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MELAG

User Manual

Steam sterilizer

Vacuklav®41 B+
Vacuklav®43 B+

as of software version 3.098



Dear Dr.

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

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

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

The MELAG management and team

CE 0197

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For physicians, physician's assistants, and service personnel

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

User Manual Vacuklav®41 B+ and Vacuklav®43 B+

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Document: BA_EN_41B+_43B+_v11.docx/ Revision: 11 – 17/2371

Alteration date: 07-12-2017

Subject to technical changes

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Foreword

Thank you for deciding to buy this Premium-Plus-Class MELAG steam sterilizer.

This User Manual describes both the steam sterilizers Vacuklav®41 B+ and Vacuklav®43 B+. They are identical except for their chamber depth and device depth.

Device name The device name "steam sterilizer" is used in this User Manual to designate the steam sterilizers Vacuklav®41 B+ and Vacuklav®43 B+.

User Manual The User Manual contains important safety instructions and information which you need to operate the steam sterilizer. Read these instructions carefully and thoroughly in proper sequence.

Avoid dangers Please read all the safety instructions attentively before using the steam sterilizer.

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 steam sterilizer.
	Important information	Indicates important information.

Table 1: Meaning of the symbols used in this User Manual

Example of emphasis	*Meaning*	*Explanation*
Universal-Program	Software citation	Words or phrases appearing on the Colour-touch display of the steam sterilizer 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 Art. no. 5 in Figure 1.

Table 2: Meaning of the emphasized text within this User Manual

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Symbols on the steam sterilizer

Symbol	Explanation
	Manufacturer of the medical device
	Date of manufacture of the medical device
	Serial number of the medical device by the manufacturer
	Article number of the medical device
	Indication of the scale of the chamber volume
	Operating temperature of the device
	Operating pressure of the device
	This User Manual contains important safety information. Failure to comply of the safety instructions could result in human and material damage.
	Please read this user manual carefully before commissioning the device. The manual includes important safety information. The functionality and value-retention of this sterilizer depends on the care accorded to it. Please store this user manual carefully and in close proximity to your sterilizer. It represents a component of the product.
	The symbol of the crossed out waste bin identifies a device that must not be disposed in domestic waste. The vendor is responsible for appropriate disposal of the device - it must be delivered to the vendor to be disposed of. With the designation of an apparatus with this symbol, the manufacturer furthermore declares that he satisfies all requirements of the law concerning the release, redemption and environmentally sound disposal of electric and electronic appliances. MELAG devices are synonymous for long-term quality. When you eventually need to decommission your MELAG device, we offer a special disposal service. Simply contact your stockist.
	In affixing the CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the medical products directive. The four-digit number confirms that this is monitored by an approved certification agency.
	In affixing this CE mark, the manufacturer declares that this medical product fulfils the basic requirements of the pressure device directive. The four-digit number confirms that this is monitored by an approved certification agency.
	Indicates that operation of the steam sterilizer should follow according to the safety instructions in the User manual.
	Indicates a hot surface. Breakdown of the cooling fan may make the cooling parts hot.

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Safety instructions

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

Instruction

- Do not sterilize any liquids with this steam sterilizer.

Power cable and power plug

- Never damage or change the main cable or power plug.
- Never operate the steam sterilizer if the main cable or power plug are damaged.
- Never pull on the main cable to take it out of the socket. Always take hold of the power plug itself.

Double jacket steam generator

- The steam sterilizer remains under pressure after being switched off. Check the pressure display of the manometer located on the steam sterilizer lower front side.

Setting up, installation, commissioning

- Only have the steam sterilizer set up, installed, and commissioned by people →authorized by MELAG.
- Only operate the steam sterilizer 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.
- Documentation media (computer, CF card reader etc.) must be placed in such a way that they cannot come into contact with liquids.

Preparation and sterilization of textiles and instruments

- 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.

Program termination

- 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 steam sterilizer. If necessary, sterilize the affected objects after re-wrapping.

Removal of the items to be sterilized

- Never open the door by force.
- Use a tray lifter to remove the tray. Never touch the sterilized items, the chamber or the interior of the door with unprotected hands. The parts are hot.
- Check the wrapping of the sterilized objects for damage when removing them from the steam sterilizer. If a wrapping is damaged, wrap the object again and re-sterilize it.

Maintenance

- Have the maintenance done only by authorized persons.
- Comply with the predetermined maintenance intervals.

Carrying the steam sterilizer

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

Errors

- If repeated error messages occur while operating the steam sterilizer, turn the device off.
- Only have the steam sterilizer 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 steam sterilizer**
- **what benefit you can achieve by using this steam sterilizer**
- **which sterilization programs you can use**

Proper use

Application area

The steam sterilizer is intended for use in the medical field, e.g. in general physician and dental practices.

Sterilization tasks

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

Danger

Observe the following instructions for using the steam sterilizer:

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

Failure to observe these instructions may lead to delayed boiling, damage to the steam sterilizer and burns.

Warning!

- Use the steam sterilizer only for the intended purposes outlined in the related technical documents and only in connection with the devices and components recommended by MELAG.
- The sterilization of instruments and textiles with this steam sterilizer, like the foregoing instrument sterilization, 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.

Failure to observe these instructions may lead to damage and/or safety of operation.

User benefit

Universal use

The steam sterilizer sterilizes on the basis of the fractionated 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
Small time expenditure
No pause times
Overheating protection

To generate the sterilization steam, the steam sterilizer uses a double jacket steam generator. Once heated up, it provides permanent steam. The walls of the sterilization chamber thus have a defined temperature. 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.

Clean feed water

The steam sterilizer works with a one-way feed water system. This means that it uses fresh purified feed water for every sterilization run. The quality

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of the feed water is constantly monitored via integrated conductivity measurement. This prevents stains on instruments and soiling of the steam sterilizer, assuming the instruments have been carefully prepared.

Automatic feed water supply

The supply with purified feed water for the steam production is automatically supplied via an internal water storage tank or a water treatment unit (e.g. MELA*dem*®-40, MELA*dem*®-47).

Optimal drying for wrapped items to be sterilized

The items to be sterilized are dried by the vacuum (vacuum drying). This way you achieve optimal drying results for wrapped objects as well.

Optimized total operating time

The steam sterilizer works with an electronic parameter control. This way the steam sterilizer optimizes the total operating time of a program depending on the load.

High degree of safety by extensive safety devices

The steam sterilizer checks the pressure and temperature in the sterilization chamber at all times and does not permit the door to be opened in case of overpressure in the chamber. The motor-operated automatic door lock slowly opens the door by turning the locking spindle and holds the door while it opens. Pressure compensation takes place even if there is any difference in pressure until the door is completely opened.
The quantity and quality of the feed water is checked.
A process evaluation system is integrated in the electronics of the steam sterilizer. During a program it compares such process parameters as temperatures, times and pressures with each other. It monitors the parameters with respect to their limit values at activation and control and guarantees a safe and successful sterilization.
A monitoring system checks the device components of the steam sterilizer with respect to their functional reliability and their plausible interaction.
If one or more parameters exceed defined limits, the steam sterilizer issues warnings or error messages, and if necessary aborts the program.
In the event of an automatic program abort, observe the information on the display.

Additional function check

You can conduct an additional function check at any time with the help of test programs.
Use the vacuum test to check the steam sterilizer for leaks in the steam system.
Use the Bowie & Dick test to check whether there is sufficient steam penetration for porous material to be sterilized (e.g. textiles).

Effective batch documentation

The steam sterilizer has an internal log memory. All data of the completed sterilization programs are automatically stored here.
You can read out the internal log memory immediately after the end of the program, or at a later time. You determine whether the logged data are issued to one or several different output media (e.g. log printer MELA*print*® 42, MELA*flash* CF card, computer).

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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
Simple hollow items (Hollow body B)	X	X	X	X	X
Narrow lumen (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
X = Conformity with all applicable sections of the standard DIN EN 13060					

Table 3: Overview of sterilization programs

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Chapter 2 – Device Description

In this chapter you learn

- **which components are included in the standard scope of delivery**
- **which components the steam sterilizer contains**
- **what safety devices the steam sterilizer has**
- **how the operating elements are designed and how you should use them**
- **how the menus of the user interface are structured**
- **which acoustical signals the steam sterilizer emits**
- **what kind of water supply the steam sterilizer needs**

Scope of delivery

Standard scope of delivery

- Vacuklav®41 B+ or Vacuklav®43 B+
- User Manual
- Technical Manual
- Record of installation and setting up
- Certificate of conformity with the Medical Device Directive
- Certificate of conformity with Pressure Equipment Devices Directive
- Warranty certificate
- Mounting for the load
- Tray lifter
- Hose for emptying the internal storage tank
- Allen key wrench for emergency opening of the door
- Torx wrench to remove the carrying strap

Optionally

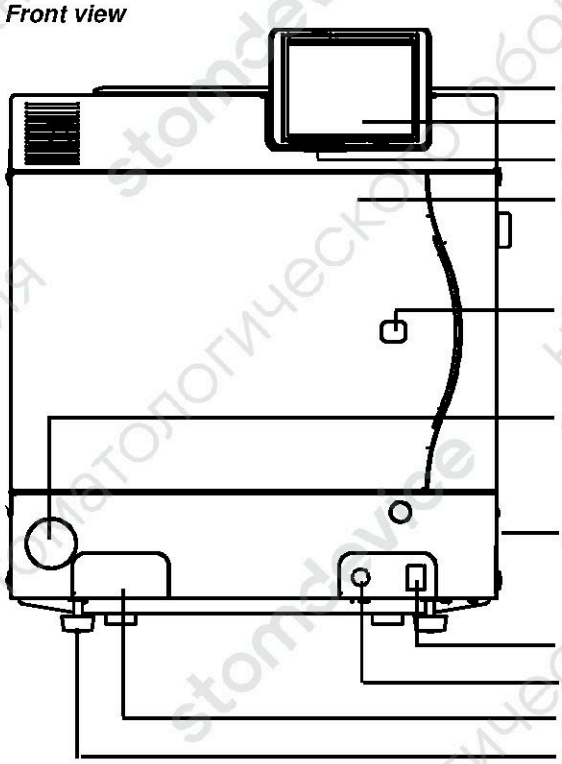
- Trays
- Standard tray cassettes and lifter
- MELAstore-Trays
- MELAstore-Boxes
- Additional tray mounts
- MELA*flash* CF card
- MELA*flash* CF card reader

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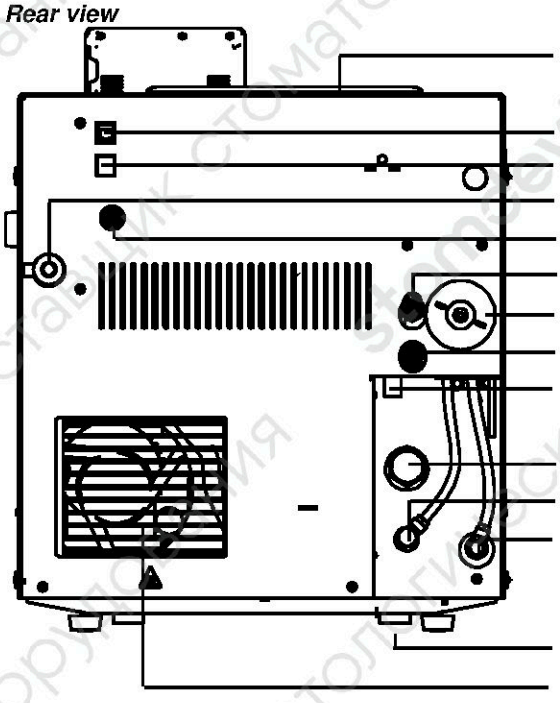
Equipment views

Front view



(1) Slot for the CF Card
(2) Colour-touch display
(3) LED status bar
(4) Door (opens to the left)
(5) Cap for emergency opening of the door
(6) Protective cap for manometer to display the pressure of the double jacket steam generator
(7) Power switch (concealed, accessible from the side)
(8) Ethernet-data connection 1*
(9) Reset button overheating protection*
(10) Quick-fitting connection for emptying the storage tank*
(11) Front foot of the unit (adjustable)
*behind covering

Rear view



(12) Tank cover
(13) Ethernet-data connection 2
(14) Ethernet-data connection 3* (can be retrofitted)
(15) Power cable
(16) Optional connection for a Flex-Display
(17) Safety spring valve, chamber
(18) Sterile filter
(19) Safety spring valve, double jacket
(20) Emergency overflow
(21) One way drain
(22) Pressure release connection
(23) Purified feed water intake (for or MELA*dem*®; swiveling threaded fitting for hose 8x1, alternatively straight)
(24) Rear foot of the unit (fixed)
(25) Cooler

Figure 1: Front and rear view

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Interior view



Figure 2: Interior view

Effective capacity

The steam sterilizers Vacuklav®41 B+ and Vacuklav®43 B+ differ only with respect to the respective depth of the units. As a result, their effective capacities are different.

