VARIOKLAV™
Steam sterilizer 25T
Operating Manual

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Thermo SCIENTIFIC

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User considerations

This operating manual is directed at users and operators (or their representatives) of VARIOKLAV Type 25 T bench-top steam sterilizers.

This audience consists of three target groups:

Target group 1: Trained laboratory staff
Target group 2: Semi-skilled laboratory staff
Target group 3: Auxiliary staff

Operators and target group 1 should read the entire Operating manual and its supplements. Chapters 1 through 9 are directed at target groups 2 and 3.

Correct use

The VARIOKLAV Type 25 T benchtop sterilizer is intended for the following purposes:

- ⇨ Sterilizing solid items such as glassware, rubber items, pipette tips, instruments, filter housings, as well as consumables, waste, and to destroy infectious or septic materials.
- ⇨ Sterilizing liquids such as solutions and culture media in open or slightly closed vessels, including cooling to a reference temperature below 90 °C to allow safe removal.
- ⇨ Sterilizing food.
- ⇨ Steaming liquids or dissolving agar-agar.
- ⇨ With Vacuum pump option only: Sterilizing and drying porous materials, fabric, or tubes.
- ⇨ With Type ST supporting pressure, Radial fan and Type RM water recooling system option only: Sterilizing liquids in pressure-sealed vessels (e.g. flasks, bags).

Incorrect use

Easily combustible or toxic liquids must not be sterilized!
The following products are not suitable for sterilization:

- Wooden items,
- Bonded parts,
- Plastic materials sensitive to hot water (e.g. screw tops),
- Electrical equipment,
- Vessels or instruments made from steel or iron,
- Metering equipment, unless their suitability for steam sterilization is specifically mentioned.

Pictographs

You will find the following pictographs in this operating manual:

DANGER
This sign refers to hazardous situations.
Hazards to human life are indicated by the word “LIFE HAZARD”.

DANGER
This sign refers to explosion hazards.

DANGER
This sign refers to dangerous voltages.

CAUTION
This sign indicates danger to equipment and machinery.

INFORMATION
This sign indicates easier working practices.

♦ Indicates an operating step.

⇨ Indicates alternatives.

Abbreviations

You will find a glossary of technical terms and abbreviations in Chapter 14.

1 Safety considerations

For your own safety, you should observe the following safety warning signs.
The warning signs indicate a possible source of danger.
At the same time they contain information on how correct action can avert danger.
You will always find warning signs attached to points of possible danger.
Safety warnings are indicated by the following signs on a grey background:

DANGER
This sign refers to hazardous situations.
Hazards to human life are indicated by the word “LIFE HAZARD”.

DANGER
This sign refers to explosion hazards.

DANGER
This sign refers to dangerous voltages.

CAUTION
This sign indicates danger to equipment and machinery.

INFORMATION
This sign indicates easier working practices.

On the following pages all safety warnings are listed to give you an overview.
Information concerning an easier working practice will appear at the appropriate places in the text.

⚠	**DANGER** **Read the detailed operating manual before switching on the sterilizer. Keep the manual in a safe place to assist other operators.**
⚠	**DANGER** **No matter what the problem, <u>never</u> use force when opening or closing the swing door of the sterilizer. LIFE HAZARD!** **The system might be damaged!**
⚠	**DANGER** **If problems occur that might be harmful to persons or property, the unit must be immediately disconnected from the power supply by pulling out the mains plug from the socket!**
⚠	**DANGER** **Should any anomalies and / or problems occur while the sterilizer is ready for use or while running a sterilization cycle: Press the green START/STOP key to terminate any ongoing programs, if necessary.**
⚠	**DANGER** **If a program is interrupted, the load must be re-sterilized for safety reasons.**
⚠	**DANGER** **Only run the sterilizer for correct use.**
⚠	**DANGER** **Only sterilize waste in open vessels (e.g. metal boat with closed bottom).**
⚠	**DANGER** **Do not open the sterilizing chamber (8) until removal is signalled.** **Watch for hot steam and hot water!** **Scalding hazard!** **Follow the specified operating steps to the letter.**
⚠	**DANGER** **Hot steam may escape when the door is opened.** **Scalding hazard!** **Step back when opening the sterilizer.**
⚠	**DANGER** **You must wear the following protective items when opening the sterilizing chamber (8) and removing the sterilized articles:** **• Apron,** **• Eye protectors,** **• Heat-insulated gloves.** **Watch for hot surfaces and hot steam!**

