MELAG

Technical Manual

Steam sterilizer

Vacuklav®41 B+
Vacuklav®43 B+

as of software version 3.098

For users and service personnel

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

CE 0197

Foreword

This manual has been created for the steam sterilizers Vacuklav®41 B+ and Vacuklav®43 B+. They are identical except for their chamber depth and device depth.

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

You also receive a User Manual with the steam sterilizer. It contains important safety instructions and information which you need to operate the steam sterilizer. Read the User Manual completely through in proper sequence before beginning operation with the steam sterilizer.

This Technical Manual among other things includes suitability statements and recommendations, instructions for setting up, installing and initial start-up of the steam sterilizer, extended technical information on the software and hardware and other technical data. The autoclave should only be set-up, installed and commissioned by MELAG authorized persons.

Technical Manual Vacuklav®41 B+, Vacuklav®43 B+

Responsible for the contents: MELAG Medizintechnik oHG

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Subject to technical changes

CONTENTS

Certificate of Suitability

According to the recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert-Koch Institute (Year 2012)

Manufacturer:	MELAG Medizintechnik oHG
Address:	Geneststraße 6-10 10829 Berlin
Country:	Germany
Product:	Vacuklav®41 B+/Vacuklav®43 B+
Type of device:	Steam sterilizer (steam sterilizer)
Classification:	Class IIb
Device type acc. to DIN EN 13060:	Type B

We herewith declare that the above designated sterilizer is suited for sterilization of

- **Solid instruments (wrapped and unwrapped)**
- **Porous goods (wrapped and unwrapped)**
- **Narrow lumen (wrapped and unwrapped)**
- **Simple hollow items (wrapped and unwrapped)**

Instructions on load quantities and loading variants are set forth in the User Manual and must be observed.

Be sure to observe the manufacturer's instructions for medical devices intended for sterilization according to DIN EN ISO 17664.

We herewith declare that the following test system is suited for testing the above cited steam sterilizer.

- **Helix-Test body according to DIN EN 867-5: MELA*control*® and MELA*control*®PRO**

Berlin, 28-06-2016

Dr. Steffen Gebauer
(General Management)

MELAG
competence in hygiene

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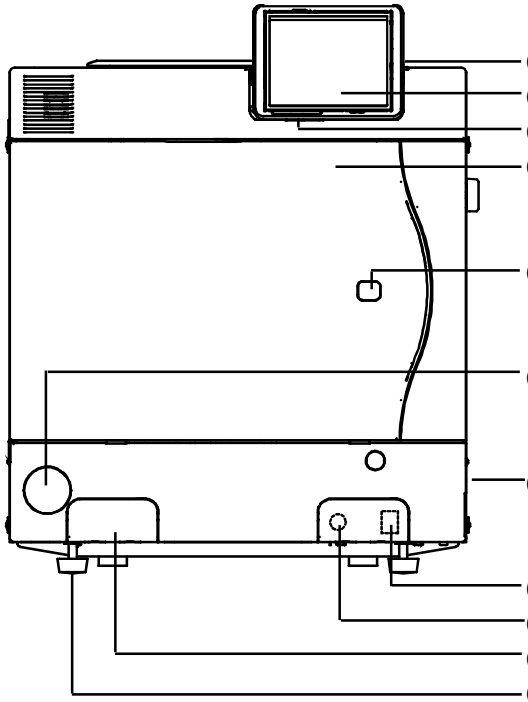
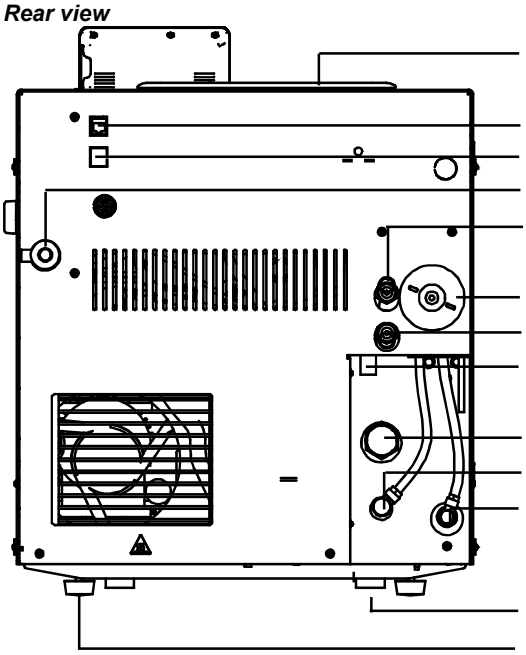
Device views

Front view



(1) Slot for the CF Card
(2) Color-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) Safety spring valve, chamber
(17) Sterile filter
(18) Safety spring valve, double jacket
(19) Emergency overflow
(20) One way drain
(21) Pressure release connection
(22) Purified feed water intake (for MELAdem; swiveling threaded fitting for hose 8x1, alternatively straight)
(23) Rear foot of the unit (fixed)
(24) Cooler

Fig. 1: Front and rear view

Installation and setting up

Warning

Please read the User Manual of the steam sterilizer and the water treatment unit before setting up the steam sterilizer.
The autoclave should only be set-up, installed and commissioned by MELAG authorized persons.

Warning

If the steam sterilizer has already been put into operation, please observe the following before setting up again in case of any eventual transport:

- To transport the steam sterilizer, for instance if the practice moves to a new location, wait until the pressure indicator on the manometer display shows null bar after the steam sterilizer is switched off. Be sure to check the pressure indicator on the manometer before moving the steam sterilizer
- To transport the unit over longer distances, an authorised person must prepare the steam sterilizer beforehand according to instructions and completely empty the double jacket steam generator. In order to do so, you can use the **`Draining`** program.

Failure to observe these guidelines may lead to severe burns and damage to the steam sterilizer as well as malfunctions.

The steam sterilizer sterilizes on the basis of the fractionated vacuum. A membrane pump is used to create the especially deep vacuum. The steam sterilizer can thus come into operation without additional installation other than providing the power supply. Please follow the following important instructions concerning the optional connection of a one way drain and general information for the proper installation which must be observed when setting up the device.

Removal from the packaging

Unpack steam sterilizer

Lift the steam sterilizer out of the carton with the carrying strap.

Danger

- Two people are necessary to carry the steam sterilizer.
- Use a suitable carrying strap to transport the a steam sterilizer.
- Make sure that the distance between the housing floor plate of the steam sterilizer and setup location is small.

Failure to observe these guidelines may result in spinal damage and contusions.

Remove carrying strap

To remove the carrying strap, unscrew the four screws on each side of the housing. Retighten these screws firmly without the washers.

Keep the carrying strap and the washers.

After switching on

After switching on the steam sterilizer and before initial start-up, open the door and remove the trays and the accessories from the chamber.
To do this you must go into door mode as below, immediately following the appearance of the start screen “Welcome”:

- At the start screen image **`Welcome,`** press and hold the second button from the right in the action bar until the display changes to the next window. After, the door can be opened by pressing the  symbol.

NOTICE!
After 5 seconds of inactivity, the display automatically switches back to the **`Programs & Tests`** menu. The steam sterilizer then begins to suck in the feed water needed for the sterilization, which triggers an error message!