	Diameter	***Depth***
Vacuklav®41 B+	25 cm	35 cm
Vacuklav®43 B+	25 cm	45 cm

Table 4: Dimensions of the effective capacity

Mountings for the load



Figure 3: Mounting C

The steam sterilizer is always delivered with a mounting to hold trays or cassettes.
The mounting (C) is standard and can hold either six trays or three MELAstore-Boxes 100 rotated by 90°.



Figure 4 Mounting B

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



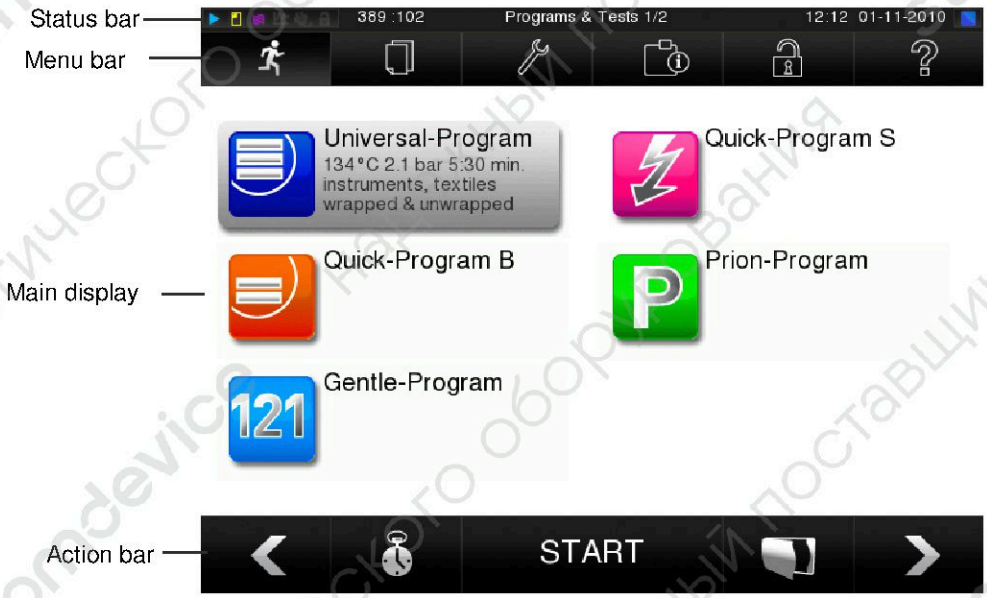
Figure 5 Mounting D

The mounting (D) can hold two high cassettes (e.g. for implants), two MELAstore-Boxes 200 or - rotated by 90°- four trays.

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The control panel

The control panel consists of a colored 5 inch Colour-touch display.



Symbols in the status bar	*Meaning*
Programs/Tests	Indicates a program is running
Immediate output	Indicates whether immediate output is activated/deactivated
Supplemental drying	Indicates whether supplemental drying is activated/deactivated
Graphic logs	Indicates whether recording of graphic logs is activated/deactivated
Energy saving mode	Indicates whether steam sterilizer is in energy saving mode
Service area	Indicates whether a service technician is logged in to the service area
CF card Status	Indicates whether a CF card is inserted and whether read or write access is in place

Symbols in the menu bar	*Meaning*
Programs/Tests	all sterilization programs and tests are found here, e.g. vacuum test, Bowie & Dick Test, etc.
Log output	the entire log list, logs from a defined time period, e.g. daily, monthly, etc. or specific log types can be found here such as the option to delete logs
Settings	various settings can be made, e.g. date and time, brightness etc., in addition, Standard log settings for log output can be set here
Info-/ Status window	indicates information regarding software version and device dates, e.g. batch lot, maintenance meter, log settings, log memory and other technical values
Service area	only for technicians
Help menu	depending on the selected window and control status, gives information for control or function of the actual window

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Symbols in the action bar		Meaning
	***Door open***	opens the steam sterilizer door
	***Back***	changes to the previous window
	***Forward***	changes to the next window
	***Terminate/ go back without saving***	returns to the superior menu, closes the window without saving
	***Zoom (+)***	indicates additional details, e.g. additional values after the end of a program run
	***Start time code***	Changes to the “Pre-selection start time” menu
	***Delete***	deletes logs from the internal log memory / deletes the log printer or label printer stored as standard
	***Find***	finds the label printer(s)/log printer(s)

LED status bar

The status bar located on the border of the display indicates colours for various situations, e.g. in Standby during the running of a program or for warning or malfunction messages.
blue - Standby, program is running, drying has not yet begun
green – drying is running, program completed successfully.
yellow – for warning messages, during software update.
red – for malfunction messages, program not completed successfully.

Supply with feed water

The steam sterilizer requires demineralized or distilled feed water for generating steam. The feed water supply is provided either with an internal water storage tank or with a water treatment unit (e.g. MELA*dem*®40 / MELA*dem*® 47). The steam sterilizer automatically sucks in the feed water.

Feed water from internal water storage tank

If you deploy an internal water storage tank for the feed water supply, you must fill it manually from time to time. Employ only water available on the market according to DIN EN 13060, Appendix C as feed water.

Internal storage tank

The water storage tank from MELAG has a capacity of maximum 5 liters. This quantity of feed water is enough for up to 7 sterilizations.

Distilling unit MELAdest®65

With the MELA*dest*®65 distilling unit, you can produce feed water cost effectively for all practices.

Feed water with water treatment unit

A water treatment unit is connected to the drinking water grid. It produces the feed water required for generating the steam for the steam sterilizer. The purified feed water connection for the steam sterilizer 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 need to fill the water storage tank.

Water treatment units MELAdem®40 and MELAdem®47

The water treatment units MELA*dem*®40 and MELA*dem*®47 produce the optimal purified feed water quality for the steam sterilizer. The selection of the respective unit depends on the number of sterilizations per day and the respective loads. Every MELAG steam sterilizer can be supplemented with a water treatment unit.

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NOTICE!
Please first consult with MELAG if you would like to use water treatment units from other manufacturers.

Turning on the steam sterilizer

Danger

Observe the following safety measures when handling the main power cable and the power plug:

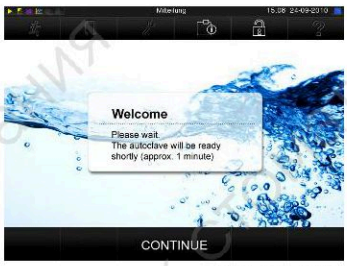
- Do not splice or alter the power cable.
- Do not bend or twist the power cable.
- Do not tug on the power cord to remove the plug from the outlet. Always grasp the plug directly.
- Do not place heavy objects on the power cable.
- Do not lay the power cable over objects in which it may get caught (e.g. doors or windows).
- Do not lay the power cord across a heat source.
- Do not use nails, staples or other such objects to affix the cable.
- If the power cable or plug becomes damaged, do not use the steam sterilizer. The power cable or plug should only be replaced authorized persons.

Failure to observe these measures may lead to damage to the cable or plug and/or to fire or electrical shock. Severe injuries may result.

Place the power plug into the power outlet
Turn on the steam sterilizer

If the steam sterilizer is not connected to the power supply, place the power plug into the power outlet.
Turn on the steam sterilizer using the power switch.

After switching on



Set-up time

The display will indicate **`Welcome`**. The software of the steam sterilizer will initialize and the device components will be tested.
The water level in the feed water in jacketed steam generator will be tested automatically and fixed if necessary during the feed process (feed pump will run). The feed water will be heated for the steam generation.

After the steam sterilizer is turned on using the power switch, a one-time warm-up period is required to heat the jacketed steam generator. For normal use, this takes:

- Vacuklav®41 B+: 9 minutes
- Vacuklav®43 B+: 13 minutes



The display indicates the program menu each time the device is turned on. The default setting is the **`Universal-Program`**.

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Closing the door

Warning

When closing the door of the steam sterilizer, observe the following instructions:

- Do not press the door too hesitantly against the steam sterilizer housing.
- Hold the door pressed closed for at least 3 seconds.
- Under no circumstances should you slam the door shut.

Failure to observe these instructions may impair the functional reliability of the door lock mechanism.



The steam sterilizer has an automatic motor-driven door lock with threaded spindle.
In order to lock the door, press it tightly closed.
The door locks pressure-proof once the program is started.

Locked door

Inputs at the display of the steam sterilizer are only possible when the steam sterilizer door is locked.

NOTICE!

Leave the door open only for loading and unloading the steam sterilizer. If you keep the door closed, you will save energy.

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Chapter 3 – Initial commissioning

In this chapter you learn

- **who may set up, install and commission the steam sterilizer**
- **which prerequisites you must create for setting up, installing and commissioning the steam sterilizer**
- **where you will find additional information**

Conditions for setting up, installing and commissioning

Danger

- Only have the steam sterilizer set up, installed, and commissioned 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.

Failure to observe this precaution may lead to damages to the steam sterilizer and/or injuries.

Warning

- The steam sterilizer is intended for use outside the patient environment. The minimum distance to the treatment area must have a radius of at least 1.5 meters.

Failure to observe this precaution may lead to damages to the steam sterilizer and/or injuries.

Set-up location requirements

Location

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

Warning

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

Distance to the surrounding surfaces

Failure to observe these guidelines may lead to heat accumulation. This could adversely affect the function of the steam sterilizer and could shorten the lifetime of the vacuum pump and increase program times. The distance from each side of the steam sterilizer to the surrounding surfaces must be at least 5 centimeters, and 10 centimeters are the rear of the steam sterilizer. The steam sterilizer should be accessible from the top, so that the built-in storage tank can be filled and so that there is good ventilation.

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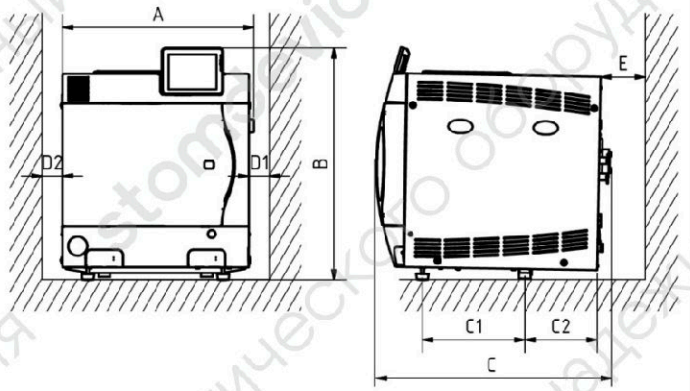
Space requirements			Vacuklav® 41 B+	Vacuklav® 43 B+
	Width	A	47 cm	47 cm
	Hight	B*	56.5 cm*	56.5 cm*
	Depth	C	57.5 cm	69 cm
		C_1	25 cm	36 cm
		C_2	18 cm	18 cm
		D_1	5 cm	5 cm
		D_2	14 cm	14 cm
		E	10 cm	10 cm
* with Flex Display B=50 cm (dimensions to upper edge of the steam sterilizer without display)				

Table 5: Space requirements of the steam sterilizer

Additional space for feed water supply

Other than the space for the steam sterilizer, you will require if necessary, space for a water treatment unit for the feed water supply.