DANGER
Do not sterilize pressure-sealed vessels.
Explosion hazard!
Watch for broken glass!
Scalding hazard!

CAUTION
Take note of all warning signs attached to the sterilizer.

CAUTION
The equipment must not be operated in hazardous locations!

CAUTION
When sterilizing liquids:
Do not fill the vessels more than two-thirds full,
as otherwise liquids may boil over.

CAUTION
Only use deionized or distilled water when topping up feed water. Do not use tap water!

CAUTION
During the heating phase, contaminated exhaust air or waste water may be emitted from the sterilizer to the on-site disposal system.
Remedy: Type FA exhaust air filtration expansion option.

CAUTION
Take care to ensure that the door seal (6) is:
free from dirt, not sticking to the door (2), and not damaged.
The door seal (6) must sit snugly in the groove.

CAUTION
Before sterilization, check to see whether there is enough feed water in the feed water tank (4).
Only use deionized or distilled water when topping up the feed water.
Do not use tap water!

CAUTION
In order to guarantee smooth operation and prevent corrosion damage, please follow the checklists for regular maintenance and care and the maintenance manual to the letter!

CAUTION
Before opening, check to see if the indicated pressure has dropped below the set removal pressure (factory setting: 110 kPa).

1.1 In case of emergencies

1.1.1 Disconnecting from mains

DANGER
No matter what the problem, never use force when opening or closing the swing door of the sterilizer. LIFE HAZARD!
The system might be damaged!

CAUTION
If problems occur that might be harmful to persons or property, the unit must be immediately disconnected from the power supply by pulling out the mains plug from the socket!

INFORMATION
The mains plug socket of the sterilizer must be freely accessible. In case of failures, it is used to disconnect the sterilizer from mains.

The sterilizer is disconnected from mains.
Contact the authorized Thermo service:

1.1.2 TERMINATION program

CAUTION
Should any anomalies and / or problems occur while the sterilizer is ready for use or while running a sterilization cycle: Press the green START/STOP key to terminate any ongoing programs, if necessary.

INFORMATION
To deactivate the Preheating program, press the Preheating key (22).

Examples of possible anomalies or problems:

- Steam escapes from behind the cover or from the disposal area;
- Water dropping from the bottom of the unit;
- Incorrect choice of program with adverse consequences for the items to be sterilized (e.g. excessive sterilization temperatures).

Pressing the START/STOP key terminates the sterilizing program. The device will enter a state in which the load can be safely removed.
If you had inadvertently chosen an inappropriate program:

- ♦ Select the correct sterilizing program for your load.
- ♦ Start the newly selected sterilizing program.

In case of anomalies and problems:

- ♦ Contact the authorized THERMO service:

CAUTION
If a program is interrupted, the load must be re-sterilized for safety reasons.

1.2 Residual sterilizing risks

The VARIOKLAV Type 25 T benchtop sterilizer ensures safe sterilization, when used as directed and if the appropriate sterilizing program has been chosen for the load to be sterilized. A complex error management system monitors the unit for technical problems, indicates and documents them (bath documentation, option), and directs the user to the correct reaction (troubleshooting, re-sterilization):
Even when all technical prerequisites for safe sterilization exist, sterility of the load cannot be guaranteed.
There is always a residual risk, depending in part on the care with which the user and operator perform their respective tasks:

- Omission of the checks for routine maintenance and care enumerated in the Maintenance Manual (weekly, monthly, semi-annually and annually).
- Feed water impurities.
- The efficacy of a sterilizing program for the actual user load, even given a constant consumable supply situation, can only be demonstrated by a validation process. The manufacturer only validates the test loads.
- Damaged items must be considered non-sterile.
- If the sterilizer is deployed in a different place, environment conditions may change.