Space requirements

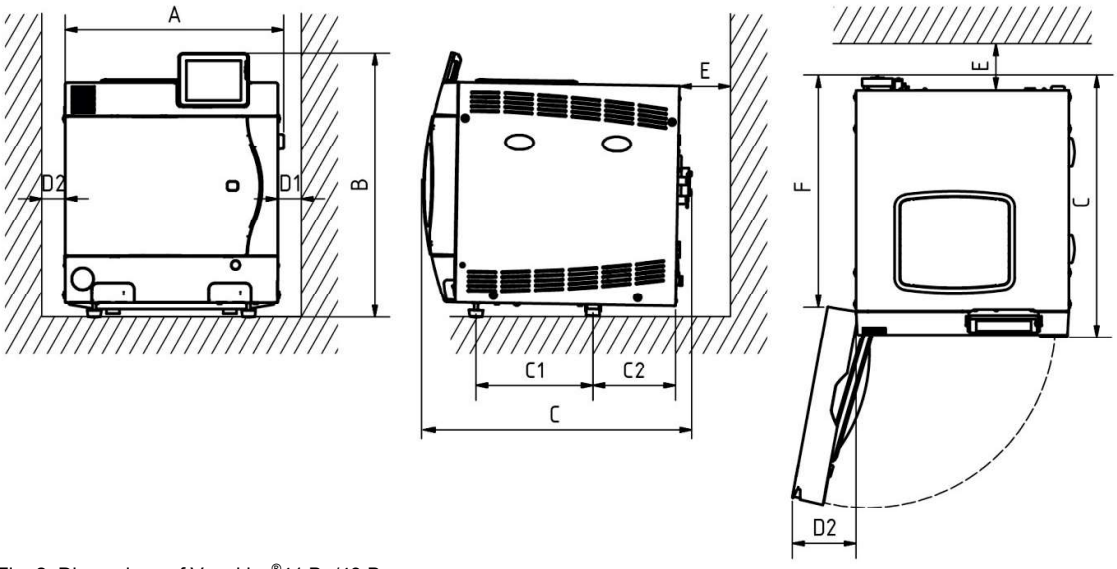


Fig. 2: Dimensions of Vacuklav®41 B+/43 B+

Dimensions		Vacuklav®41 B+	Vacuklav®43 B+
Width	A	47 cm	47 cm
Hight*	B	56.5 cm	56.5 cm
Depth, total	C	57.5 cm	69 cm
Clearance between device feet	C_1	25 cm	36 cm
Clearance from the rear device foot tot he rear panel	C_2	18 cm	18 cm
Min. clearance to the side	D_1	5 cm	5 cm
Min. clearance to the door hinge side	D_2	14 cm	14 cm
Min. clearance to rear	E	10 cm	10 cm
Depth when door open	F	49.5 cm	60.5 cm

*with Flex Display B=50 cm (dimensions to upper edge of the steam sterilizer without display)

The space requirements for the steam sterilizer correspond to its dimensions plus at least 5 cm on both sides and 10 cm behind. Above the tank should remain clear, in order to easily fill the storage tank and to provide sufficient ventilation. The steam sterilizer uses a cooling system that has a cooler at the rear of the device.
The function and lifetime can be affected if heat dissipation via the cooler is restricted.

Therefore we do not recommend incorporating the steam sterilizer; this is only possible if sufficient air circulation is ensured.

For Feed water supply

In case of external feed water supply there is additional space required for a water treatment unit MELA*dem*®40, MELA*dem*®47.

Installation surface

Flat and level

Place the steam sterilizer on a flat and level surface.

Load capacity

The Vacuklav®41 B+ weighs 59 kg without load and without feed water.
The Vacuklav®43 B+ weighs 66 kg without load and without feed water.

Electrical connections

Power socket

- 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

The power socket must be accessible after installation, so that the steam sterilizer can be disconnected from the power supply if necessary.

Power cable

The power cable is 1.35 m long.

Log printer MELAprint®42

If you want to connect a log printer to the steam sterilizer, you need another socket for its power supply.

One way drain

Wall drain or siphon drain

A wall drain, nominal width DN 40 or a siphon drain (sink drain) is required for the one way drain.

Waste water hose

A 1 m wastewater hose (MELAG Art. No. 39180) can be ordered from MELAG to directly connect the steam sterilizer to the waste water, i.e. the pressure release goes directly into the siphon of the domestic water supply.

One way overflow hose to siphon

If you connect the one way overflow hose from the steam sterilizer to the siphon of the built in water system, you need a drain hose of 2 meters (Art. No. 36585), which you can also request from MELAG.

The drain must be located at least 30 cm beneath the steam sterilizer and be installed dip-free with continuous descent.

The waste water temperature in front of the siphon may reach up to 98 °C for short terms).

Supply with feed water

Feed water one way system

Because the steam sterilizer's feed water becomes dirty in the process of the water cycling, the steam sterilizer functions according to the feed water one way system. That means that it uses fresh feed water for the steam generation for every sterilization. For this purpose the steam sterilizer gets the feed water either from the internal water storage tank or fully automatically from the water treatment unit MELA*dem*®40 or MELA*dem*®47.

Quality of feed water

The quality of the distilled or demineralized feed water for the steam generation must be at least DIN EN 13060, Appendix C.

Provide the feed water from the internal storage tank

Before the initial start-up of the steam sterilizer, the right chamber of the internal storage tank must be filled with feed water up to the maximum mark.

At the initial start-up of the steam sterilizer, the steam sterilizer requires a one-time filling of 2.5 liters to fill the double jacket. We therefore recommend that the right chamber of the internal storage tank is then immediately refilled.

Installation material

Additional material, that can be ordered	***MELAG Art. No.***
Water connection set MELA*dem*®40	09033
Water connection set MELA*dem*®47	09034
Water connection set consisting of (contained in Art. No. 09033 and 09034):	25655
Feed water inflow nozzle for ∅6x1 hose (substitute nozzle for ∅8x1)	21140
Hollow screw for feed water inflow nozzle	53430
2x Cu seals 1/8“ for Art. No. 53461	42360
2x Cu seals 1/4“ for Art. No.53471 (for twisting, substitute Art. No. 53471)	36060
Pressure release nozzle (1/4“ – quick connect for ∅8x1 hose (twist onto the device)	53471
One way drain hose PTFE-pipe ∅8/6 – cut to size	39180
One way drain hose (overflow hose, 2 m)	36585
Surface mounted siphon with double hose nozzle	37410
Double hose nozzle with anti-flooding flap for connection to existing sink siphon	37400
Water tap 3/4“ (safeguard combination)	37310
Additional water tap with return flow inhibitor and pipe aerator (to attach to an available angle valve)	58130
Safeguard combination, consisting of return flow inhibitor and pipe aerator according to EN 1717	49600

Installation examples

Example 1 – Standard scope of delivery

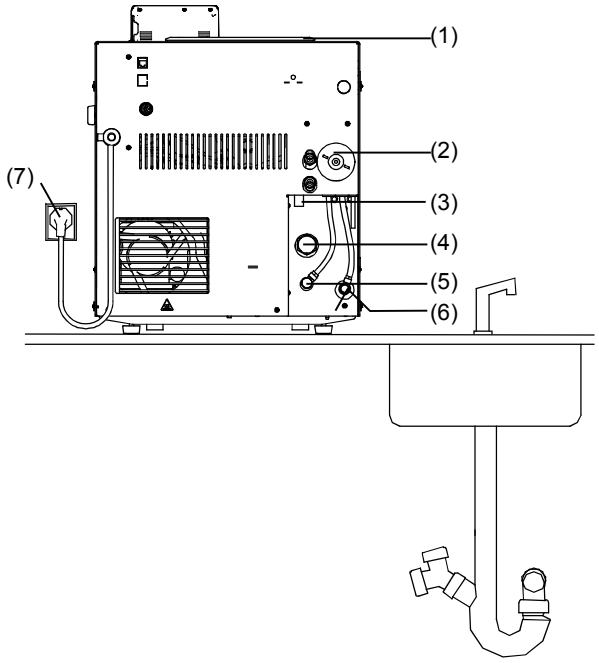


Fig. 3: Feed water supply from an internal storage tank

(1) Tank cover
(2) Sterile filter
(3) Emergency overflow
(4) One way drain
(5) Pressure release connection
(6) Feed water inflow
(7) Power cable