Space requirements for a water treatment unit

MELA*dem*®40

- Can be directly attached to the steam sterilizer
- The attachment can be next to the steam sterilizer or above or below the steam sterilizer

MELA*dem*®47

- Attachment next to the steam sterilizer or above or below the steam sterilizer (e.g. lower cabinet)

	Width	Height	Depth	Diameter
MELA*dem*®40	32 cm	35 cm	15 cm	
MELA*dem*®47 module housing	39 cm	47 cm	15 cm	
MELA*dem*®47 water storage tank		51 cm		24 cm

Table 6: MELA*dem*® Space requirements

Connections required

Danger

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

Failure to observe this caution may lead to a short-circuit and/or fire and/or water damage and/or electrical shock. Serious injuries may result.

Electrical connection

Provide the following electrical connections for the steam sterilizer:

- Electric circuit with 220-240 V (max. voltage range 207-253 V) and 50/60 Hz
- Connected load 3400 W (at least 15 A separate fuse protection)
- Connected load for UK, Ireland, Malaysia 2760 W (at least 13 A separate fuse protection)
- Protection from leakage current 30 mA

Waste water discharge

You can optionally connect the steam sterilizer via the pressure release connection (see page 9, Figure 1/(20)) or via the one way drain (see page 9, Figure 1/(21)). Follow the instructions in the Technical Manual carefully.

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NOTICE!

The waste water hose must be able to be laid with a continuous dip-free descent.
For wastewater paths which are longer than two meters, MELAG recommends a fixed layout of HT (high temperature) pipe carried out by a specialized installation firm.

Prerequisites for initial commissioning

The following prerequisites must be satisfied for initial commissioning:

- The feed water supply must be secured. For the first-filling of the steam generating system the steam sterilizer requires about three liters feed water.
- The power supply of the steam sterilizer must be assured.
- If available, the MELA*flash* CF card should be plugged in the card slot.

Record of installation and setting up

NOTICE!

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

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Chapter 4 – Sterilization

In this chapter you learn

- **which prerequisites you must create for successful sterilization**
- **what you should observe on preparation of the items to be sterilized**
- **how you correctly load the steam sterilizer**
- **which programs you should use for what**
- **how you start a program**
- **which stages a program runs through**
- **how to cancel a program**
- **how you can recognize that 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

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

Provide feed water

- If you are employing the internal water storage tank for the feed water supply, watch the filling level on the tank (right side), and fill up the water storage tank if necessary with fresh feed water to the MAX line.
- If you employ a water treatment unit, e.g. MELA*dem*®40, MELA*dem*®47, and the water feed is closed, then open it up. If the water storage tank of the MELA*dem*®47 is empty, turn the water feed tap on at least one hour before the sterilization.

Switching on

- If the steam sterilizer is still not switched on, switch it on at the main switch (See page 15, **Turning on the steam sterilizer** and **After switching on**).

Plug in CF card

- If you would like to use a CF card as the output medium for logging and the MELA*flash* CF card is still not plugged in, plug it in the card slot (see page 31, **Plug in CF card**).

Manufacturer's recommendations for daily routine operation

Observe the manufacturer's recommendations from MELAG on the routine operation of Class B steam sterilizers.

Prepare items to be sterilized

An essential prerequisite for the secure disinfection and sterilization of sterilizing materials is the appropriate cleaning and maintenance of the items to be sterilized according to the manufacturer's instructions. Furthermore, the materials, cleaning agents and processing procedure employed are important.

NOTICE!

If possible, sterilize textiles and instruments separately from each other in separate sterilization containers or sterilization packages.

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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, e.g. of RKI and DGSV.
- 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 current channels can form.
- If textile packages do not stay together, wrap the textiles in sterilization paper.
- Sterilize only dry textiles.
- The textiles must have no direct contact to ground and walls of the sterilization chamber, otherwise they absorb condensate.

Failure to observe these guidelines may result in the steam penetrating the washing packet and obstruction and/or bad drying results may result. In that case, the textiles cannot be sterilized, which may entail endangerment to the health of the patient and the practice team.

Instruments

Danger

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, e.g. of BGV A1, RKI and DGSV.
- Clean the instruments very thoroughly, e.g. with the help of a washer-disinfector.
- After disinfection and cleaning, rinse the instruments 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.

Failure to observe these guidelines may result in residual dirt loosening up during sterilization in the steam pressure. Remnant of the disinfection and cleaning agents can lead to corrosion. Increased maintenance requirements and the impairment of the function of the steam sterilizer may result.

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. To disinfect and clean the instruments, MELAG recommends the use of auxiliary materials such as:

- Ultrasonic units
- Maintenance appliances for hand and angle pieces
- Washer-disinfector

Load the steam sterilizer

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

NOTICE!

Place trays or cassettes in the chamber only with the accompanying mounting.

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.

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Wrapping

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

Warning

Only use packaging materials and systems which satisfy the DIN EN 868 standard.

You can employ recyclable rigid packaging such as standard tray cassette or soft packaging such as transparent sterilization packages, paper bags, sterilization paper, textiles, and fleece.

Closed sterilization containers

Use sterilization containers made of aluminum. Aluminum conducts and stores heat well and thereby quickens drying.
When using closed sterilization containers, observe the following instructions for bearing the sterilizing materials:

Warning

- Closed sterilization containers must be equipped at least on one side with perforations or valves.
- When using sterilization containers perforated on one side the perforation should be possibly on the top, e. g. MELAstore-Boxes.

Failure to comply may lead 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 the endangerment of the health of the patient and the practice team.

The MELAG sterilization containers satisfy all requirements for successful sterilization and drying.

Stack sterilization containers

If possible, stack only sterilization containers of the same base surface on top of each other, where the condensate can run off to the side at the walls.

Warning

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

Failure to comply may mean the condensate is unable to 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 the endangerment of the health of the patient and the practice team.

Soft sterilization wrapping

Soft sterilization wrapping can be sterilized in sterilization containers as well as on trays. When using soft sterilization packages such as e.g. MELA*fol*®, observe the following instructions:

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Warning

- Order soft sterilization packages vertically standing and at a small interval to each other.
- Do not lay 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 not the case, re-wrap the instruments and sterilize them once again.
- If the welding seam tears open during sterilization, extend the sealing cycle of the package sealing device or weld a double seam.

Failure to comply may ultimately lead to unsterile instruments and thereby to the endangerment of the health of patient and practice team.

Multiple wrapping

The steam sterilizer works with the fractionated 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 are on the bottom
- Transparently wrapped sterilization packages and paper packaging on the top – exception: in combination with textiles on the bottom
- Transparent sterilization packages if possible vertically endwise, and if this is not possible, with the paper side facing downwards

	Vacuklav®41 B+		***Vacuklav®43 B+***	
	Instruments	Textiles	Instruments	Textiles
Maximum measurements for each component	2 kg	2 kg	2 kg	2 kg
Loading variant mounting C[1)]	max. 6 trays, depth 290 mm max. 3 steriliz. containers 15K max. 3 steriliz. containers 15M max. 2 steriliz. containers 15G max. 3 steriliz. containers 17K max. 3 swab drums 17R max. 2 swab drums 23R max. 2 steriliz. containers 28M max. 1 steriliz. containers 28G max. 3 standard tray cassettes		max. 6 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. 2 sterilization containers 23M max. 1 sterilization containers 23G max. 2 swab drums 23R max. 2 sterilization containers 28M max. 1 sterilization containers 28G max. 3 standard tray cassettes	
Maximum total weight	6 kg	2 kg	7 kg	2.5 kg
Maximum total weight when using MELAstore[2)]	9 kg			

1) Tray mounts, trays, sterilization containers, standard tray cassettes from MELAG: see **Appendix A – Accessories.**
2) Other loading configurations in accordance with on-site validation

Table 7: Loading variants, example of mounting C, and maximum load

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Select program

Select the sterilization program accordingly, depending on whether and how the sterilizing materials are wrapped. Furthermore, consider the resistance to high temperature of the items to be sterilized.
All sterilization programs are displayed in the menu **`Programs & Tests`**.
The following tables show which program to use for which items to be sterilized and which auxiliary programs are available.

	Universal-Program	Quick-Program B	Quick-Program S	Gentle-Program	Prion-Program
Sterilization temperature	134 °C	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2,1 bar	2,1 bar	2,1 bar	1,1 bar	2,1 bar
Sterilization time	5:30 min.	5:30 min.	3:30 min.	20:30 min.	20:30 min.
Operating time*	ca. 21 min.	ca. 14 min.	ca. 10 min.	ca. 36 min.	ca. 38 min.
Drying	12 min.	6 min.	2 min.	12 min.	12 min.

*) without drying (full load) and depending on the load and installation conditions (such as supply voltage)

Program		*Wrapping*	*Especially suitable for*	*Load 41 B+/43 B+*	*Load with MELAstore*
Universal-Program		mixed loads; long, narrow-bore hollow bodies	mixed loads; long, narrow-bore hollow bodies	6 kg/7 kg	9 kg
Quick-Program B		single wrapping and unwrapped instruments (no textiles)	long narrow-bore hollow bodied instruments	single wrapped max. 1.5 kg --- unwrapped 6 kg/7 kg	--
Quick-Program S		only unwrapped (no textiles)	Simple solid instruments; trans-mission instruments; simple hollow bodies	6 kg/7 kg	--
Gentle-Program		single and multiple wrapping	Larger quantities of textiles; Thermo-instable goods (e.g. plastic, rubber articles)	Textiles 2 kg (41B+) 2.5 kg (43B+) --- Thermoinstable goods 6 kg/7 kg	9 kg
Prion-Program		single and multiple wrapping	Instruments where a danger of infection by pathological-ly-modified proteins is suspected (e.g. Creutzfeld-Jacob, BSE)	6 kg/7 kg	9 kg

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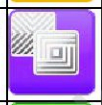
Auxiliary program		*Use/Function*
Vacuum test		For measuring leak rate, a test for dry and cold device (test without load)
Bowie & Dick test		Steam penetration test with special test package (available from your specialist dealer)
Conductivity measure-ment		For manually measuring the quality of the feed water
Draining		For draining and pressure release of the double-jacket steam generator, e.g. for service, for maintenance or before transport.

Table 8: Overview of the application of sterilization programs

Additional drying



The program-specific drying times guarantee very good drying of items to be sterilized for a load as described in this Chapter (see page 21, **Load the steam sterilizer**).
For difficult drying tasks you can extend the drying time of a program by 50% in the menu **`Settings`** with the option **`Additional drying`**.

NOTICE!
Working in the **`Settings`** menu, you can also activate the additional drying function retrospectively during a running program.

Pre-selection start time



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

- After selecting the program, touch the symbol in the action bar. The display changes to the pre-selection start time image.
- For example, to change the time, tap the Hour or Minute symbol. The selected field will become light blue.
- You may now change the time by pressing the and buttons.
- Finally, press START. The display will remain in the pre-selection start time image.

NOTICE!
Please note that the function pre-selection start time is not possible with the Quick Program S for safety reasons.

After setting the program start time, no other menu can be selected other than the menu **`Info & Status`**.
The pre-selection start time is only active for the unique time and program selection, that is, after the completion of the program the pre-selection start time is deleted.
You may turn off the steam sterilizer while the pre-selection start time is running. However, the steam sterilizer must be turned on again in time for the timer to progress again.

Warning

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

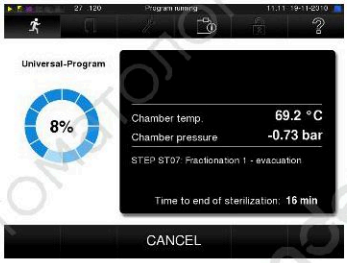
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Start program



If you have selected a program with the navigation keys, it is displayed marked (inversely highlighted). You can now activate it by pressing the START key.
The door locks pressure-proof as soon as the program starts. The steam sterilizer checks the quantity of the feed water and its conductivity.
At the start of the Quick-Program S a cautionary note appears, coupled with an acoustic signal. Unwrapped instruments may exclusively be sterilized with the Quick-Program S. If the load exclusively contains unwrapped instruments, confirm with YES to start the program.