2 Short operating manual

INFORMATION
Attach the short operating manual close to the sterilizer.

3 Equipment description

3.1 Components

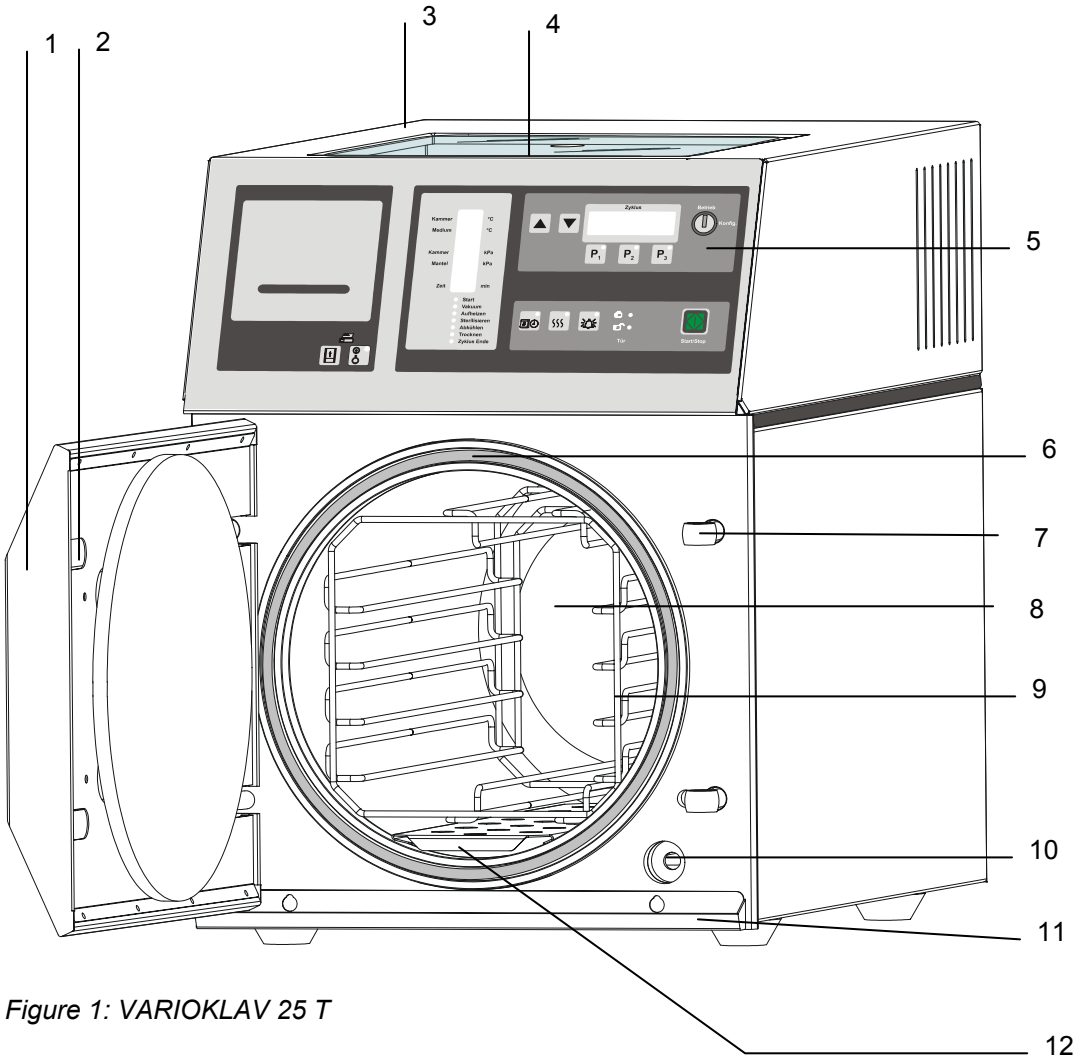


Figure 1: VARIOKLAV 25 T

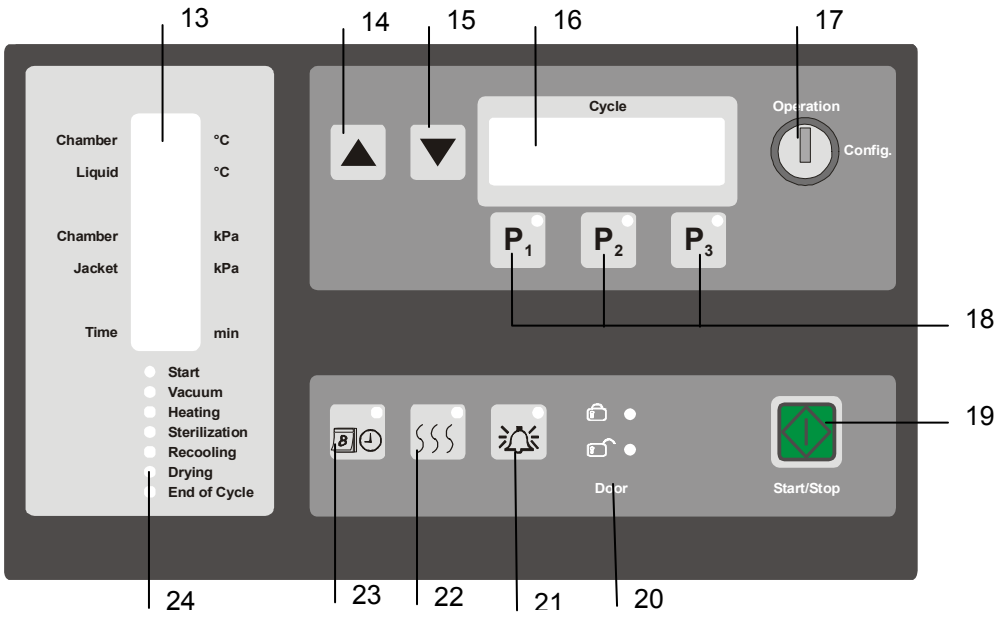


Figure 2: VARIOKLAV 25 T control panel, detail