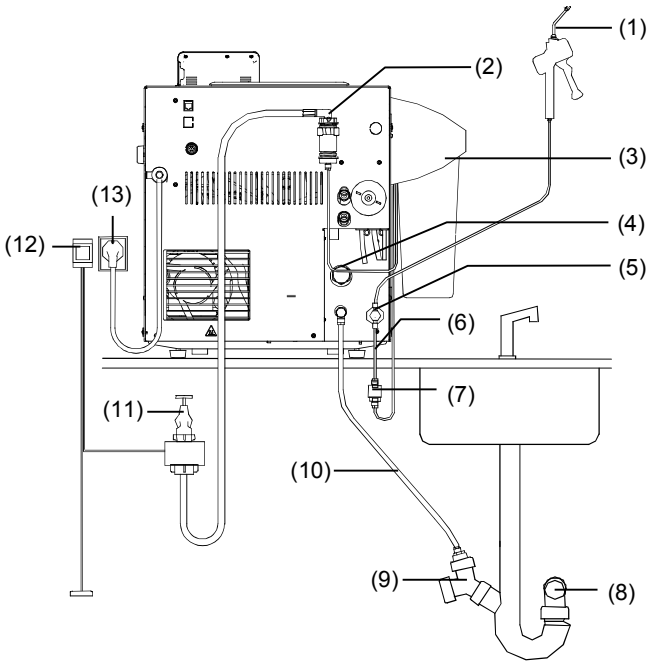
Supply of the feed water is from an internal supply tank

Waste water is collected in the waste water chamber of the storage tank

No water connection is required

The steam sterilizer is supplied with feed water directly via a hose from the internal storage tank. Thus, other than power connection, no other connection is needed. A float switch built into the device notifies low feed water. The program starts immediately after filling.
The used feed water (waste water) is collected in the waste water chamber of the internal storage tank and is later drained manually. There is also a float switch for a full waste water chamber.

Example 2 – MELAdem®40



Supply of the feed water from the ion exchanger MELAdem®40

Pressure release directly connected via a siphon

Connection of the ion exchanger MELAdem®40 with MELA*jet*®. The simplest installation is to connect the MELA*dem*®40 directly to the purified feed water inlet of the steam sterilizer and thus generate demineralized water from normal tap water. The spray pistol MELA*jet*® is for the final rinsing of the instruments with demineralized water before sterilization.

Fig. 4: Feed water supply from the ion exchanger MELA*dem*®40

(1) MELA*jet*® (MELAG Art. No. 27300 – optional)

(2) Safeguard combination consisting of the return flow inhibitor and pipe aerator according to EN 1717, recommended with fixed water connection

(3) MELA*dem*®40

(4) One way drain

(5) Feed water inflow nozzle (Swivel screw for ∅6x1 hose, alternatively straight)

(6) Feed water inflow hose

(7) Feed water filter MELA*dem*®

(8) Wall drain (available on site)

(9) Double-chamber waste water trap (MELAG Art. No. 37400 – contained with the wastewater trap Art. No. 37410)

(10) Drain hose (MELAG Art. No. 39180)

(11) Water tap (available on site)

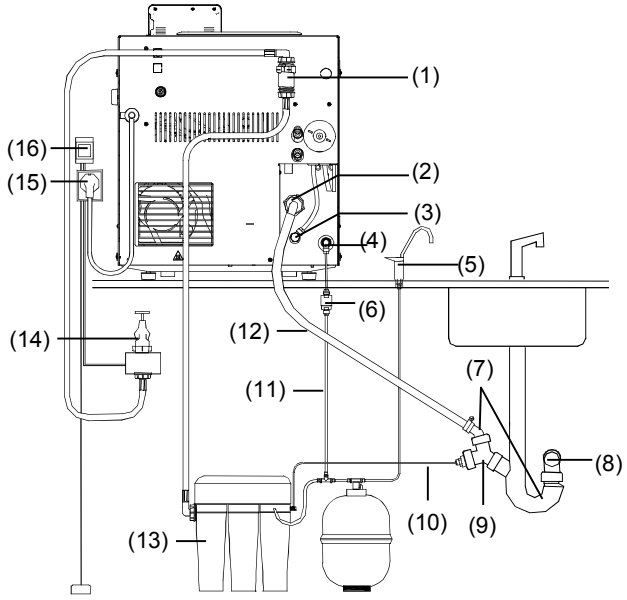
(12) Leak monitor (water stop) with shut-off valve and probe (optional), recommended with fixed water connection

(13) Power cable

Before converting from the standard version to one with a water treatment unit, both chambers of the internal storage tank must be emptied!

The feed water inflow nozzle (5) on the steam sterilizer must be exchanged for the ∅6x1 hose (MELAG Art. No. 21140) instead of the hollow screw (MELAG Art. No. 53430) with feed water inflow nozzle, because of the different hose diameter. Likewise the two Cu-seals (MELAG Art. No. 42360) – in the water connection) must be exchanged. The required feed water (waste water) is led directly by means of pressure over the one way drain hose (MELAG Art. No. 39180) into the drain in the buildings' water system. An automatic one way overflow is also possible and is described in Example 3.

Example 3 – MELAdem®47



Supply of the feed water from a reverse osmosis unit MELAdem®47

Drainage via the one way drain and double-chamber waste water trap

Connection of the reverse osmosis unit MELAdem®47, which can be directly attached to the purified feed water inlet of the steam sterilizer. Other water treatment units with corresponding water quality can also be connected after consultation with MELAG.

Fig. 5: Feed water supply from the reverse osmosis unit MELA*dem*®47

(1) Safeguard combination consisting of the return flow inhibitor and pipe aerator according to EN 1717- optional

(2) One way drain

(3) Pressure release connection

(4) Feed water inflow nozzle (Swivel screw for ∅6x1 hose, alternatively straight)

(5) Feed water tap

(6) Feed water filter MELA*dem*®

(7) Double-chamber waste water trap (MELAG Art. No. 26635)

(8) Wall drain (NW40 – available on site)

(9) Double hose nozzle with non-return valve (MELAG Art. No. 37400 – included in the surface-mounted siphon (MELAG Art. No. 37410)

(10) Concentrate drain of MELA*dem*®47

(11) Feed water inflow hose

(12) One way overflow hose (MELAG Art. No. 36585)

(13) MELA*dem*®47

(14) Water tap (available on site)

(15) Power cable

(16) Leak monitor with shut-off valve and probe (optional), recommended with fixed water connection

Installation as for Example 2 – MELA*dem*®40. The draining of waste water is automated here. The one way overflow hose (12) is connected on the one way drain of the steam sterilizer and joined over the double hose nozzle (9) with the double-chamber waste water trap (7). With direct connection of the water treatment unit to the building's water supply, we recommend an additional installation of the leak monitor with shut-off valve and probe (16).

Display settings

In the **`Settings`** menu you can change the following display parameters:

Brightness

Using the buttons  and  you can change the brightness and thus also the contrast of the display.

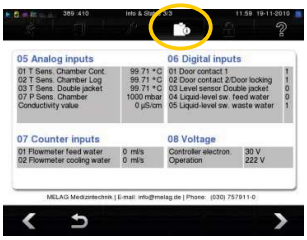
Touch tone

By selecting YES or NO, choose whether a tone is produced each time a button is pressed. This can be deactivated at any time.