Program is running



A program runs in three phases.
After starting a program, you can track the program sequence on the display. Chamber temperature and pressure as well as the duration until sterilization or end of drying are displayed.

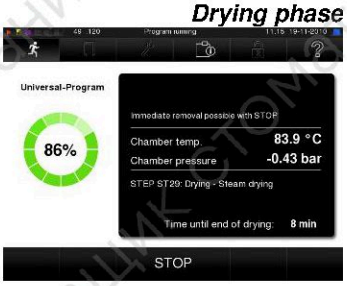
Evacuation phase

Air is repeatedly evacuated in the evacuation phase until a program-dependent pressure is achieved. This occurs in alternation with the inflow of steam up to a slight overpressure.

Sterilization phase

After achieving the sterilization parameters of pressure and temperature, the sterilization phase begins. The sterilization time is shown on the display. There is a pressure release at the end of the sterilization phase.

Drying phase



The drying phase begins after the pressure release.
The regular drying time for the Quick-Program S is two minutes, for the Quick-Program B six minutes and for all other programs is 12 minutes.

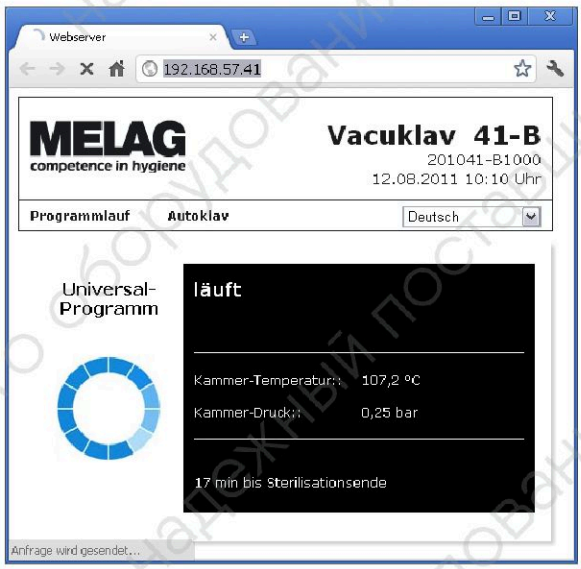
Tracking program progress with a computer

You can follow the actual progress of a running sterilization program on any computer in the lab network over a website integrated with the steam sterilizer via a web browser.
A prerequisite is that there is an IP address for the steam sterilizer that is linked to the lab network:

- Open a web browser window (we suggest Mozilla Firefox or Internet Explorer).
- Enter the IP address of the steam sterilizer into the lab PC in the address line of the web browser, e.g. 192.168.57.41 and confirm with “enter”.

Now you are able to record the program completion and other information such as serial number, device software version and other selected values to the steam sterilizer.

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Manually terminate program

Danger

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

- Please note that hot water steam can escape upon opening the door after you terminate a program, depending on the time of the termination.
- 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.

Failure to observe these precautions may lead to burns.

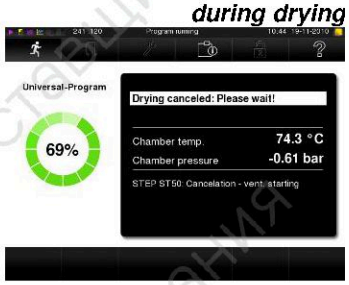
To terminate a running program, press the **STOP** key and confirm with YES. After a short time, as shown on the display, you can open the door by briefly pressing the door symbol.

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.
A cautionary note appears on the display. The log reports that the sterilization was **NOT successful**.

Manual termination during drying



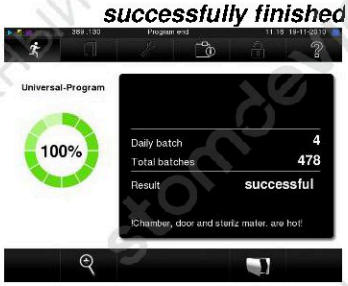
In the drying phase, you can terminate the program with the **STOP** button without the steam sterilizer registering an error.
You must then, especially for wrapped sterilized items, expect insufficient drying. Sufficient drying is a prerequisite for sterile storage.
Therefore, if possible, let programs with wrapped items to be sterilized 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 steam sterilizer.

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Sterilization phase is finished

Sterilization successfully finished



From a distance you can recognize from the display whether the sterilization phase is already successfully completed.
As soon as the drying phase is initiated, the colored ring as well as the LED status bar change from blue to green.

Sterilization not successfully finished

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

Program abort by the system

At a system abort, the system puts the double jacket into a pressureless state. Therefore a system abort takes longer to complete than a termination executed by the operator.

Drying phase

The steam sterilizer does an excellent job of drying the items to be sterilized. However, in the event of difficult drying tasks it might be necessary to take the following measures to further improve drying:

Improve drying results

- Load the steam sterilizer correctly for drying. Place items wrapped in clear plastic or paper upwards like filing cards. Observe the section on page 21, **Load the steam sterilizer**. Use the optional package holder where applicable.
- Activate the function Additional Drying. Observe instructions under the section **Additional drying** on page 25.

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.

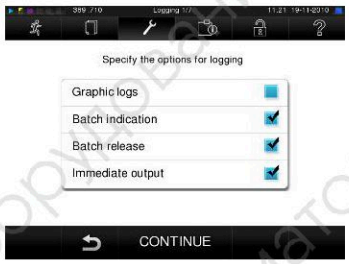
Look at the log header on the display

Before you open the door, you can look at additional values of the just-completed program, for example, the plateau time, the conductivity, etc. on the display by pressing the magnify symbol .

Automatic log output

If the automatic log output is activated in the **`Settings`** menu under **`Logging`**, the log from the completed program will be produced in the activated output device after the door is opened (see page 30, **Chapter 5 – Logging**).

Release process



According to RKI [Robert Koch Institute] - “Recommendations for hygiene in the preparation of medical products” the preparation of instruments ends with the documentation of release to storage and use of the sterilized products.
The release process is comprised of the batch indication and the batch release and must take place by authorized and qualified personnel.

Batch indication

This includes the review of the indications shown during the sterilization program, e.g. MELA*contro*®/ MELA*contro*® Pro.

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Only once the indicator stripe has completely changed colour can the release of the indicator occur.

Batch release
This includes the review of the process parameters with reference to the sterilization results in the steam sterilizer and the sterilization log, as well as the review of the single wrapping for damage and residual moisture. The release of the batch and the potential indications shown during the process are documented on the sterilization log.
Depending on the setting in the user administration, the release of the sterilized items requires a user PIN from the person who releases the batch and the indications.

Remove sterilized items

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

Danger

- Never open the door by force. The steam sterilizer 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 interior of the door with unprotected hands. The parts are hot.

Failure to observe these warnings may result in burns.

Danger

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

Failure to observe these warnings may result in unsterile instruments. This endangers the health of the patient and the practice team.

Condensate residues on the sterilized items

If you remove the sterilized items from the steam sterilizer directly after the end of the program, it can happen that slight quantities of condensate moisture are found on the sterilized items.
According to the Arbeitskreis für Instrumentenaufbereitung (engl.: Working group Instrument Reprocessing) (AKI; Red Broschure; 10 Edition; p. 57): "in practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable."

Storage of sterilized items

Only wrap items to be sterilized in wrappings that comply with the standards.
Do not store sterilized items in the preparation room. For the storage of the sterilized items, observe DIN 58953, Part 7 and the criteria 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.

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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**
- **Where you can find the logs for the batch documentation**
- **How to read the logs correctly**
- **How to set the date and time at the steam sterilizer**

Batch documentation

The batch documentation is indispensable as documentation for the successfully completed sterilization process and as an obligatory measure of quality assurance.
The data, such as type of program as well as batch and process parameters of all completed programs, are stored in an internal log memory of the steam sterilizer.

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.

Output media

You have the possibility of storing the logs of the completed programs on the following output media and to archive them accordingly.

- MELA*flash* CF card
- Computer (over the network)
- Log printer MELA*print*®42

You can arbitrarily combine the output media. It is thereby possible, for instance, to store logs on the MELA*flash* CF card and additionally to permit printing.
The logs are outputted on several activated media in sequence.
You select the desired output media by selecting **`logging`** in the **`Settings`** menu or in the **`Logging`** menu for the subsequent log output.

Detailed information on activating and setting up the log output is found in **Chapter 6 – Settings**.

State on initial delivery

In the state at initial delivery of the steam sterilizer, the MELA*flash* CF card is defined as the output medium for text and graphic logs and automatic logging thereby the activated (see page 32).

Capacity of the internal log memory

The capacity of the internal storage suffices for about 100 logs.
If the internal log memory is almost full and at least one log has not yet been issued to an activated medium, the cautionary warning **`Internal memory of program logs almost full`** appears on the display.
If this cautionary warning appears, you should prepare the output media determined in the menu **`Settings`** → **`Logging`** and output the respective logs (menu **`Logs`**).
Shortly thereafter the notification **`log memory full`** is displayed. Then you have the last opportunity of archiving logs that have not yet been outputted (Confirm with YES), before the data in the log memory of the steam sterilizers is automatically deleted except for the last 40 logs.

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CF card as output medium

Warning

Observe the following tips for using a CF card:

- Do not force the CF card into the card slot.
- Do not remove the CF card from the card slot during the writing or reading access. During write access a yellow square is lit up in the upper right corner of the display.

Failure to observe these tips may result in loss of data, damage to the card and/or the steam sterilizer and/or the software. The card may become unusable.

CF card as output medium

If no CF card is plugged into the card slot, but was already activated, a cautionary warning appears on the display.
Thus if you would like to employ the CF card as the output medium, it must be inserted in the card slot if this has not yet been done.
If you at this time have no CF card at hand, you can output the logs later with the **`Log output`** menu.

Plug in CF card

The card slot for the CF card is located to the right next to the control panel.



To insert the CF card in the card slot, with the palpable grip edge facing right insert fully into the card slot. If the CF card is correctly placed, a blue square lights up in the upper right corner of the display.

NOTICE!

Due to the large memory requirements with real time graphical recording, it is recommended that you use only MELA*flash* CF cards with a memory capacity of 1GB or more from MELAG. These are dispatched in a certified and formatted state. It is known that some older CF cards with 256 MB memory capacity can cause file system problems.

Using the PC as output medium

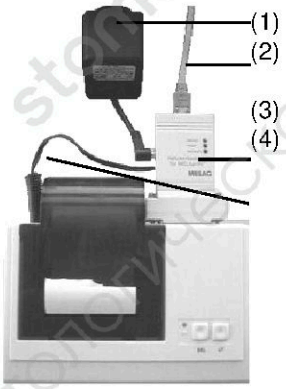
You can connect a computer to the steam sterilizer directly or over a network.
A prerequisite is that the PC has a network card with RJ45 (LAN) socket.
The logging occurs either via FTP or a TCP connection. For the first issue, you need an FTP server (communications program) on your PC or an FTP service. Log output via TCP requires an additional suitable program e.g. MELA*view*.

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Using the log printer as output medium

Connect printer



If you want to employ the log printer MELA*print*®42 as the output medium, connect it as follows to the steam sterilizer:

- Plug the power supply (1) into the wall socket.
- Connect the MELAG network adapter (3) with the supplied cable (2) to an Ethernet data connection point of the steam sterilizer.
- Plug the MELAG network adapter (3) into the serial connection of the log printer MELA*print*®42 (can be screwed).
- Plug cable (4) of the adapter (3) into the power supply socket of the log printer.
- Switch on steam sterilizer.
- The printer is switched on when the power supply cable (1) is plugged into the power supply socket of the network adapter (3).
- Set the log printer as the output medium in the steam sterilizer (see p. 39, **Chapter 6 – Settings**).

