

MELAG

Operating Manual

For Autoclaves of the Pro-Class

Vacuklav[®] 23 B+
Vacuklav[®] 31 B+

as of software version 4.06



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

Subject to technical changes

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Safety instructions

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

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

Proper use

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

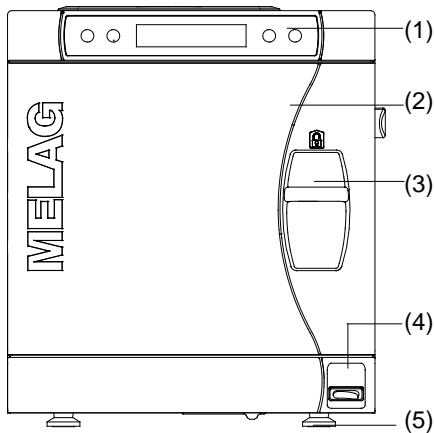
According to DIN EN 13060 this autoclave is considered a Class B sterilizer. It is suited as a universal autoclave for demanding sterilization tasks. For instance, you can sterilize narrow-bore instruments and transmission instruments – wrapped or unwrapped – and larger quantities of textiles.

Application area

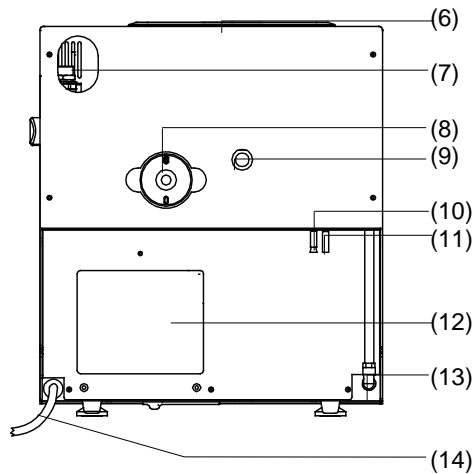
Sterilization tasks

Device views

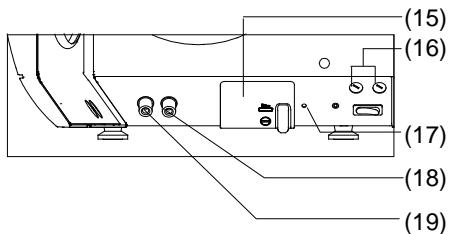
Front side



Back side



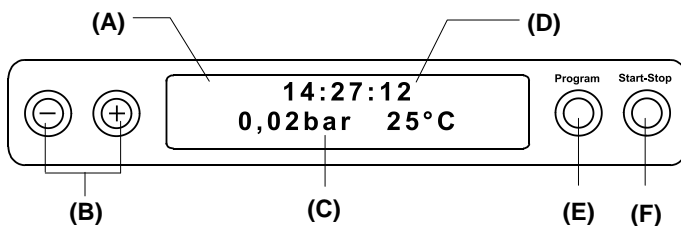
Front side below with opened door



- | | |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| (1) Operating and display field | (11) Emergency overflow hose |
| (2) Door (pivots opens to the left) | (12) Cooler |
| (3) Sliding-closure grip | (13) Purified feed water inlet for MELAdem®, fast screw connection for hose Ø 8x1 |
| (4) Mains switch | (14) Power cable |
| (5) Front foot of the unit (adjustable) | (15) Serial data and printer connection (RS232) |
| (6) Tank cap | (16) Device fuses – 2x 16A/gRL |
| (7) Slot for optional upgrade with the safeguard combination EN1717 | (17) Reset button for overheating protection |
| (8) Sterile filter | (18) Connection for emptying the storage tank feed water |
| (9) Safety valve | (19) Connection for emptying the storage tank waste water |
| (10) One-way drain (optional) | |

Control panel

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



- (A) **2-line LED display**
for program status display and parameter display
- (B) **Function key (-) and (+)**
to select, set and display special functions, press KEY (+) to unlock door
- (C) **Chamber pressure (bar) and temperature (°C)**
- (D) **Time (hh:min:ss)**
- (E) **Program selection button (P)** to select the sterilization programs/ test programs and select or set options (submenus) of the special function
- (F) **Start – Stop button (S)**
to start programs, terminate programs

Conditions for setting up, installing and starting up

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

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

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

The space requirements for the autoclave corresponds to its dimensions plus at least 5 cm on the side and 10 cm at the back side.

For a fault-free operation, the autoclave must be set up with a distinct tilt back. Starting from a horizontal position (check by using a water level at the chamber flange) the front feet of the unit must be screwed out by about five rotations for the Vacuklav®23 B+ and three rotations for the Vacuklav®31 B+ .

Connections required

Electronical connection

Electric circuit with 220-240 V and 50/60 Hz; 16 A separate fuse protection; Protection from leakage current 30 mA.

One-way drain

In order to attach the autoclave to the effluent pipe, you can order an upgrade set (MELAG Art. No. 26695) from MELAG. The waste water is collected in the storage tank (waste water tank) and flows through the one-way outflow hose into the flush siphon, using the MELAG double chamber waste water trap (Art. No. 26635). The drain must be located at least 30 cm beneath the autoclave and installed dip-free with continuous descent.



Notice:

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

Supply with feed water

The autoclave works in the gentle yet effective one-steam way water system. This means that it uses fresh purified feed water for every sterilization run for the steam generation. For this purpose the autoclave gets the feed water either from the internal storage tank, which the practice team has refilled e.g. with distilled water from the MELAdesf®65. Or it gets the feed water fully automatically from the water treatment unit MELAdem®40 or MELAdem®47.

Only use feed water according to VDE 0510 as feed water.