Touch Sensitivity

Using the buttons  and  you can confirm how strong the pressure for touching a button must be in order to achieve a result.

Counter readings



You can retrieve counter readings and other current technical data of the steam sterilizer in the **`Info & Status`** menu.

Program modifications

The steam sterilizer program cycles correspond to the practice-relevant requirements of fractionation, heating up, sterilization, pressure release, drying and ventilation with their parameters of pressure, temperature and time.

Additional drying

The standard function of **`additional drying`** in the **`Settings`** menu provides an option for influencing the program cycle.

Further changes to the program cycles are possible in individual cases and within the scope of the guaranteed sterilization efficiency, but can only be executed by authorized persons. Please consult your specialist dealer or contact MELAG.

Connecting the steam sterilizer to a network

The best way to connect the steam sterilizer to a network is with the aid of the computer support company with which your practice works.
You can directly connect a computer to the steam sterilizer or over a network. A prerequisite is that the computer has a network card with a RJ45 connector jack (LAN). An FTP server (communications program) or an FTP service is required for connection over FTP. For log output via TCP there is no FTP program, but an applicable program, for example MELA*view* or MELA*soft* is required.

Connect the Ethernet cable

1. a) Steam sterilizer – computer with 1:1 cable
   b) Steam sterilizer – network with crossover cable
   If a so-called “intelligent switch” is used in the network, the cable connection is the same. Every interface can be employed at the steam sterilizer.

Determining the IP address of the computer

2. Find out the IP address of the computer from the computer support administrator or determine this yourself (see question 6, page 24).

Determine the network situation

3. Fundamentally important: The chosen computer must always have a fixed IP address that is not dependent on automatically or manually configured networks.
   For automatically configured networks, the DHCP server in the area must be informed of the range of the number or the number itself as a static IP address(es). The computer can also be assigned several IP addresses, in case the one already existing in the computer cannot be used.
   The steam sterilizer and the computer must belong to a subnetwork. In most cases this means that the IP address of the subnetwork must be the same for the first three numbers sets (e.g. 192.168.40.xx).
   The IP address of the steam sterilizer and the computer must differ in the fourth number set (e.g.: IP of the steam sterilizer: 192.168.40.40 and IP of the computer: 192.168.40.140).
   The default setting of the IP address in a MELAG steam sterilizer meets these requirements.

Entering a fixed IP address

4. Enter the fixed IP addresses for the steam sterilizer and the connected devices into the steam sterilizer (see **Verifying and changing IP addresses**, page 13).

Specifying the computer for the FTP server program

5. Because the steam sterilizer itself is equipped with a hub, direct connection to a computer creates a network. For this reason the procedures for direct connection only minimally differ from connection over a network. In a network a computer must be specified on which the small program FTP server can run. This program receives the logs via data transfer. The steam sterilizer seeks this computer using the IP address that is set in the steam sterilizer and logs on via the FTP server. The completed program logs are also later stored on this computer. In the selection of this computer, note that it is advantageous to have the stored logs included with the automatic data backup system of the practice.

Setting up the server (MELAG FTP server)

6. MELAG offers a free, specifically developed FTP program for this. With the MELAG FTP server, it is possible to log on as a user at several devices simultaneously and to receive data from the steam sterilizer and other devices, for example a washer-disinfector, in parallel. The FTP server supports the so-called multithread capability. You can determine for yourself the destination folders in which the device directory along with log data are stored in the FTP server program.

Connection to a practice network

In the standard ex factory delivery, the steam sterilizer contains IP addresses that all belong to the network with the subnetwork mask listed in Table 1.
To integrate the steam sterilizer into a medical practice network (and only then!), two possibilities are to be distinguished:

Manually configured network

If the network is manually configured, then the subnetwork mask of the medical practice network must be known. If a subnetwork mask is used other than the one preset in the steam sterilizer, a software expert should adapt the IP addresses in the steam sterilizer. If the masks conform and the above-mentioned IP addresses are not assigned, then a log printer or label printer can be connected directly to the steam sterilizer.

Automatically configured network (DHCP)

The network is automatically configured in a dynamic network.

- In this case, in the **`Settings`** → **`Logging`** menu set the IP address of the steam sterilizer on DHCP.

If logging takes place over a computer via FTP, then a fixed IP address must be determined for the computer, which is then registered in the steam sterilizer.

NOTICE!

If a DHCP server cannot be located in the practice network, the steam sterilizer will automatically recieve the pre-set static IP address.

The IP addresses for the following devices are saved in the steam sterilizer as parameters:

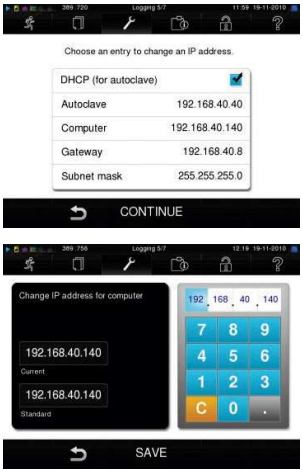
Device	***IP address***	***Comment***
Steam sterilizer itself	192.168.40.40	Default setting ex factory
Computer	192.168.40.140	Default setting ex factory
Log printer	192.168.40.240	Default setting ex factory
Label printer	192.168.40.160	Default setting ex factory
Gateway	192.168.40.244	Not relevant within a network
Subnetwork mask	255.255.255.0	Possibly take over from the customer network

Table 1: IP addresses saved in the steam sterilizer

Warning!

- **The input of false IP addresses can lead to disturbance of the practice network.**

Verifying and changing IP addresses



The IP addresses are changed in the **`Settings`** → **`Logging`** menu.

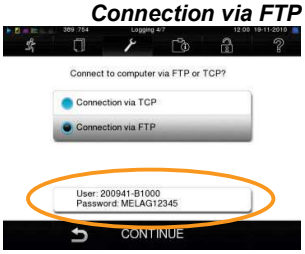
- Follow the logging assistance until you reach the window in which the IP addresses for the specific devices are listed.
- Select, for example, the steam sterilizer. It opens the next window.
- Select the numeric keypad which you wish to change directly by choosing each respective number.
- Delete the digits with the **C** button, then enter a new number and confirm with SAVE.
- Proceed in the same way with the other devices that are to be connected to the network.

Connection via FTP or TCP

If you have selected the computer as the output medium in logging help (**`Settings menu`** → **`Logging`**), determine in the following window whether the connection will be via FTP or TCP.

Connection via FTP

For connection via FTP you must first set up a user name with password in the FTP program of the computer. The user name and password must then be registered in the steam sterilizer in the **`Settings menu`** → **`Logging:`**

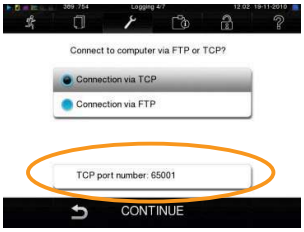


- Select Connection **`via FTP`**.
- In the lower button you will see the currently set user data (***standard username:*** year of manufacture + type + serial number; ***password:*** MELAG12345). If you wish to change this, proceed to the settings window by pushing the buttons.

- Enter the user name and password and confirm with SAVE.

Connection via TCP

For connection via TCP you must register the TCP port number in the steam sterilizer:



- Select Connection **`via TCP`**.
- In the lower button you will see the currently set TCP port (***standard TCP***: 65001).
- To change the TCP port indicated at the bottom, press the button. If you wish to change it, proceed to the settings window by pushing the buttons.
- Use the numeric keypad to select the corresponding TCP port. The current TCP port must first be deleted with the **C** button.
- Confirm with SAVE.
- To output logs via TCP, an additional special program, e.g. MELA*soft*/MELA*view* is required.