NOTICE!

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

Using the label printer as output medium

The use of a label printer enables the traceability of the batch: with details of sterilization date, storage duration, batch number, user ID for the person who released the instruments, the patients' sterilized instruments and the sterilization batch can be easily be associated with the steam sterilizer used and the file name.
Flawless packaging with the sterilized items is identified following sterilization with a raised sticker. In this way the requirements for a proper "release" are fulfilled by the person entrusted with the preparation.

Thus all information about the correct sterilization of the used instruments is associated with the patient's file.

NOTICE!

For further information of the MELA*print* 60 label printer (for example for the duration of for the labels) please refer to the respective operating instructions

Immediate automatic log output

Output of the text log

If you wish automatically to have the text log issued to an output medium immediately following the end of a program, use the automatic log output with immediate output. As delivered, the steam sterilizer is set to deliver the automatic log output as well as the text and graphic output to the CF card.

Requirements for automatic output of the text log immediately following the end of the program

For the output of text logs immediately following the end of a program, the following requirements must be met:

- In the **`Settings menu`** → **`Logging`** immediate output is activated.
- In the **`Settings menu`** → **`Logging`** at least one output medium is selected.
- The activated output medium is connected (e.g. computer, log printer MELA*print*® 42) or inserted (MELA*flash*CF card).

In the **`Settings menu`** → **`Logging`** you are guided step-by-step through the installation of the automatic log output.

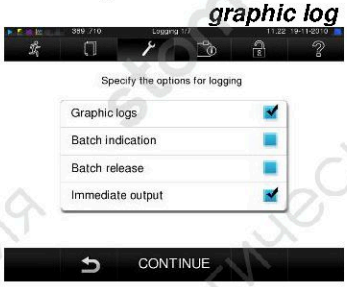
If automatic log output is not able to produce a log, e.g. because the

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activated output medium is not connected, then a warning will appear. The steam sterilizer registers not yet issued logs for each activated output medium. The output for this log is offered at the next opportunity.
MELAG recommends you use the automatic log output with immediate output of the log (according to the delivery status).
For the recording of graphic logs in real-time, the following requirements must be met:

- In the **`Settings menu`** → **`Logging`** the output **`Graphic log`** must be activated.
- At least one of the selected output medium must be connected with the output medium for the text log.
- The activated output medium is connected (computer) or inserted (MELA*flash*CF card).

Optional output of the graphic log





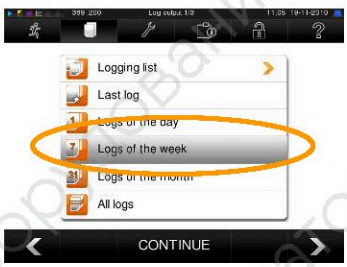
Explanation of the possible settings for graphic recording:
CF card (CFC) recording interval in sec. – indicates the time intervals in which the program curve is recorded on the CF card. The smaller the time interval, the more exact the curve. In the example, the time interval is set at 1 second.
PC recording interval in sec. – indicates the time intervals in which the program curve is recorded, if the computer is selected as the output medium. The smaller the time interval, the more exact the curve.
In the example, the time interval is set at 1 second.
PC backup interval in sec. – indicates the time interval in which the graphic data is saved from the steam sterilizer is saved on the computer.
In the example, the backup interval is set at 1 second.

NOTICE!
Graphic logs cannot be saved in the internal log memory. If you wish to record optional graphic logs in addition to the text logs, please always ensure that at least one common output medium has been set for issuing text and graphic logs. This means that at least the computer or the CF card should correspond as output medium for both log types.

Subsequent output of stored logs

With the **`Log output`** menu you have the option of subsequently outputting logs independent of the time of a program end.
You can confirm the output medium yourself. By default, the output media are pre-selected as those under the **`Settings`** → **`Logging`**, as long as the automatic immediate output is activated.
Below is an example of how you can deactivate the immediate output, if you e.g. would like all text logs of the completed programs to be output collectively once a week:

Immediate output deactivated



- Select the menu **`Settings`** → **`Logging`**.
- Remove the tick beside immediate output to deactivate this. The system is now restarted.
- Select the menu **`Log output`**.
- Navigate to **`logs of the week`**.
- Press CONFIRM.
- Finally, press OUTPUT, to issue the log(s).

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Example: Output all stored logs on CF card



In the following example, read how you can output all stored logs onto the CF card. Prerequisite is that the CF card is plugged into the card slot.

- Select the menu **`Log output`**.
- Select All **`Log output`** and finally select CONTINUE to set the output medium.
- Finally, press OUTPUT, to issue the log.

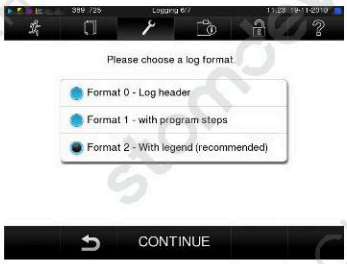
Log output options

Diverse log output options are offered in the selection list of the **`Log output`** menu (see example above). A few examples are shown below:

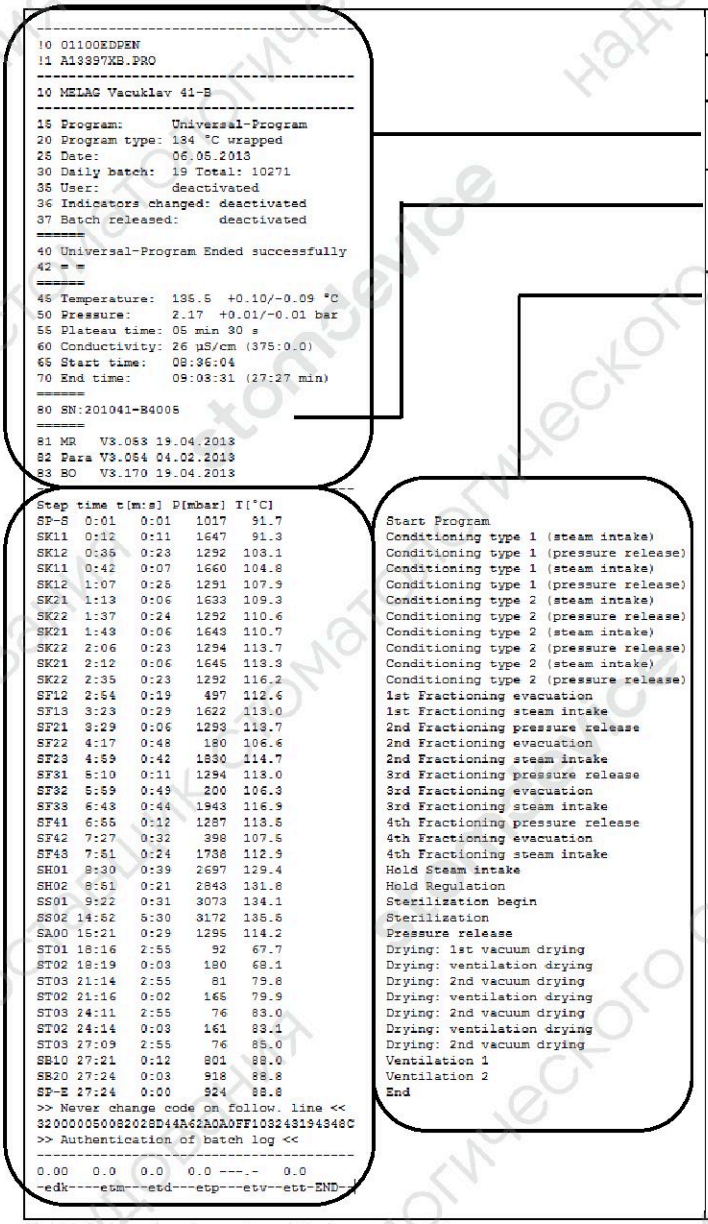
Menu item under Log output menu	***File extension***	***Explanation***
Logging list		All program logs existing in memory are shown on the display. You can sort the list by date, time, program and result by pressing the column heading.
Last log	.PRO	The log report of the last successfully completed program is outputted.
Daily log files	.PRO	The logs of the current day are outputted.
Log files of the week	.PRO	The logs of the successfully completed programs for the week – Monday to Sunday – are outputted.
Log files of the month	.PRO	The logs of the successfully completed programs for the current month are outputted.
All logs	.PRO	The logs of all the successfully completed programs for are outputted.
Last error log	.STR	The last error log is outputted.
Error logs for the day	.STR	The error logs of the current day are outputted.
etc.		...
Legend log	.LEG	Contains an explanation of all abbreviations in the logs.
Status log	.STA	A summary of all important settings and system information (counts, measurements, etc).
Errors in Standby	.STB	This log type is generated if errors are encountered when a program has not run.
System log	.LOG	A log book that lists all encountered errors and changes in chronological order.
Delete all logs		Deletes all logs in the internal log memory. !CAUTION! Even logs that have not previously been output to an output medium will be deleted.

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Determine format for program log files



One log report is stored in the internal log memory for every completed program. You determine with the logging format which of the stored data should be outputted. You can choose between a short form (0), a medium-sized form (1) and a long form (2).
The long logging format 2 is the standard format.
You determine the print formats for the program log files in the **`Settings Menu`** under the menu item **`Logging`**.



	Logging format		
Component	***0***	***1***	***2***
Header	X	X	X
Values for the program steps		X	X
Legend			X

Standard format

Table 9: Logging format and their components

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Reading log files correctly

Header

The header is outputted for all three selectable log report formats. The format 0 contains only the header of a log record.
The header of the program log record comprises the lines 10 to 83 and contains the most important information for the completed program, such as whether the program was successfully concluded and the authenticity proof.

Values of the program steps

Among other data, the time pressure and the temperature are recorded during the program. If you select the program format 1 or 2 then these values are outputted.

Legend

The legend is a component of the most extensive logging format 2. It serves for the designation of the program steps to which the specified values refer.
In digitally outputted logs (CF card, PC), the legend is directly next to the values of the respective program step. Every legend line thereby refers to the line just to the left of it.
For logs which are outputted to the log printer MELA*print*® 42, the appropriate legend line is always below the line to which it refers.

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```
----------------------------------------
!0 01100EDPEN
!1 A13397XB.PRO
----------------------------------------
10 MELAG Vacuklav 41-B
----------------------------------------

15 Program:       Universal-Program
20 Program type: 134 °C wrapped
25 Date:         06.05.2013
30 Daily batch:  19 Total: 10271
35 User:         1002
36 Indicators changed: Yes
37 Batch released:     Yes
======

40 Universal-Program ended successfully
42 = =
======

45 Temperature:  135.5  +0.06/-0.14 °C
50 Pressure:       2.17  +0.00/-0.01 bar
55 Plateau time: 05 min 30 s
60 Conductivity:    6 µS/cm (698:21737.0)
65 Start time:   08:28:57
70 End time:    09:00:17 (31:20 min)
======

80 SN:201041-B4005
======
81 MR   V3.053 19.04.2013
82 Para V3.054 04.02.2013
83 BO   V3.170 19.04.2013
----------------------------------------

Step  Time t[m:s] P[mbar] T[°C]

SP-S  0:01   0:01   1017   91.7
SK11  0:12   0:11   1647   91.3
SK12  0:35   0:23   1292  103.1
SK11  0:42   0:07   1660  104.8
SK12  1:07   0:25   1291  107.9
SK21  1:13   0:06   1633  109.3
.
.
SF32  5:59   0:49    200  106.3
SF33  6:43   0:44   1943  116.9
SF41  6:55   0:12   1287  113.5
SF42  7:27   0:32    398  107.5
SF43  7:51   0:24   1738  112.9
SH01  8:30   0:39   2697  129.4
SH02  8:51   0:21   2843  131.8
SS01  9:22   0:31   3073  134.1
SS02 14:52   5:30   3172  135.5
SA00 15:21   0:29   1295  114.2
ST01 18:16   2:55     92   67.7
ST02 18:19   0:03    180   68.1
ST03 21:14   2:55     81   79.8
ST02 21:16   0:02    165   79.9
ST03 24:11   2:55     76   83.0
ST02 24:14   0:03    161   83.1
ST03 27:09   2:55     76   85.0
SB10 27:21   0:12    801   88.0
SB20 27:24   0:03    918   88.8
SP-E 27:24   0:00    924   88.8

