Apart from a proper device function, the drying process depends decisively on the correct setting up and loading of the autoclave.

What you can do

- Check the correct set-up of the autoclave. If necessary increase the tilt by further screwing out the front feet of the unit of maximum 2 rotations.
- The floor of the vessel must be free. Where applicable, remove fallen instruments, filter paper, etc.
- The tank filter is clogged. If necessary, check and clean it.
- Pay attention to the correct loading of the autoclave (see page 20 **Load the autoclave**).
- Do not overload the autoclave. Pay attention that textiles have no direct contact with the chamber wall and floor.
- Activate the pre-heating (see page 23, **Select automatic pre-heating**).
- Employ the function Additional Drying (see page 24, **Additional Drying**).

Glossary

Air leakage – checking the air leakage

Air leakage is a poorly sealed location through which unwanted air can enter or escape; Checking the air leakage serves to verify that the volume of the air leak in the sterilization chamber during the vacuum stages does not exceed a value where it would prevent the intrusion of steam into the sterilizer load, and that the air leakage is not a possible cause of a renewed →contamination of the sterilizer load during drying

aqua dem

→demineralized water

aqua dest

→distilled water

Authorized persons

Medical specialist dealers, technician from depots or with customer service designated by MELAG, who were trained by MELAG

Heating-up period

After switching on the autoclave or after starting a sterilization program, it is the time required for heating up the steam generator before the sterilization process starts; duration depends on the temperature of the sterilizing process

Batch

Collection of the →items to be sterilized that together passed through one and the same sterilization program

BGV A1

Trade association regulations – Principles of Prevention

Bowie & Dick test

Steam penetration test with standard testing packet; described in →DIN EN 285; test is recognised for large-scale sterilizations

CF card

Compact Flash Card; Memory card for digital data of compact model size; CF is a normed standard, i.e. this memory card can be employed in every device with a CF slot. The CF card can be read and possibly written by every device that supports the standard,

Condensate

A liquid (e.g. water), which forms upon cooling from the vaporous state and thereby separates

Conductivity

is the reciprocal value of the electrical resistance; unit of measurement in microsiemens/centimetre ($\mu\text{S}/\text{cm}$); the more materials are dissolved in water, the better it conducts electrical current and the higher is its conductivity.

→distilled water ideally has the conductivity zero

Conductivity measurement

Measurement of the →conductivity

Contamination

here: Soiling of the sterilized load with unwanted or harmful materials

Corrosion

Chemical change or destruction of metallic materials by water and chemicals

Delayed boiling

This is the phenomenon that in certain conditions liquids can be heated beyond their boiling point without boiling; this state is unstable; a slight shock can cause a very rapid formation of a large gas bubble which expands like an explosion

Demineralized water

Also designated as aqua dem; water to a large extent without the minerals which occur in normal mineral or tap water; is obtained by ion exchange from normal tap water. It is employed here as →feed water

DIN EN 867-5

European standard: non-biological systems for use in sterilizers – Part 5: Stipulations of indicator systems and testing bodies for performance tests of small sterilizers of Type B and Type S

DIN EN 868

European standard: Packaging materials and systems for medical devices to be sterilized

DIN EN ISO 11140-1

European standard – Sterilization of products for health care – chemical indicators – Part 1: General requirements

DIN EN ISO 11607-1

Standard – Requirements on materials, →sterile barrier systems and packaging systems; this standard is a harmonization of the DIN EN 868 Part 1 and the international standard DIN EN ISO 11607.

DIN EN 13060

European standard –Small steam sterilizers

DIN EN 285

European standard – sterilization – steam sterilizers – large sterilizers

Display

Display device on electronic devices; here: Graphic display of the control panel

Distilled water

From lat. aqua destillata; also designated as aqua dest; water, which is largely free of salts, organic materials and microorganisms, is obtained by distillation (evaporation and subsequent condensation) from normal tap water or pre-cleaned water. It is employed here as →feed water

Dynamic pressure test of the sterilization chamber

Serves to verify that the rate of the change of pressure occurring in the sterilization chamber during a sterilization cycle does not exceed a certain value, which could lead to damage of the wrapping material
[→DIN EN 13060]

Empty chamber test

Test without load; carried out in order to evaluate the performance of the sterilizer without the influence of the load; permits checking the maintained temperatures and

pressures with respect to the intended settings
[→DIN EN 13060]

Evacuation

Creation of a →vacuum in a vessel

Feed water

is required for the creation of water steam for the sterilization; typical values for the water quality according to →DIN EN 285 or →DIN EN 13060 – Appendix C, at least however battery water according to →VDE 0510

Fractionated pre-vacuum method

Technical methods of steam sterilization;
the repeated →evacuation of the →sterilization chamber alternating with steam intake

FTP

(engl.: File Transfer Protocol) is a data communication method which serves for the transmission of data from the internet. These data can contain programs, files or information. Special FTP programs (FTP clients) serve for uploading any data on a server.

Hollow bodies A

One-sided open bodies, for which applies:

1 = $L/D = 750$ and $L = 1500$ mm or

a double-sided open body for which applies:

2 = $L/D = 1500$ and $L = 3000$ mm and which does not

correspond to the hollow body B

L...hollow body length

D...hollow body diam

Hollow bodies B

One-sided open bodies, for which applies:

1 = $L/D = 5$ and $L = 5$ mm or

a double-sided open body for which applies:

2 = $L/D = 10$ and $D = 5$

L...hollow body length

D...hollow body diameter

[→DIN EN 13060]

Initialization

Creation of a certain initial state of the →software at start-up

Items to be sterilized

Unsterile objects, materials still to be sterilized

LED

Abbreviation for Light Emitting Diode; Semiconductor diode which lights up when powered by current. LEDs are predominantly employed for status displays in devices, for example to display hard disk access.