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

Fill up the storage tank

Fill up the internal storage tank with fresh purified feed water of the respective quality. You can use the removable funnel insert to conveniently fill fresh feed water into the right chamber of the storage tank up to the MAX mark. The internal storage tank holds maximum 5 litres. This quantity of feed water suffices for up to 7 sterilizations.

Emptying both chambers of the storage tank

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

To remove the drain again, press the grey release knob at the quick-fitting connection. The hose detaches itself automatically from the connection. (Warning spring tension! Please stand to the side of the connection when removing the hose).

Prerequisites for initial start-up

- Trays and accessories must be removed from the chamber after switching on the autoclave and before initial start-up.
- The feed water supply must be secured.
- The power supply of the autoclave must be assured.

Record of installation and setting up



NOTICE:

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

Prepare items to be sterilized

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



Notice:

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

Load the autoclave

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



Notice:

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



Warning!

Employ only packaging materials and -systems (sterile barrier systems), which satisfy the DIN EN ISO 11607-1 Standard, e.g. Standard-tray-cassettes or transparently wrapped sterilization packages.

Closed sterilization containers

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

Stack sterilization containers

Stack on top of each other, if possible, only sterilization containers of the same size and with respectively identical spacer feet, where the condensate can run off on the side at the walls.

Soft sterilization wrapping

Soft sterilization packages can be sterilized both in sterilization containers on trays or standing when using a package holder – do not place several soft sterilization wrappings flat on top of each other on the trays or in a sterilization containers.

Multiple wrapping

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

Mixed loads

For sterilizing mixed loads, observe the following instructions:

- Always place textiles on the top
- Sterilization containers at the bottom
- Unwrapped instruments at the bottom
- Transparently wrapped sterilization packages and paper packaging on the top – exception: in combination with textiles on the bottom
- The heaviest loads at the bottom

- Stack transparently wrapped sterilization packages if possible edgewise in such a way that alternately paper side lies on paper side and foil side on foil side; if this is not possible, then with the paper side facing downwards.

Select program

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

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

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

** Please notice your national regulations of your country

Start program

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

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

Select additional drying:

- Press KEY (S) and KEY (+) simultaneously at the start of a program.

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

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

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

Manually terminate program

You can manually terminate a running program in any of the phases with the KEY (S). If you terminate a program before the beginning of drying, **then the items to be sterilized are still unsterile**.

In the drying phase, the expired drying time is shown in alternation with the message **Immed. Removal Press "stop"** is displayed. By pressing the KEY (S) the program is cancelled during the drying. The termination is confirmed with **Drying stopped** on the display.

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

Remove sterilized items

After the request **Quit with button '+'** at the end of a program press the **KEY (+)**. After unlocking the door you can open the door and remove the sterilized items.



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

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

If you remove the sterilized items from the autoclave directly after the end of the program, it can happen that slight quantities of condensate moisture are found on the sterilized items. Smaller quantities of water which may be found on the upper side of the paper bags and clear plastic sterilization packages are unobjectionable if they dry out within 30 minutes after removal from the autoclave.

Storage of sterilized items

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.

- 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

Batch documentation

The batch documentation is indispensable as documentation for the successfully completed sterilization process and as an obligatory measure of quality assurance.

The capacity of the internal storage suffices for about 40 logs.

If the internal log memory is full, when starting the next program the respectively oldest log is automatically overwritten.

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

- Log printer MELAprint®42, MELAflash CF Card Writer on CF card
- MELAnet Box, Computer, e.g. with software MELAview®/ MELAwin®, modem

Please learn from the operating manual of the respective device how to connect the additional devices and which settings you take at the autoclave.

Set date and time

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

- Select the **SETUP Menu Function** by short simultaneous pressing of the **KEYS (+) and (-)**.
- Navigate with the **KEY (+)**, up to the display **Function: Date/ Time** are displayed.
- Press the **KEY (P)** in order to confirm.
- Select between the setting possibilities with the **KEY (+) or (-)** hour, minute, second, day, month or year.
- In order to adjust the **hour** parameter, press the **KEY (P)** for the confirmation.
- The value can be increased or reduced with the **KEYS (+) and (-)**.
- In order to store the value, confirm with the **Key (P)**.
- Press **KEY (S) 2x**, in order to leave the **SETUP Menu**.

Pause times

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

Longer operating pauses

After operating pauses which last longer than two weeks, carry out a vacuum test and thereafter an empty sterilization with the Quick-Program B.

The following situations can occur after longer pauses:

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

After pauses, carry out the tests described below depending on the pause duration.

Testing in daily operation

Vacuumtest

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

- Select with the KEY (P) the program Vacuum test and start by pressing the KEY (S).

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

The evacuation pressure and the equilibration time or measurement time are shown on the display. If the leak rate rises too high that means ≥ 1.3 mbar, there is shown an appropriate notification on the display.

Bowie & Dick test

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

For this purpose it is especially recommended when sterilizing larger quantities of textiles.

- Select with the KEY (P) the program Bowie&Dick test and start with the KEY (S).

Helix test body system MELAcontrol® / Pro

The test body system MELAcontrol® / PRO is an indicator and batch monitoring system. It consists of a test specimen, the helix, and an indicator strip. If you sterilize instruments of the category "Critical B", the MELAcontrol® / PRO test specimen should be included as a batch control for every sterilization cycle.

Display water quality

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

- To do this keep the KEY (-) pressed.

Errors

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

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

Follow the operating procedures shown in the connection with a warning text or an error message on the display.

After that you can continue the operation of the autoclave.

Only if the messages appear repeatedly turn to your specialist dealer or the authorised MELAG customer service centre in your vicinity.