>> Never change code on follow. line <<
320000050082028D44A62A0A0FF103243194348C
>> Authentication of batch log <<
----------------------------------------



0.00   0.0   0.0   0.0   0.0   0.0
-edk----etm---etd---etp---etv--ett-ENDE-
```

Header

!0 Identification number
!1 File name

10 Type of the steam sterilizer

15 Program name
20 Sterilization parameters of the program
25 Date
30 Daily and overall batch number
35 User-ID
36 Batch indication } Release process
37 Batch release

40 Control message
42 Warning or error message for program interruption

45 Sterilization temperature with max. deviations
50 Sterilization pressure with max. deviations
55 Sterilization time
60 Conductivity of the feed water
65 Time at start of the program
70 Time at finish of the program

80 Serial number of the steam sterilizer

81 Current version of the device firmware
82 Current version of the device parameter
83 Current version of the user interface

Values in the program steps and legend

Time — Time (minutes:seconds) elapsed since the start of the program

t [m:s] — Duration (minutes:seconds) of a program step

P [mbar] — Pressure in the chamber in millibar

T[°C] — Temperature in the chamber in degrees centigrade

At the beginning of the individual lines are initials which indicate the type of the respective program step. You will receive a listing of all step initials when you output a legend log report with the **`Log output`** menu.

Program steps:

SK Conditioning
SF Fractionation
SH Hold
SS Sterilization
SA Pressure release
ST Drying
SB Ventilation
SP-E End

Authenticity proof (electronic signature) should never be changed; deciphering of the code by MELAG permits inference whether the data was created and changed on an steam sterilizer from MELAG.

Sensor measured values are shown here in case of a malfunction. The values are helpful for the technician.

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Table 10: Example of a program listing for a successfully concluded Universal-Program

Finding logs

After a log output you will find a directory on the storage media CF card or PC.

Directory name, log file name

The name of this directory consists of five characters, e.g. 810RS. These characters encrypt the serial number of your steam sterilizer. The directory is therefore also called the device directory.

Subdirectories



A device directory has subdirectories which are named after the months of the log creation, e.g. 07_2010.
In the subdirectories you will find all the logs generated in the respective month. Every log file name, like the device directory, begins with the five characters of the encoded serial number (e.g. 810RS).

Log output

The steam sterilizer checks the output medium at every log output. If it does not already exist, the steam sterilizer automatically creates a device directory with the encoded serial number and a subordinate month directory.

Log output on the CF card

The device directory is created directly on the CF card, and thus without a superior directory.

Log output on a PC

If you output the logs on a PC, then the device directory is created in the directory which is specified in the FTP server program. For very simple FTP servers it is the directory in which the FTP server program itself is located.
For issue via TCP and, for example, MELA*view2* designate the destination folder directly in the program.

NOTICE!
If possible, do not rename the directories. The steam sterilizer would create a new directory, because it would no longer recognize the existing one. There would be logs in the renamed directory as well as in the directory created once again by the steam sterilizer.

Multiple output of log files

If there is a multiple output of logs on the same output medium, a subdirectory named **`Double`** is created in the device directory. The logs are only stored once in this directory.

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Chapter 6 – Settings

In this chapter you learn

- **Which settings you can make**
- **How you can change previous settings**



Observe time re-settings

Setting date and time

Date and time of the steam sterilizer 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. Once set, the clock of the steam sterilizer is very precise. Set date and time as described below:



- Select the **`Settings menu`**.
- Navigate to **`Date & Time`**.
- The display changes to the **`Date & Time`** window.
- Directly select the parameters you wish to change (Day, month, year or hour, minute, second). The marked parameter becomes light blue.
- Use the  and  buttons for each parameter value.
- Repeat the steps for all parameters which you want to change.
- Confirm the modification with SAVE.
- The display will restart after saving and then automatically return to the **`Programs & Tests menu`**.



User administration



For reliable traceability of the release process following the end of a sterilization program, each user can be given a unique ID and PIN with which the user can authenticate before release of a batch.
You can determine if authentication of the user with a PIN input is required in the **`User administration`** window by checking the box for **`Release process with PIN`**.
If this option is activated, the user ID and the result of the release process are recorded in the log header.

To set up/edit a new user



To set up a new user, read the following:

- Select the **`Settings menu`**.
- Navigate to **`User administration`**.
- To get to **`User administration`** and make the settings there, you must enter the Admin PIN. Enter the Admin PIN (Standard: 1000) and confirm by pressing LOGIN.

The display changes to the **`User administration`** window.

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- Press **`continue to user list`**, to see the user list.
- To set a new use, select an open ID and select EDIT. Note that the first ID is reserved for the Admin PIN.
- Enter a 4-digit PIN for the selected user ID in the right keypad and confirm with SAVE.

With SAVE you apply all settings and leave the menu. By pressing the symbols you leave the menu.

Changing the Admin PIN

The Admin PIN (Standard: 1000) is used in the same manner as all other user PIN and should be changed on handing over.

NOTICE!

If you forget the Admin PIN, contact customer service at your supplier / MELAG.

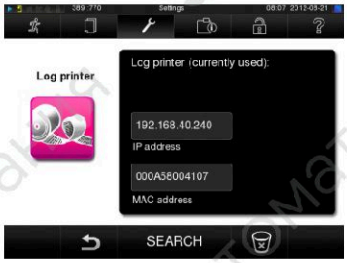
To delete a user from the list

To delete a user from the list, read the following:

- Select the **`Settings menu`** as above, and open the user list.
- Select the user ID that you wish to delete.
- Select the symbol to delete the user. A warning message follows. When you confirm with YES, the PIN number for this ID is set to 0.

At any time a new PIN can be set for this user ID.

Setting up the log printer as the standard printer





If you want to issue the sterilization log via the log printer, you must first make this setting in the steam sterilizerd.
Read the following to set up the log printer:

- Select the **`Settings menu`**.
- Navigate to **`log printer`**. The display changes to the **`log printer`** window.

Before a log printer is set up, the fields “IP-Address” and “MAC-Address” are empty.

- Select SEARCH, to show all available log printers connected to the network in the list. The window switches to the list of printers. If one or more than one log printer is available, these will be shown in the list.
- Select the desired log printer from the list and confirm with SAVE.

The display changes back to the “log printer” window.

- Press the to leave the menu.
- Finally, in the **`Settings menu`** → **`Logging`** select log printer to issue the logs.

NOTICE!

If the desired log printer is not displayed in the printer list, you can repeat this by repeated pressing of the printer symbol .

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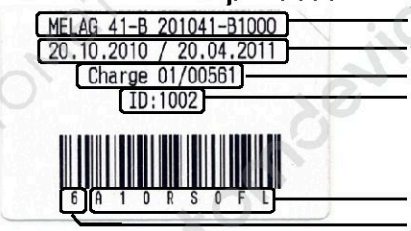
Setting up the label printer as standard printer

Read the following to set up the label printer:

- Select the **Settings menu**.
- Navigate to **label printer**. The display changes to the **label printer** window.
- Follow the same steps as above for the **log printer**.
- Finally, in the **Settings menu** → **Logging** select label printer to issue the logs.

NOTICE!
So that labeled wrapping for a batch can easily be assigned afterwards with a sticker, the file name for a sterilization log should always be given.

Legend of the label print out



Type, Serial number
Sterilization date / expiry date
Batches of day / number of total batches
User-ID (see page 39, **User administration**)
File name
Storage life



Water supply

According to whether the feed water supply comes from the internal storage tank or you have made the connection to a water treatment unit, choose the following settings on the display:

- Select the **Settings menu**.
- Navigate to **Device settings** → **Water supply**. The display changes to the **Water supply** window.
- Select **INTERNAL**, if the supply is from the internal storage tank, or **EXTERNAL**, if you have made the connection to a water treatment unit.
- Confirm with SAVE.



Energy saving mode

If the steam sterilizer is not be switched off during longer operating pauses, the energy saving mode can be set. This reduces the time which the steam sterilizer requires in order to pre-heat the double jacket steam generator to the necessary start temperature.
Two levels can be set in energy saving mode:
Waiting time 1 (W1): After a preset waiting time of 15 minutes, the temperature of the double jacket steam generator is reduced to 103°C. The program run time becomes c. 2 minutes longer upon the next start.
Waiting time 2 (W2): After a preset waiting time of 60 minutes, the double jacket steam generator is no longer heated. Accordingly, the length of the program run time increases by about 5 minutes upon the next start, depending on the length of the operating pause, as the double jacket steam generator must first be pre-heated to the necessary start temperature.

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Set the energy saving mode as follows:

- Select the **`Settings menu`**.
- Navigate to **`energy saving mode`**. The display changes to the **`energy saving mode`** window.
- Follow the same steps as above for the **Setting date and time**.



Screensaver

In order to save with the display in standby, you can activate the Screensaver, so it will show a continuous slide show of random images.

In order to activate the Screensaver and select the images for the slide show, follow the steps below:

- Select the **`Settings menu`**.
- Navigate to **`screensaver`**. The display changes to the **`screensaver mode`** window.
- In order to select a picture, tap the corresponding image. The white border indicates that the picture has been selected.
- Further tapping will deselect the image for the slide show.

You will know by the tick in the lower right corner ☑ whether the picture has been selected for the slide show.

- In order to make further settings, press CONTINUE.
  The display changes to the next window.



Here you have the option to make the following parameter changes:
Display time per image: Indicates how many seconds an image is displayed before changing to the next image.

Delay time: Indicates how long the display remains in normal mode, before the slide show is initiated.

Activated: Setting the tick mark means the Screensaver is activated or deactivated.

The parameters are changed as follows:

- Directly select the parameter that you wish to change.
  The chosen parameter will become light blue.
- Use the  and  button to change each parameter value.
- Confirm the changes with SAVE.

Turn off the display



You may also turn the display off after a set time.

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Chapter 7 – Function test

In this chapter you learn

- **How the steam sterilizer 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**

Automatic function test

Process evaluation and monitoring system

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 steam sterilizer compares the process parameters with each other during the program and monitors them with respect to their limit values.
The monitoring system of the steam sterilizer checks the device components with regard to their functional reliability and their plausible interaction. If the parameters exceed defined limit values, the steam sterilizer 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

On the display and based on the logs

You have the possibility of tracking the program sequence, based on the values shown on the display.
Furthermore based on the logs recorded for every program, you can logically reconstruct whether a program was successful (see page 30, **Chapter 5 – Logging**).

Vacuum test

Weekly in routine operation, at initial commissioning, 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 commissioning
- After longer operating pauses
- In case of a respective error (e.g. in the vacuum system)

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

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



- Turn the main switch on to power the steam sterilizer.
- In the menu **`Programs & Tests`**, select the vacuum test.
- Press START.

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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. At the end of the measurement time you will see a message with a specification of the leakage rate at the display. If the leakage rate is too high, an appropriate message is issued on the display (with repeated occurrence, contact your specialist dealer).

Bowie & Dick-Test



The Bowie & Dick test serves the verification of the steam penetration of porous materials such as textiles. As a function check, you can routinely conduct the verification of steam penetration. For this purpose, use the test program Bowie & Dick test.
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.

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Chapter 8 – Maintenance

In this chapter you learn

- **How to clean the steam sterilizer and which cleaning agents are suitable**
- **How to avoid the formation of spots**
- **Which feed water to use**
- **How to oil the door spindle**
- **What you must observe for the steam sterilizer maintenance**

Cleaning

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

Examine the chamber including the door seal and chamber sealing surface and the mounting for loading (page 12, Figure 2) for contaminants, deposits or damage once a week.

In case of contaminations

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

! Warning

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

- Switch the steam sterilizer off before cleaning and pull the power plug from the wall socket.
- Make sure that the chamber is not hot.
- Employ a soft and lint-free cloth.
- Use chlorine- and vinegar-free cleaning agents.
- First drench the cloth with cleaning alcohol or methylated alcohol and attempt to wipe off the contamination.