Technical tables

Precision and drift behaviour – Sensors

Sensor type	PT 1000 Class A according to DIN EN 60751
Precision at 135 °C	±0.42 K
Drift per year	±0.05 K
Drift in 5 years	±0.25 K

Table 2: Precision and drift behaviour of the temperature sensors

Sensor type	piezoresistive absolute pressure sensor 0 to 4000 mbar					
Precision	±0.3 %	corresp. to	±12 mbar	corresp. to ca.	±0.13 K	steam
Drift per year	±0.2 %	corresp. to	±8 mbar	corresp. to ca.	±0.09 K	steam
Drift in 5 years	±1.0 %	corresp. to	±40 mbar	corresp. to ca.	±0.44 K	steam

Table 3: Precision and drift behaviour of the pressure sensor

Precision and drift behaviour – Measuring chain

Precision at 135 °C	±0.2 K
Drift per year	±0.005 K
Drift in 5 years	±0.025 K

Table 4: Precision and drift behavior of the measuring chain for the temp. measurement on the electronics (w/o sensor)

Precision	±0.2 %	corresp. to	±8.0 mbar	corresp. to ca.	±0.09 K	steam
Drift per year	±0.004 %	corresp. to	±0.16 mbar	corresp. to ca.	±0.017 K	steam
Drift in 5 years	±0.02 %	corresp. to	±0.8 mbar	corresp. to ca.	±0.09 K	steam

Table 5: Precision and drift behavior of the measuring chain for the pressure measurement on the electronics (w/o sensor)

Precision and drift after 1 year

Precision at 135 °C	at pure addition of indiv. errors	ca. ±0.70 K
Precision at 135 °C	per Gaussian law of propagation	ca. ±0.47 K

Table 6: Precision including drift of the entire measuring chain of the temperature measurement after 1 year

Precision	at pure addition of indiv. errors	±0.70 %	corresp. to	±28.0 mbar	corresp. to ca. ±0.30 K	steam temp.
Precision	per Gaussian law of propagation	±0.41 %	corresp. to	±16.5 mbar	corresp. to ca. ±0.18 K	steam temp.

Table 7: Precision including drift of the entire measuring chain of the pressure measurement after 1 year

Precision and drift after 5 years

Precision at 135 °C	at pure addition of indiv. errors	ca. ±0.70 K
Precision at 135 °C	per Gaussian law of propagation	ca. ±0.47 K

Table 8: Precision including drift of the entire measuring chain of the temperature measurement after 5 years

Precision	at pure addition of indiv. errors	±0.70 %	corresp. to	±28.0 mbar	corresp. to ca. ±0.30 K	steam temp.
Precision	per Gaussian law of propagation	±0.41 %	corresp. to	±16.5 mbar	corresp. to ca. ±0.18 K	steam temp.

Table 9: Precision including drift of the entire measuring chain of the pressure measurement after 5 years

Nominal value tolerances

	Universal program		Quick B		Prion pr.		Gentle pr.		Quick S		◄ same meaning as in universal	
Step	Pressure P	Tolerance	P	Tol.	P	Tol.	P	Tol.	P	Tol.	*All values in mbar*	
SK11	1600	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	steam intake	Conditioning
SK12	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	pressure release	
SK11	1600	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	steam intake	
SK12	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	pressure release	
SK21	1600	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	steam intake	
SK22	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	pressure release	
SK21	1600	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	steam intake	
SK22	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	pressure release	
SK21	1600	+100/- 20	---	---	◄	◄	◄	◄	---	---	steam intake	
SK22	1300	+ 20/- 50	---	---	◄	◄	◄	◄	---	---	pressure release	
SF12	500	+ 30/- 30	◄	◄	◄	◄	◄	◄	◄	◄	evacuate	Fractionation
SF13	1600	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	steam intake	
SF21	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	pressure release	
SF22	180	+ 30/- 30	◄	◄	◄	◄	◄	◄	**380**	◄	evacuate	
SF23	1800	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	steam intake	
SF31	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	pressure release	
SF32	200	+ 30/- 30	◄	◄	◄	◄	◄	◄	---	---	evacuate	
SF33	1900	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	steam intake	
SF41	1300	+ 20/- 50	---	---	◄	◄	◄	◄	---	---	pressure release	
SF42	400	+ 30/- 30	---	---	◄	◄	◄	◄	---	---	evacuate	
SF43	1700	+100/- 20	---	---	◄	◄	**1500**	◄	---	---	steam intake	
SH01	2750	+ 60/- 60	◄	◄	◄	◄	**1850**	◄	◄	◄	keep steam intake	
SH02	2850	+ 60/- 60	◄	◄	◄	◄	**1950**	◄	◄	◄	keeping control	
SS01	3080	+ 60/- 60	◄	◄	◄	◄	**2080**	◄	◄	◄	sterilisation start	
SS02	3170	+ 60/- 60	◄	◄	◄	◄	**2150**	◄	◄	◄	sterilisation	
SA00	1300	+ 20/- 50	◄	◄	◄	◄	**1300**	◄	◄	◄	pressure release	