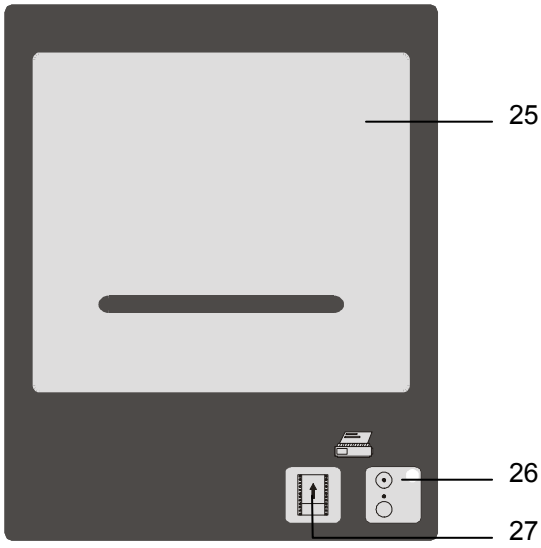


Figure 3: Printer control panel, detail

1	Door	:	Closes the sterilizing chamber.
2	Locking lever (inside the inner door moulding)	:	Lock the door. Two locking levers keep the closed door tightly locked to the housing anchors (7).
3	Case	:	The case contains the control elements and fittings.