- For 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 for cleaning the door seal.
- No cleaning agents may get into the piping system which exits the steam sterilizer chamber.
- Do not use any rough objects such as pot cleaners made of metal or steel brushes.

Failure to observe these guidelines may mean the cleaned surface becomes scratched or damaged and the sealing surfaces become loose. 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 employ an internal water storage tank for feed water, check it for contaminants every time it is topped up. Clean the water storage tank before refilling it with fresh feed water. Clean the left side of the water storage tank (waste water) every two weeks.

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Emptying the internal storage tank



Empty the chambers of the internal storage tank as follows:

- Pull forward the cover for the tank drain at the lower front of the device.
- Attach the drain hose to the quick-fitting connection (drain tank on the left, feed water tank on the right) until it is well latched.
- Drain the water into a receptacle with at least 5 liter capacity.
- To remove the drain hose, pull the release button on the quick-fitting connection. The hose releases automatically.

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.

Failure to observe these tips may lead to injuries.

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 can clog the filter, nozzles and valves of the steam sterilizer and form as stains and deposits on the instruments and in the chamber (see page 20, **Prepare items to be sterilized**).

Formation of spots due to third-party rust

All steam-conducting parts of the steam sterilizer are made of non-rusting materials. This excludes the formation of rust caused by the steam sterilizer. 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 steam sterilizer.
Remove third-party rust from the instruments with a chlorine-free stainless steel cleaning agent (see page 45, **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:

Warning

Use only demineralized or distilled water according to DIN EN 13060, Appendix C.

Failure to observe these guidelines may lead to stains forming on the instruments and the functional readiness of the steam sterilizers can be adversely affected.

NOTICE!

Feed water which you can inexpensively produce by the osmosis method with MELA*dem*®47 or with the ion exchanger MELA*dem*®40 or by distillation with MELA*dest*®65 satisfies the feed water requirements.

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Oil door spindle

Oil the door spindle at 2-month intervals as follows:

- Clean the spindle with a lint-free cloth.
- Apply two drops oil from the supplied oil bottle (Art. no. 27515) in the threaded bushing (page 12, Figure 2(4)), in the steam sterilizer door.

NOTICE

You will find the instructions for oiling the door spindle on the inner surface of the steam sterilizer door.

Maintenance

Danger

- 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.

Failure to observe these guidelines may lead to damage of the steam sterilizer and to serious injury to health.

For retention of value and functional reliability

Regular maintenance is indispensable for the retention of value and the reliable practice operation of the steam sterilizer.
During maintenance, all functional and safety-relevant components and electrical facilities must be checked, and replaced if necessary. The maintenance must be carried out according to the maintenance instructions relevant for this steam sterilizer.

Maintenance intervals

Have the maintenance regularly carried out at intervals of two years or after 2000 program cycles. At this point in time, the steam sterilizer issues a maintenance reminder message.

Notice of National pressure vessel requirements

National pressure vessel requirements §15 may ask the user of pressure vessel, such as steam sterilizers, 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.

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Chapter 9 – Operating pauses

In this chapter you learn

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

Sterilization frequency

No pause times required

Pause times between individual programs are not required, since the sterilization chamber is permanently held 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 steam sterilizer and start a program.

Pause times

Short pauses between sterilizations

Keep the door closed in the pauses between the sterilizations if the steam sterilizer is switched on. This requires less energy to maintain the double jacket steam generator at the desired temperature.

Pauses which last longer than one hour

If the pauses between two sterilizations last longer than one hour, MELAG recommends that you switch off the steam sterilizer. You can save energy this way. If the steam sterilizer was switched off for one hour, then it requires about four minutes in order for the double jacket steam generator to heat up again and be ready for operation.
If the steam sterilizer is not be switched off during longer operating pauses, the energy saving mode can be set (see **Chapter 6 – Settings**, **Energy saving mode**).

Longer operating pauses

Switch the steam sterilizer off for longer operating pauses, e.g. overnight or on the weekend, and leave the door ajar. The door seal is thus relieved and protected from premature fatigue. It also prevents the sticking of the door seal.

Operating pauses which last longer than two weeks

After operating pauses which last longer than two weeks, conduct a vacuum test and thereafter an empty sterilization with the Quick-Program S (see page 43, **Chapter 7 – 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 MEL*Adem*® unit.
Despite running motor, the door does not open	Door seal is sticking to the sealing surface	Switch the steam sterilizer off and pull vigorously at the door to open it.

Table 11: Possible situations after operating pauses which last longer than two weeks

Function test after pauses

After pauses and depending on the pause duration, conduct tests described in **Chapter 7 – Function test**.

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Decommissioning

If you would like to decommission the steam sterilizer (put it out of operation) for a longer period of time, for instance because of holidays, proceed as follows:

- Switch the steam sterilizer off at the mains switch.
- Pull the power plug from the wall socket.
- Empty the internal water storage tank.
- If applicable, turn off also the water feed of the water treatment unit.

Transport

Carrying the steam sterilizer

Observe the following when carrying the steam sterilizer:

Danger

- Two people are necessary to carry the steam sterilizer.
- Use a suitable carrying strap to transport the steam sterilizer.
- Make sure that the distance between the housing floor plate of the steam sterilizer and setup location is small.
- After switching off the autoclave, wait until the pressure display manometer for the pressure display double-jacket steam generator shows zero bars before moving the autoclave.

Failure to observe these guidelines may result in spinal damage, contusions or serious injuriy.

Transport within the medical practice

Observe the following for transporting the steam sterilizer within a room or within the practice:

Warning

- Before you move the steam sterilizer, wait after switching off the power until the manometer for the pressure display of the double jacket steam generator shows zero bar.
- Empty the internal water storage tank.
- Close the water intake and empty the hose connections on the side of the device if you use a water treatment unit.
- 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 steam sterilizer before you move the device.

Failure to observe these guidelines may result in damage to the steam sterilizer and errors can occur.

Empty double jacket

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

In order to do so, the steam sterilizer is heated once, building up pressure in the double jacket so that the water can be drained fully from the double jacket steam generator. Switch off the steam sterilizer in the program end graphic **`Drainage completed`** so that the steam sterilizer does not feed water back into the double jacket.

Transport over larger distances, shipping

To transport the equipment, for instance to remove or ship the steam sterilizer, observe the following:

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Warning

- To transport over a longer distance and/or when danger of frost and/or to ship the unit, an authorized person must prepare the steam sterilizer according to instructions and completely empty the double jacket steam generator (see **Empty double jacket**).

Failure to observe these guidelines may result in damage to the steam sterilizer and errors can occur.

Re-commissioning after change of locality

Proceed as with the initial commissioning

For re-commissioning the steam sterilizer after a change of locality, proceed as for an initial commissioning (see page 17, **Chapter 3 – Initial commissioning**).

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Chapter 10 – 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 there are bad drying results**

A warning is not an error

Not all messages which appear on the display are error messages. Warning messages and error messages are shown on the display with an event number. This number serves for the identification.

Messages



Many messages are communications which serve for your Information. Messages are not error messages or warning messages. Such information supports you in the operation of the steam sterilizer.

Warning messages



Warning messages are displayed when necessary. These contain operating procedures for you. 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 messages



Faults messages are displayed if safe operation or sterilization security is not guaranteed.
These can appear on the display shortly after switching on the steam sterilizer or while a program is running.

The program is aborted if an error occurs during a program run.



- If a program is aborted before the drying cycle is complete, then the load is unsterile. Possibly rewrap and repeat the sterilization for the affected sterilizing materials.

Failure to observe this warning endangers the health of your patient and the practice team.

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Before you call

Follow the operating procedures which are shown in connection with a cautionary warning or an error message on the display of the steam sterilizer. 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 authorized MELAG customer service centre in your vicinity. In order for us to help you, keep the serial number of your steam sterilizer and a detailed fault description in readiness.

Event	*Possible causes*	*What you can do*
61	For internal storage tank for feed water: No water in the storage tank For water treatment unit: Produces no water because the water tap is not open	Fill internal storage tank Open water inlet for the water treatment unit
63 **64** **65**	For internal storage tank for feed water: Water with inadequate water quality was poured into the water storage tank (>60µS/cm) For water treatment unit: Mixed bed resin pellets in the water treatment unit are exhausted	Empty and clean storage tank and fill with feed water of the quality DIN EN 13060, Appendix C or Renew mixed bed resin pellets for the water treatment unit
67 **68**	Water outlet not guaranteed; the measures for warning of a sink mechanism did not occur	Let water drain out, check siphon
72 **73** **74** **75**	The feed water quality is declining (>40 µS/cm) Mixed bed resin pellets soon exhausted	You can still carry out all work with the steam sterilizer but should fill up with new feed water as soon as possible or renew the mixed bed resin pellets
76	See event 67	
78 **79** **80**	Waste water tank was not or not fully emptied	Empty waste water tank completely
102	Waste water hose is bent or installed with a large droop	Check waste water hose: It must be laid dip-free with continuous descent
113	Steam sterilizer was switched off while a program was running Power connection not completely made Power plug was withdrawn Power loss in the building power supply	Do not switch off steam sterilizer at the main switch while a program is running Check building-end installation; operate steam sterilizer on a separate electric circuit.
116	Maximum permissible difference between the theoretical temperature and that measured by temperature sensor 1 (AIN01) is too large	Upon repeated occurrence, inform your specialist dealer.
117	Temperature sensor 1 or 2 is defective; temperature difference is too large.	Upon repeated occurrence, inform your specialist dealer.
118	Maximum admissible sterilization temperature has been exceeded at temperature sensor 1 (AIN01).	Upon repeated occurrence, inform your specialist dealer.
119	Minimum admissible sterilization temperature not reached at temperature sensor 1 (AIN01).	Upon repeated occurrence, inform your specialist dealer.

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Event	*Possible causes*	*What you can do*
123 **124** **125** **126**	Ambient temperature too high Built-in steam sterilizer gets no or too little cooling air Steam sterilizer is overloaded Steam sterilizer was operated without mounting so that for instance a washing packet has direct contact with the chamber and large quantities of condensate were absorbed. Cool air intake openings in the base plate are covered, for example, by sucked in papers	Observe installation instructions (see page 17, **Set-up location requirements**). Check loading, observe instructions for loading (see page 20, **Load the steam sterilizer**). Remove objects (e.g. paper) from under the steam sterilizer
128	See event 102	
129	Steam sterilizer overloaded Defective power supply (under-dimensioned house connection for the outlet, defective outlet, numerous devices to one outlet or fuse)	Check load, (see page 21, **Load the steam sterilizer**) Check power supply
134	See event 123	
136	Ambient temperature too high Ventilating louvers covered, minimal edge spacing (5 centimeters) not maintained Door is permanently open	Observe installation instructions (see Page 17, **Set-up location requirements**). Close the door
183	See event 123	
175 **176**	ACOUT1 main heating or ACOUT2 regular heating, electrical supply interrupted; FOY1+ FOY2 can occur in alternation.	1. Turn off the power and press reset button overheating protection again. 2. Acknowledge error message 3. Switch the steam sterilizer off and then on again 4. Continue sterilization or conduct an empty sterilization.
192	Observation of successive rinsing procedure. Rinsing condition in the feed water storage tank should be produced	Top up water storage tank with feed water or ensure water supply of the water treatment unit