Table 10: Tolerances for normal values in the program cycle

Pressure-Time Charts

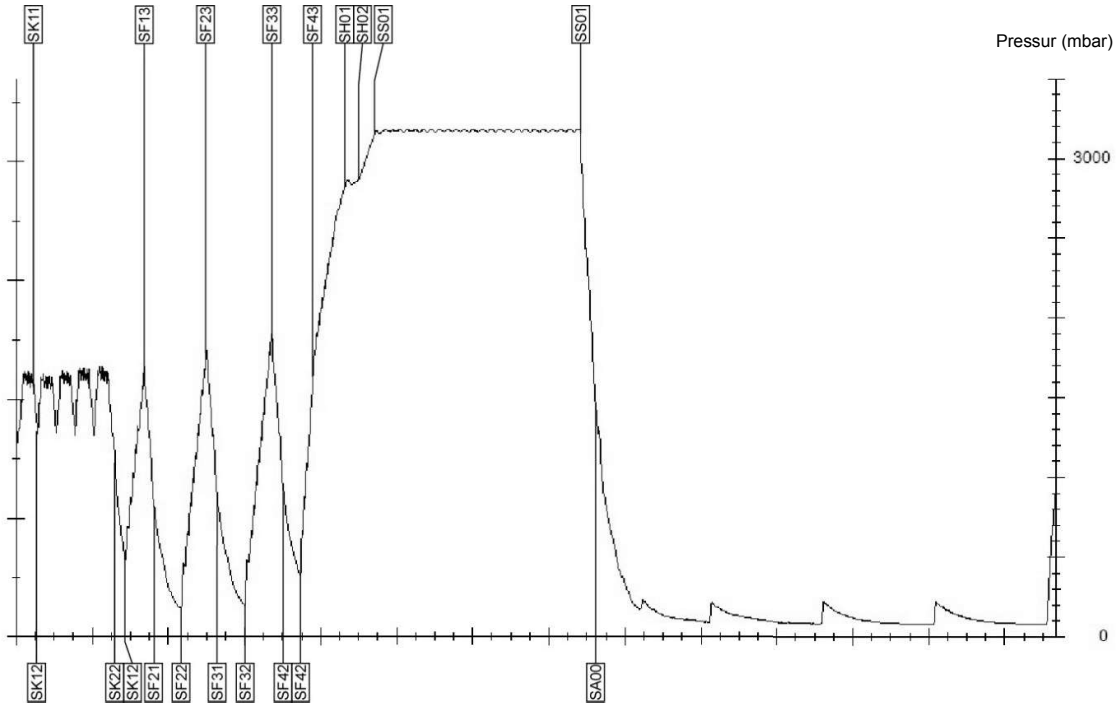


Fig. 6: Pressure-Time chart for Universal-Program, 134 °C and 2.1 bar

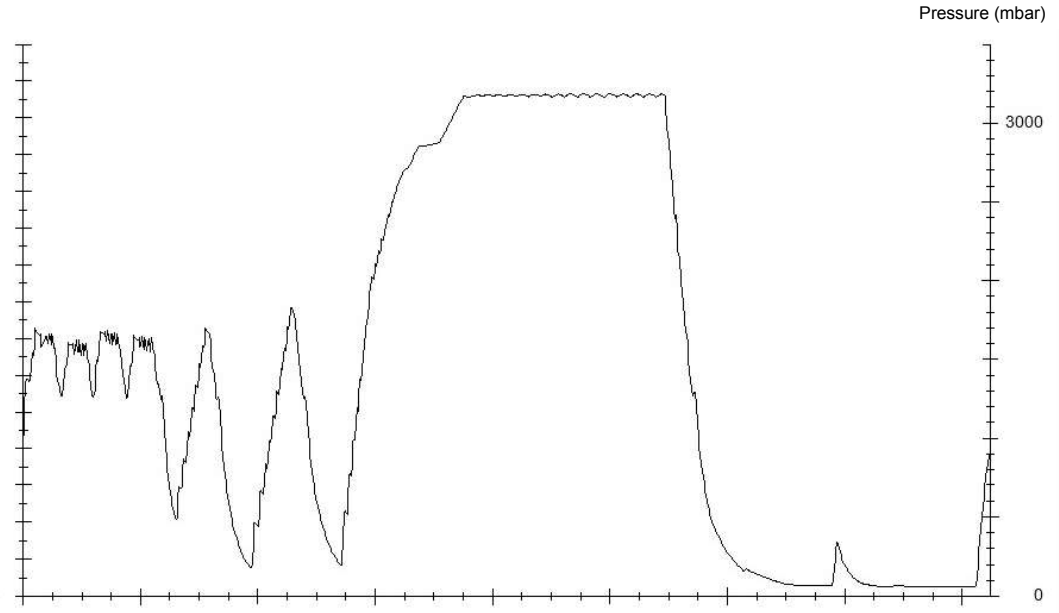


Fig. 7: Pressure-Time chart for Quick-Program B, 134 °C and 2.1 bar

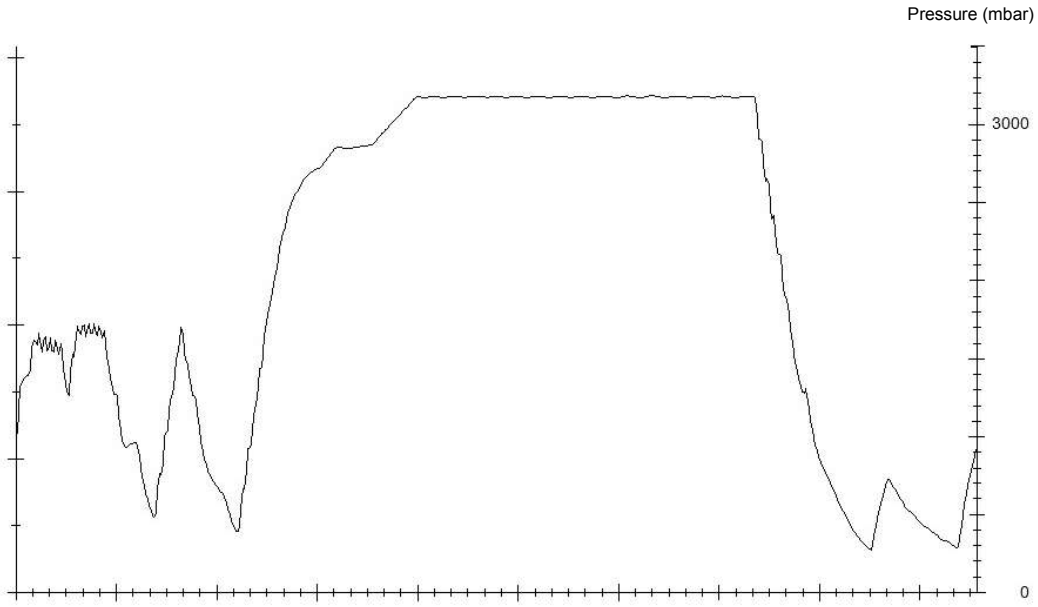


Fig. 8: Pressure-Time chart for Quick-Program S, 134 °C and 2.1 bar

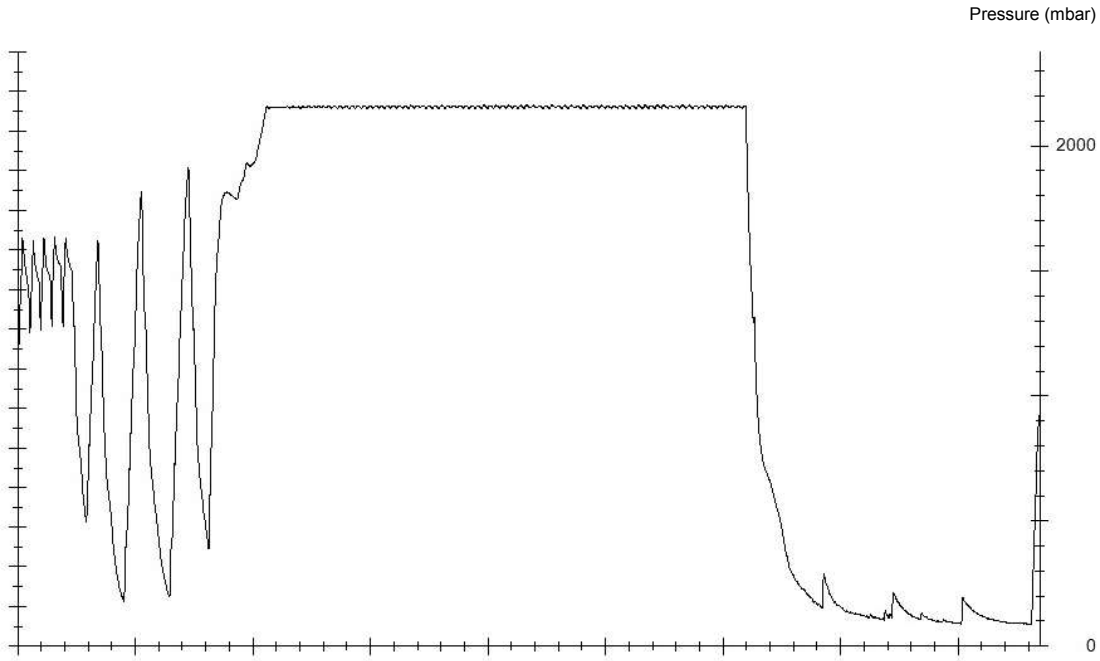


Fig. 9: Pressure-Time chart for Gentle-Program, 121 °C and 1.1 bar

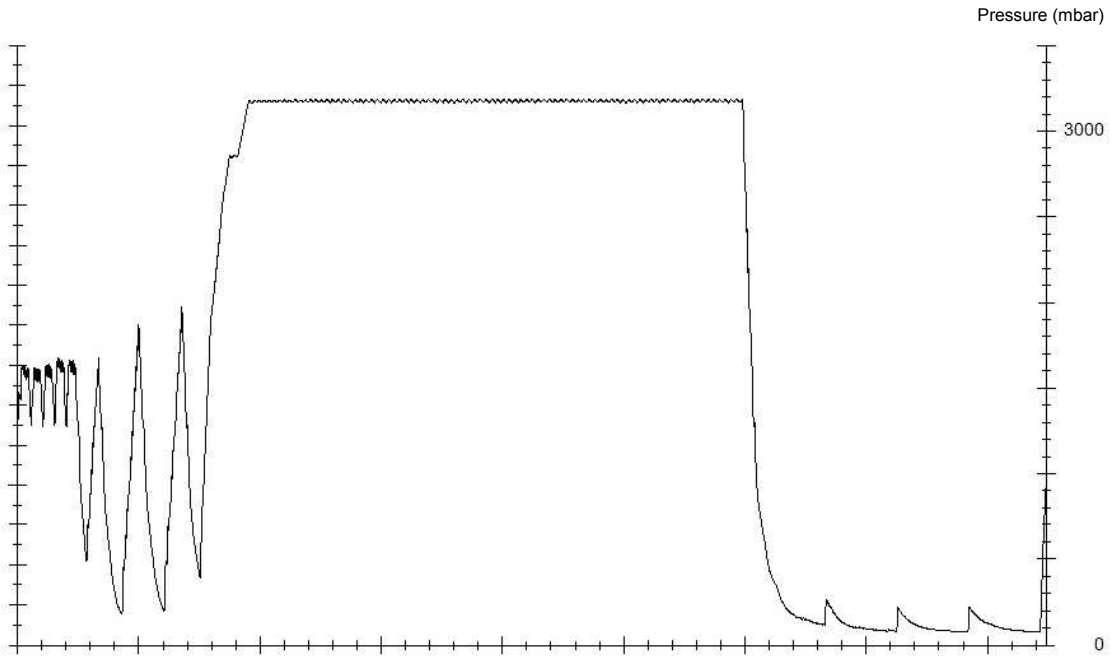


Fig. 10: Pressure-Time chart for Prion-Program, 134 °C and 2.1 bar

Quality of the feed water

Residue on evaporation	≤	10	mg/L
Silicon, SiO2	≤	1	mg/L
Iron	≤	0.2	mg/L
Cadmium	≤	0.005	mg/L
Lead	≤	0.05	mg/L
Heavy metals except for those named above	≤	0.1	mg/L
Chlorides	≤	2	mg/L
Phosphate	≤	0.5	mg/L
ph value	5 – 7		
Colour	colourless, clear, without sediments		
Hardness	≤	0.02	mmol/L

Table 11: Minimum requirements to the feed water following the EN 13060, Appendix C

Information regarding the validation

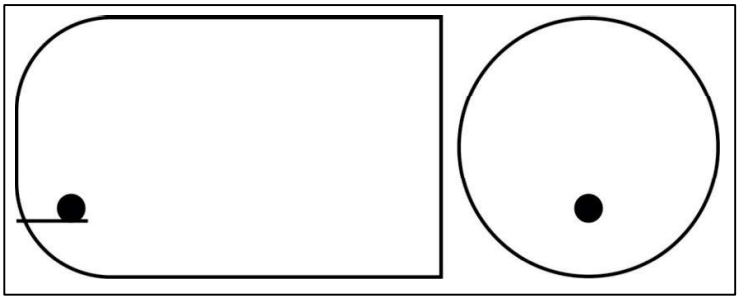


Fig. 1: Schematic side and fore view of the sterilization chamber

The coldest point in the sterilization chamber during the empty chamber test lies directly on the temperature sensor (see circular marking in fig. 1). The temperature in the rest of the sterilization chamber is almost the same all over (0.6 K range).

Frequently asked questions (FAQ) about the software

1 How can I open and print a log file?

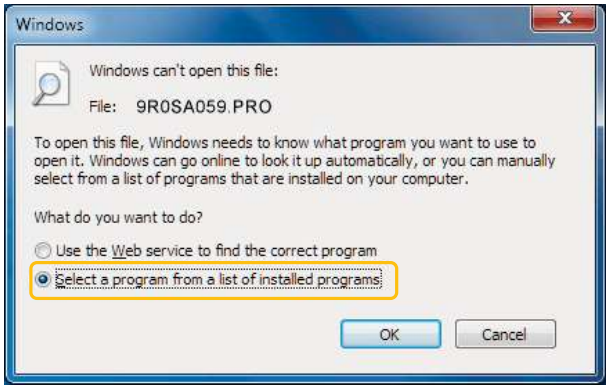
Log files can also be read with other text editors

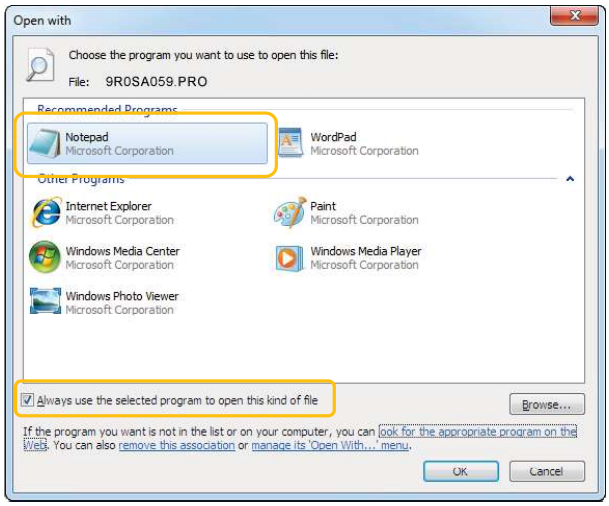
All log files are text files in UTF-8 format, which you can read, edit, and print with the simplest text editors of every operating system or with text processing or table calculation programs.

Graphic logs can only be displayed with MELA*view* (available as of MELA*view* 3).

Link with the Windows Editor

An operating system uses the file extension to recognize which program it should use to open or edit the file. Using the following example of the Windows editor, you will learn below how you link other Windows programs (here the Text Editor) with a certain file extension.