4	Feed water tank with glass cover (optional with spent-steam condenser)	:	The feed water tank contains the feed water (deionized water) used to generate the sterile steam. The glass cover protects the feed water from contamination. The spent-steam condenser (option) subsequently condenses the steam, which can then be disposed of separately or returned to the feed water tank.
5	Control panel	:	Keys and switch keys for programming; displays.
6	Door seal	:	Seals the sterilizer door.
7	Anchors for locking levers	:	This is where the locking levers (2) engage when the door is closed.
8	Sterilizing chamber	:	Chamber in which items are sterilized.
9	Rack system (accessory)	:	Accommodates the insert trays with the items to be sterilized.
10	Feed water tank drain	:	Connector for draining the feed water tank. A piece of hose with a suitable coupling is included. (The jacket space is emptied using a special jacket evacuation program; see Maintenance Manual.)
11	Condensate gutter (accessory)	:	Catches condensate that has formed on the door or in the chamber.
12	Insert tray	:	For placing items in the sterilizing chamber.
13	Current values display	:	Indicates the current conditions prevailing in the sterilizing chamber Chamber temperature (in °C) (additionally, if Media temperature control option is installed: Media temperature, in °C) Chamber pressure (in kPa) (additionally, if Drying option is installed: Jacket pressure, in kPa) (additionally, if the Multiple sterilization special program is installed: Number of remaining sterilization cycles) Remaining sterilizing time or drying time (in min)
14	▲ key	:	Increases values of sterilization parameters.
15	▼ key	:	Decreases values of sterilization parameters.
16	Cycle display	:	Shows set temperature, multiple sterilization number (option), sterilizing time, and the name of the selected program.
17	Key-operated switch	:	The software and hardware versions can be viewed only when the key-operated switch is turned to the configuration position (“Konfig.”).
18	Program keys	:	Select the sterilizing program.
19	Green START/STOP key	:	Turns the sterilizer on and starts the sterilization process.
20	Door indicator	:	Indicates the condition of the door: yellow door closed, locked. green door open, unlocked. While the door is being locked or unlocked by the locking levers, both indicator lights are off.

21	Acoustic signal key	:	Turns the acoustic signal (buzzer) at program end on or off.
22	Preheating key	:	Out of function
23	Timer key	:	Turns the timer on or off, and for checking the preset date or time.
24	Sterilization phase display	:	Shows the phases of a sterilization cycle.
25	Printer cover	:	Covers the printer head, the ribbon, and the paper roll (option).
26	Printer ON/OFF key	:	Turns the printer on or off.
27	Paper feed key	:	Advances the printer paper.

The VARIOKLAV Type 25 T steam sterilizer is a compact benchtop unit with an electrical heater built into the jacket space:
The feed water is pumped from the feed water tank to the jacket space where it is heated. The heated feed water then supplies the sterilizing steam. The sterilizing steam is introduced directly into the sterilizing chamber (8). A rigidly mounted temperature sensor is measuring the chamber temperature.

The following components are stored in the case (3):

- the sterilizing chamber (8),
- the safety valve,
- the feed water tank (4),
- the control panel (5).

The control panel (5) is used to select sterilization parameters and to start the sterilizing program. Sterilizing chamber (8) pressure and temperature are shown on the control panel display.

The built-in timer is used to set a start time for the sterilization cycle.

The sterilizer may include additional expansion options indicated on the front page. Expansion options are described in Chapter 4.

We highly recommend having the sterilizer serviced regularly by an authorized service agency. Furthermore, please observe the Maintenance Manual. This will give you guaranteed trouble-free, safe operation and a long service life.
We offer you a low-priced yearly safety check and benefits such as calibration and qualification (see Chapter 10.6).

4 Function

VARIOKLAV Type 25 T benchtop sterilizers are used to sterilize and disinfect various kinds of articles.