193	Note subsequent draining, requirements in the waste water tank must be prepared	Completely empty the waste water tank
231	In the following situations, no CF card is plugged in: CF card is selected in the **`Settings`** → **`Logging`** as the output medium and immediate output is activated or log output is started from the **`Log output`** menu and CF card is set as the output medium or the CF card must be formatted.	Plug CF card in card slot (see page 31, **Plug in CF card**) Change to the **`Log output`** and from there save the desired logs on the CF card (see page 33, **Subsequent output of stored logs**), Reformat the CF card.
239	Month directory on the CF card is full (more than about 100 logs)	At the computer, transfer logs from month directories into newly created directories.
248	Vacuum test at residual moisture in the chamber or with load	Repeat vacuum test if steam sterilizer is cold, dry and empty
351	Two years have elapsed since the initial commissioning or since the last maintenance or 2000 sterilization programs have been completed	Call MELAG customer service or specialist dealers and make a maintenance appointment; steam sterilizer can continue to be used
377	Attempt to output log over the log printer, but no log printer is connected	Connect printer (see page 32, **Using the log printer as output medium**)
386	Internal memory of the steam sterilizer for the logs of the completed programs is almost full	Read out the internal log memory on the storage medium of your choice with the **`Log output`** menu (see page 33, **Subsequent output of**

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Event	*Possible causes*	*What you can do*
		stored logs)
387	Steam sterilizer internal memory for the error logs is almost full	Error logs are required, for example, by the technicians for maintenance and fault analysis. Read the internal error log memory to a storage medium of your choice with the **`Log output`** menu.
394	In the menu **`Settings`** → **`logging`**, **`immediate output`** is activated, and the CF card is activated as the output medium, but was previously not plugged in	Press YES if you now would like to output the still not outputted logs to the CF card.
395	In the menu **`Settings`** → **`logging`**, **`immediate output`** is activated and the log printer is activated as output medium, but was previously not connected.	Press YES if you now would like to print the logs still not printed out.
396	In the menu **`Settings`** → **`logging`**, **`immediate output`** is activated and the computer is activated as the output medium, but was previously not connected or switched on.	Press YES if you now would like to output the log files still not transferred to the PC.
408	See event 135	
414	With direct waste water connection: kinked effluent hose Steam sterilizer is overloaded The temperature surrounding the steam sterilizer is too hot; the steam sterilizer is obstructed and is getting no or too little cooling air The steam sterilizer was operated without an insert frame with the result that e.g. the packages of textiles has come into direct contact with the chamber and absorbed a large amount of condensate; this condensate vaporized upon evacuation and forms a large amount of steam; cooling air ingress holes on the base plate are covered e.g. by paper.	Check the effluent hose for kinks or pinching; observe the maximum loads; make sure there is sufficient air flow at the rear of the steam sterilizer use insert frame; check for packaging residue in the chamber.
428 **439**	With direct waste water connection: kinked effluent hose Poor installation (multiple devices attached to a single siphon, sagging effluent hose. Pressure release clips blocked by packaging residue.	Check the effluent hose for kinks or pinching. Check for packaging residue in the chamber.
433	Maximum permissible difference between the theoretical temperature and that measured by temperature sensor 2 (AIN02=Display) is too large	Upon repeated occurrence, inform your specialist dealer.
434	Maximum admissible sterilization temperature has been exceeded at temperature sensor 2 (AIN02=Display).	Upon repeated occurrence, inform your specialist dealer.
435	Minimum admissible sterilization temperature not reached at temperature sensor 2 (AIN02=Display).	Upon repeated occurrence, inform your specialist dealer.

Table 12: Important warning messages and error messages

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Bad drying results

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

What you can do

- Check the correct set-up of the steam sterilizer. If necessary increase the tilt by unscrewing the front feet of the unit by max. two revolutions.
- The floor of the vessel must be free. Where applicable, remove fallen instruments, filter paper, etc.
- Pay attention to the correct loading of the steam sterilizer. Do not overload the steam sterilizer. Pay attention that textiles have no direct contact with the chamber wall and floor.
- Employ the Additional Drying function.

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Technical Specifications

Description	**Vacuklav®41 B+**	**Vacuklav®43 B+**
Device dimensions (HxWxD)	56.5 x 47 x 57.5 cm	56.5 x 47 x 69 cm
Sterilization chamber (WxD)	Ø 25 cm x 35 cm	Ø 25 cm x 45 cm
Volume of the sterilization chamber	18.4 litres	23.8 litres
Weight (empty)	59 kg	66 kg
Electrical connection	220 - 240 V* 50/60 Hz, at least 15 A separate fuse (UK, Ireland, Malaysia: 13 A), protection from leakage current 30 mA	
Electrical operating level	3400 W (UK, Ireland, Malaysia: 2760 W)	
Heat emission	6.2 MJ (total emission which is emitted into the air within one hour)	
Max. sound power	64 dB(A)	
Max. altitute	2000 m	
Ambient temperature	5-40 °C (recommended max. 25 °C)	
Relative humidity	80% at 31 °C, decreasing in a linear fashion up to a relative humidity of 50% at 40 °C	
Quality of the feed water	distilled or demineralized water according to DIN EN 13060, Appendix C	
Length of the power cable	1.35 m	
IP code (protection type) (according to IEC 60529)	IP20	
CE identification	CE 0197, CE 0035	

*Note the maximum voltage range of 207-253V

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Appendix A – Accessories

	Article	*Order Number*	
		41 B+	*43 B+*
Tray mounts	B for 4 standard tray cassettes	40234	40224
	C for 6 trays or 3 standard tray cassettes	40232	40242
	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 centimeters: 18/12/4.5	01151	
	15M depth/width/height in centimeters: 35/12/4.5	01152	
	15G depth/width/height in centimeters: 35/12/8	01153	
	17K depth/width/height in centimeters: 20/14/5	01171	
	17M depth/width/height in centimeters: 41/14/5		01172
	17G depth/width/height in centimeters: 14/14/9		01173
	23M depth/width/height in centimeters: 42/16/6		01231
	23G depth/width/height in centimeters: 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 drum with filter cloth	17R diameter/height in centimeters: 13/10,5	00174	
	23R diameter/height in mm: 18/14	00233	
Standard tray cassettes	perforated, depth/width/height in mm 29/19/4		
	with filter cloth	00289	
	without filter cloth	00286	
MELAstore System	MELAstore-Tray 50 (LxBxH: 18 x 11.8 x 3 cm)	01180	
	MELAstore-Tray 100 (LxBxH: 27.5 x 17.6 x 3 cm)	01181	
	MELAstore-Tray 200 (LxBxH:27.5 x 17.6 x 4.3 cm)	01182	
	MELAstore-Box 200 (LxBxH: 31.2 x 19 x 6.5 cm)	01191	
	MELAstore-Box 100 (LxBxH: 31.2 x 19 x 4.6 cm)	01192	
Trays	Tray	00280	00230
Helix test body system	MELA*control*® consisting of Helix test body and 250 indicator strips	01080	
	MELA*control*® PRO consisting of Helix test body and 40 indicator strips	01075	
Water treatment units	MELA*dem*®40 ion exchanger	01049	
	MELA*dem*®47 reverse-osmosis system	01047	
For the documentation	Label printer MELA*print*®60	01160	
	Log printer MELA*print*®42	01042	
	MELA*flash* CF card	01043	
	MELA*flash* card reader	01048	
	MELAG Ethernet adapter necessary for use of MELA*print*®42	40295	
Miscellaneous	Surface trap	37410	

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Glossary

1:1 cable
(also “straight through” cable) or “normal” network cable for connecting a computer (using a network card) with the hub/switch; corresponds also to the direct connection of a computer to the network interface of the steam sterilizer. The cable runs in parallel between the connector jacks, in contrast to the crossover cable.

Air leakage – checking the air leakage
Air leakage is a loose 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 prevents 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
Technicians from depots or employees from service companies designated by MELAG that are trained by MELAG

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 recognized 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/centimeter (µS/cm); the more materials are dissolved in water, the better it conducts electrical current and the higher is its conductivity.
distilled water ideally has conductivity measurement of zero

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

Corrosion
Chemical change or destruction of metallic materials by water and chemicals

Crossover cable
A crossover cable networks two computers (with network cards) directly, without using a hub/ switch. This type of connection corresponds to the network integration of the steam sterilizer in the practice network. The crossover cable does not run in parallel between the connector jacks, but rather certain cable lengths are exchanged and “crossed-over”.

DGSV
Deutsche Gesellschaft für Sterilgutversorgung (German Association for Sterile Material Directive); the training guidelines of the DGSV are listed in DIN 58946, Part 6 as "Personnel Requirements"

Demineralized water
Water without the minerals which occur in normal mineral or tap water; obtained from normal tap water by ion exchange, here used as feed water

Distilled water
also aqua dest from lat. aqua destillata; is largely free of salts, organic materials and microorganisms, obtained by the distillation (vaporizing and subsequent condensation) of normal tap water or pre-cleaned water, here used as feed water.

DIN 58953
European standard: sterilization, sterile goods supply.

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 13060
European standard –Small steam sterilizers

DIN EN 285
Normal – sterilization – steam sterilizers – large sterilizers

Double jacket steam generator
Serves the rapid steam production outside of the actual sterilization chamber, surrounds the sterilization chamber

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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

Firewall
is a combination of hard- and software used as network security components. The purpose of a firewall is to secure the data traffic between network segments with various confidentiality levels. A typical application is to control the transfer between a local network (LAN) – higher confidentiality – and the internet – no confidentiality. For example, you can prevent an FTP-server (-program) from receiving data from another network component (steam sterilizer) or computer.

Fractionated vacuum method
Technical methods of steam sterilization;
the repeated evacuation of the sterilization chamber alternating with steam intake

FTP
(**F**ile **T**ransfer **P**rotocol) is a data transfer method that transfers data from the internet. This data could contain programs, files or also information. Special FTP programs (FTP clients) serve to upload the data to a server.

Handshake
A handshake procedure is a simple method of data flow management, in which two participants of a data transfer synchronies transfer via instant confirmations over control line.

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

Hollow A
One-sided open bodies, for which applies:
$1 \leq L/D \leq 750$ and $L \leq 1500$ mm or
a double-sided open body for which applies:
$2 \leq L/D \leq 1500$ and $L \leq 3000$ mm and which does not correspond to the hollow body B
L…hollow body length
D…hollow body diameter
[DIN EN 13060]

Hollow A
→Narrow lumen

Hollow B
→Simple hollow items

Hub
A hub serves to radially connect several computers in a network, for example, through an Ethernet, that is, all devices in the network are connected to the hub.

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

LED
Abbreviation for Light Emitting Diode; Semiconductor diode which lights up when powered by current. LEDs are predominantly employed for status displays in devices.

Lubricant
e.g. Instrument oil

MELAG-Network adapter
Ethernet printer module for the MELAG printer MELA*print*®42; on one side is the printer connection, on the other the connector socket for the network cable

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

Multithread capable
indicates the simultaneous handling of multiple threads (performance tasks in a process). With reference to an FTP server program, several users can simultaneously enter data, that is, several steam sterilizers can simultaneously send logs to the FTP server.

Narrow lumen
An article open on one side to which the following applies:
$1 \leq L/D \leq 750$ and $L \leq 1500$ mm or an article with an opening on both sides which is:
$2 \leq L/D \leq 1500$ and $L \leq 3000$ mm and which does not correspond to a hollow body article B
L…length of hollow body article
D…Diameter of hollow body article [DIN EN 13060]

Ping
is a diagnostic program to test the availability and reaction time of computers in networks.

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

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required sterilization conditions are achieved in porous loads with the maximum density 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

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

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

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

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

Solid
Without hollows or spaces; firm, dense, closed

Solid load – check of solid load
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]

Sterilization chamber
Interior of a sterilizer
Takes up the items to be sterilized

Sterilization items
Goods that are unsterile, but yet to be sterilized

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

Stainless steel cleaning agent
e.g. Sidol

Standards compliant
Conformity with all relevant standards

Superheating
is the phenomenon by which, under certain conditions, one can heat a liquid to beyond its boiling point, without it boiling; it is in an unstable state; with minimal agitation it can build up a large gas bubble in very short time that expands explosively.

Switch
A switch is a network component for connecting several computers and network segments in a local network (LAN). Because switches analyze and network traffic and make logical decisions, they are also known as intelligent switches.

TCP
(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)

Warming-up time
→ heating-up period

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