Your computer normally does not yet recognize the extensions of the log files explained under question **Fehler! Verweisquelle konnte nicht gefunden werden.**. Therefore, you have to "tell" the operating system that a file with the extension PRO, STR or LOG, for example, is always to be opened with the Text Editor.





Example: file.PRO represents a log file whose extension "PRO" is not yet recognized by the operating system.

1. Double-click on the log file in the Windows Explorer.

2. If the extension is not known, Windows XP issues the following message. Choose **`Select program from a list of installed programs`** and confirm with **`OK.`**

3. Select the Editor from the list of programs in the window that opens. It is important that you check the box for **`Always use the selected program to open this kind of file`** so that the operating system will recognize the extension in the future as well. Confirm with `OK`.
(From now on you can always open files with this extension by double-clicking the Windows Editor.)

2 What do the numerals and letters in the directories and log file name mean?

Position	1	2	3	4	5	6	7	8		X	X	X
Example	**A**	**4**	**D**	**0**	**J**	**0**	**B**	**M**	**.**	**P**	**R**	**O**
Meaning	Serial number					Batch				Log file extension		
	Year of manuf.	Type	Manuf. No.									
Explanation	A...2010 B…2011 C…2012	0…40 B+ 1…41 B+ 3…43 B+ 4…44 B+								.PRO successful program .STR malfunction .STB malfunction in standby .LOG system log .STA status log .LEG abbreviation legend .GPD graphic log (.DEM) (demo log) (.DES) (demo malfunction)		

Table 12: Explanation of the numerals and letters in the directory and log names based on an example

Do not rename log file names

A complete encryption of both the serial number as well as the total batch number is carried out directly in the eight-place log file name. A manual renaming of a file is therefore discernible, but not recommended. A file name is not allocated twice. The log file name ensures a good sortability of records.