Lubricants

Instrument oil or instrument milk

Mixed load

Wrapped and unwrapped materials to be sterilized within one load

Multiple wrapping

e.g. instruments doubly sealed in foil or wrapped in foil are additionally found in one container or in a textile wrapped container

Porous

Pervious to liquids and air, e.g. textiles

Porous full load – Check of porous full load

Serves to verify that for the values set on the control, the

required sterilization conditions are achieved in porous loads with the maximum mass for their sterilization in a sterilizer designed according to →DIN EN 13060
[DIN EN 13060]

Porous partial load – Check of porous partial load

Serves to verify that for the values set on the control, the steam quickly and uniformly penetrates into the defined test packet
[→DIN EN 13060]

Porous small parts

Made of materials which can absorb fluids (e.g. liquids)

Process evaluation system

Also self-monitoring system – observes itself, acts during the programs, compares sensors with each other

RKI

Robert Koch Institute

Self-Monitoring-system

→Process evaluation system

Separate steam production

The steam generator is located outside the sterilization chamber. The sterilization chamber is protected from overheating in this way.

Simple wrapping

Wrapped once, e.g. instruments sealed in a foil. – contrasted to: →Multiple wrapping

Software

non-material components of a EDP system; e.g. computer programs

Soft sterilization package

e.g. paper bags or clear-plastic sterilization packages

Solid

Without hollows or spaces; firm, dense, closed

Solid load – check of solid load

Serves to verify that for the values set on the control, the required sterilization conditions were achieved within the entire load. The load must represent the maximum measurements of solid instruments for whose sterilization a sterilizer has been designed according to →DIN EN 13060
[DIN EN 13060]

Stainless steel cleaning agent

e.g. Sidel

Standards-compliant

Conformity with all the relevant standards

Sterile barrier systems

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

Sterilized items

also designated as →batch, if already successfully sterilized: sterile goods

Sterilization chamber

Interior of a sterilizer

Takes up the →items to be sterilized

TCP

(engl.: transmission control protocol) designates a standard-protocol for a connection between computers and networks

Vacuum

colloquially: Space free of matter
in the technical sense: Volume with reduced gas pressure (usually air pressure)

Vacuum drying

Gentle drying; the drying goods are exposed to an underpressure which reduces the boiling point and thereby also at low temperatures leads to a vaporizing of the water

VDE

Verband der Elektrotechnik, Elektronik und Informationstechnik e.V. (Association of German Electricians)

VDE 0510

Standard of the →VDE – Provisions for accumulators and battery units

Appendix A – Accessories

	Article	Order number*	
		Vacuklav [®] 23 B+	Vacuklav [®] 31 B+
Tray mounts	A for 5 trays or 3 standard-tray cassette	40244	40233
	B for 4 standard-tray cassettes	40224	40234
	D for 2 high cassettes or 4 trays	46840	
Sterilization containers with single-use paper filters according to 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	
	17K depth/ width/ height in cm: 20/ 14/ 5	01171	
	17M Depth/ width/ height in cm: 41/ 14/ 5	01172	
	17G depth/ width/ height in cm: 14/ 14/ 9	01173	
	23M depth/ width/ height in cm: 42/ 16/ 6	01231	
	23G depth/ width/ height in cm: 42/ 16/ 12	01232	
	28M depth/ width/ height in mm: 32/ 16/ 6	01284	
	28G depth/ width/ height in mm: 32/ 16/ 12	01285	
Swab drums with filter cloth	17R diameter/ height in cm: 13/ 10,5	00174	
	23R diameter/height in mm: 18/ 14	00233	
Package Holder	for chamber Ø 25 cm X 45 or 35 cm	22420	22410
Standard tray cassette	Perforated, depth/width/height in mm: 29/ 19/ 4		
	with filter cloth	00289	
	without filter cloth	00286	
Trays	tray	00230	00280
Test body system	MELAcontrol [®] consisting of helix test body and 250 indicator strips	01080	
	MELAcontrol [®] PRO consisting of helix test body and 40 indicator strips	01075	
Water treatment units	MELAdem [®] 40 ion exchanger	01049	
	MELAdem [®] 47 reverse-osmosis unit	01047	
For the documentation	MELAflash CF card printer incl. MELAflash CF card and card reader	01039	
	MELAnet Box	40296	
	MELApri [®] 42 log printer	01042	
Other	Water stop valve	01056	
	Device fuses 16A/ gRI	57592	

*All specified articles are available at the specialist dealers

Appendix B – Symbols on the autoclave



The manufacturer of the apparatus declares with the accompanying sticker that the medical device corresponds to the basic requirements of the European Standard EN1717 – "Protection of drinking water from contaminants...."



The symbol of the struck out trashcan identifies a device that may not be disposed with domestic waste. An appropriate and competent disposal must be carried out by the marketing party.

With the designation of an apparatus with this symbol, the manufacturer furthermore declares that he satisfies all requirements of the law concerning the release, withdrawal and environmentally compatible disposal of electric and electronic appliances.



With the CE sign, the manufacturer declares that the medical device corresponds to the basic requirements of the German Medical Device Guideline. The four-digit number means that an approved certification body monitors the product certification.



With the CE sign, the manufacturer declares that the medical device corresponds to the basic requirements of the German Printing Device Guideline. The four-digit number means that an approved certification body monitors the product certification.