Date and time of the log files

Date and time of the log files in the Windows Explorer are identical with the date and time of the program start, provided that these were saved on the respective medium by immediate printout. For later collected output on a medium or for sending by e-mail, this information is lost.

Serial No. and total batch number are found in the log file

It is not necessary to know the encryption within the name of the log file, since by double-clicking on the file the contents and hence also the serial number and total batch number can be seen. The prerequisite is the above mentioned allocation of the log file to a text editor (see Question **Fehler! Verweisquelle konnte nicht gefunden werden.**).

Total batch number must be entered when the control electronics is exchanged

In the rare event that a control electronics must be exchanged, the total batch number must be entered. This is possible for authorized experts in the service menu.

3 How can I format a CF card at the steam sterilizer itself?

! Attention

- All saved data on the CF card is deleted during formatting! Therefore you should check the CF card contents and save possibly existing backup records or other data on the PC or on some other storage medium.

Procedure for formatting

1. Insert the CF card correctly into the card slot (the noticeable raised rib at the edge points back and to the right). Never apply force.
2. Select Settings → **`Format CF card`** → in the window **`Format CF card now?`** Press OK
3. Confirm the confirmation message with YES.
4. If the message **`Formatting CF card... completed`** appears, you may remove the CF card.

4 How is a CF card formatted at the PC so that it is recognized by the steam sterilizer?

The CF card can be formatted (bringing even more security) on the steam sterilizer

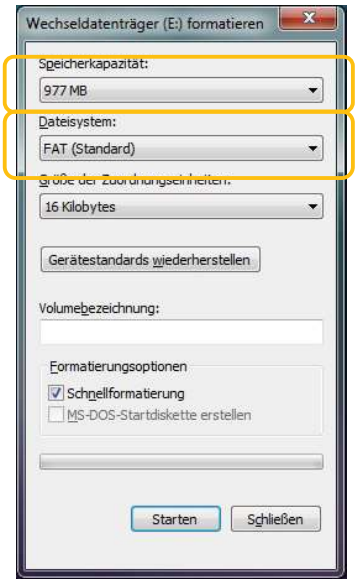
The CF card should only be formatted on the steam sterilizer.

This can be performed on the computer in exceptional cases. The CF card used may have a maximum memory capacity of 4GB and must be formatted with the file system FAT16. Only on CF cards formatted in this way is it possible for the steam sterilizer to file or read data.

MELAG CF cards fulfil all these requirements and are already formatted.

Formatting on a PC is exemplary described in Windows 7:

1. Enter the CF card in the MELA*flash* card reader installed and connected to the computer.
2. Working in Windows Explorer **Computer → Devices with removable storage** select the corresponding drive and open the menu window with a mouse right-click.
3. Working in the menu window, select the **Format** option. The following dialogue box opens:



4. Working in **Capacity,** select Format FAT (Default).
5. Working in **Allocation unit size**, Windows automatically selects the appropriate unit allocation appropriate to the size of the CF card. The allocation unit is dependent on the size of the CF card.

5 What do the terms DHCP, IP address and subnetwork mean?

IP address

The IP address is the identification of the respective computer in a network expressed in numbers and unambiguously identifies the respective computer or steam sterilizer with four number blocks (e.g. 192.168.88.8).

Subnetwork and IP address

Every IP address is divided into a network and an appliance part (host part). The division is carried out by the network mask (subnetwork/Sub Net Mask). The network part of the IP address must be the same for devices to be able to communicate with each other on the network. With a network mask = 255.255.255.0 (the most frequent), the first three number sets (e.g. 192.168.88.x) must match. The device part of the IP address is assigned individually and only once. The first (network itself) and the highest (broadcast) device address may not be assigned here.

6 How do I ascertain the IP address and network settings of a PC?

Determination of the IP address of a PC

1. Start → Settings → Network connections → LAN Connection → Register Network support → IP address
2. For instance you can discern whether a PC is integrated into a dynamic network: Start → Settings → Network connections → right mouse button on LAN Connection → Properties: Scroll in the window This connection uses the following elements to Internet protocol (TCP/IP) and click with left mouse key, then press on button Properties. If in the window Properties of Internet protocol (TCP/IP) the option obtain IP address automatically is selected, the PC in the network is dynamically addressed.

7 How do I register the steam sterilizer as a user with MELAG FTP server?

1. Create the steam sterilizer as a new user in the FTP server (e.g. MELAG FTP server). User name = serial number of the steam sterilizer, e. g. 201040-B1000; user password = MELAG12345. Click on the folder and choose the desired directory for the program logs. You can find more information in the accompanying operating manual.

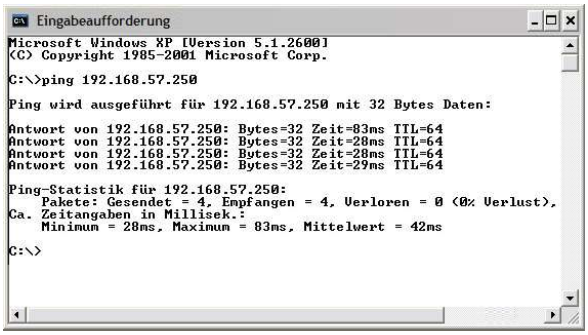
NOTICE!

Moving the FTP server to another folder on the computer results in the loss of the user settings.

Depending on the computer's configuration, it might be necessary to inform the computer's firewall that the FTP server is an exception.

Testing

2. Make a test run with the immediate output of a log.
In the event of problems with the FTP server it is advisable to send a ping to the IP address of the steam sterilizer.



Start the input prompt at the computer with the FTP server (**`Start` → `programs` → `Accessories (input prompt`**). Enter the following lines: xxx.xxx.xxx.xxx
(X = IP address of the steam sterilizer)
If this ping is answered successfully as displayed here, then the data transfer between computer and steam sterilizer has been established. Cable, network or the IP address of the steam sterilizer can be excluded as causes for errors that can occur.

Fig. 11: Sending a ping to the IP address of the steam sterilizer on the Windows XP input prompt

Messages which can enter in the window of the FTP server	*Possible cause/significance*
The following line remains on the screen for a longer time: `! Server started on Port 21`	▪ Cable connection defective ▪ IP address of the computer not set correctly in the steam sterilizer (see **Verifying and changing IP addresses**, page 13).

Over a longer time period, the following lines are repeated:
`< 14:12:22 192.168.40.100 USER: 201040-B1000`
`< 14:12:22 192.168.40.100 USER: 201040-B1000 << Incorrect login or password >>`
	▪ The password was not entered correctly

The following rows enter c. every eight seconds:
`< 14:03:22 192.168.40.100 USER: 201040-B1000`
`> 14:03:22 192.168.40.100 USER: 201040-B1000 << is logged in.>>`
`> 14:03:52 192.168.40.100 USER: 201040-B1000 << C:\Documents and Settings\Admin\own files \protocols >>`
`< 14:12:22 192.168.40.100 QUIT`
	▪ Successful handshake between steam sterilizer and FTP server in which however no steam sterilizer log was imported

Table 16: Possible messages in the window of the FTP server and their significance

8 How can I verify the version of the steam sterilizer software?

Version check in the Info and Status menu

You check the version of the software of the steam sterilizer in the **`Info & Status`** menu on the running steam sterilizer.