Standard Equipment	**Program**	**Items / Special Notes**
	Instruments	Solid items such as instruments, filter housings, glassware, rubber items, pipette tips and food.
	Destruction (Waste)	Used consumables, infectious or septic materials which need to be destroyed.
	Liquids	Liquids in open or slightly closed vessels.
Expansion Option		
Type RM water recooling system	Liquids RM	Liquids in open or slightly closed vessels; recooling reduces batch times.
Media temperature control	All Liquids programs	Flexible media temperature sensor: sterilizing time actuated by media temperature.
Type FA exhaust air filtration	All programs	Safety feature: sterile air filter.
Water post-feed	All programs	Sterilization cycles > 40 min.
Batch documentation	All programs	Sterilization values are logged.

Furthermore, this unit is suitable for non-pressurized steaming of liquids, culture media and solutions at 98 °C.

The functional description will start by presenting the basic functions of the VARIOKLAV Type 25 T benchtop sterilizers. In addition, you will find here a description of the expansion options.

The VARIOKLAV Type 25 T benchtop sterilizer is microprocessor-controlled. This means that sterilization can proceed without supervision. You must set the desired sterilizing program on the control panel (5).

The P_1, P_2, and P_3 program keys (18) are preset for programs for different types of sterilizing items. The program settings can only be changed permanently (configured) when the key-operated switch is turned to the configuration position (“Konfig.”) (see Chapter 9).

Once the program has started, the sterilizing chamber is first closed automatically. The control panel (door indicator, 20) indicates the electronic and mechanical door lock (yellow). Now the sterilizing chamber is sealed with the pneumatic door seal: the inflatable seal is pressed onto the door using pressurized air.

The sterilizing chamber (8) is automatically heated and deaerated. At a chamber temperature of 96 °C, the sterilizing chamber (8) is again deaerated for further 3

minutes.Once the specified sterilizing temperature has been reached, the sterilizing time will start running. Then the sterilizer is used as a steam pot (set temperature of 98 °C), no pressure builds up in the sterilization chamber (8).

When the sterilizing time has run out, the sterilizing chamber (8) cools according to the selected program:

- **Instruments program:** rapid pressure release to a removal pressure below 110 kPa .
- **Waste (Destruction) program:** delayed pressure release to a removal pressure below 110 kPa .
- **Liquids:** slow pressure release. The sterilization cycle is not ended until the reference temperature has dropped below 90 °C (thermolock).

In the case of the Multiple sterilization special program, the program cycle of heating, sterilizing, cooling and drying (optional) repeats itself according to the selected multiple sterilization number.

The sterilization phase display (24) shows the current status of program execution. When the program has been completed, the acoustic signal will be sound and the light in the green START/STOP key (19) will flash. Pressing the green START/STOP key (19) will terminate the program. The door is unlocked, and the door indicator (20) changes to green again.

The sterilizer is ready for a new cycle immediately after the sterilized items have been removed and the feed water tank has been filled up (if required) with deionized water.

4.1 Options

⇨ **Media temperature control**
With this option, the sterilizer is additionally equipped with a *flexible temperature sensor*. The flexible temperature sensor measures the media temperature in a reference flask. In all *Liquids programs*, the sterilizing timer is not actuated until the media has reached the sterilizing temperature. The program is not terminated until the *media temperature* has dropped below 90 °C. The thermolock prevents the sterilizer from being opened prematurely. This allows safe removal of liquid sterilizing articles at the end of sterilization.

⇨ **Type RM water recooling system**
With this option, the sterilizer is additionally equipped with a *fast recooling system*. In the *Liquids RM program*, cooling water is led through a separate cooling coil within the jacket space during the cooling phase. This cools the sterilizing chamber from outside, and batch times are shortened.

⇨ **Type FA exhaust air filtration**
With this option, the sterilizer is additionally equipped with a *sterile air filter* (FA) (see also Chapter 4.3.1). The exhaust air filtration is effective in all programs. Once commissioned, it can not be decommissioned. In this way you can exclude the possibility that contaminated materials are sterilized without exhaust air filtration. The cycle display (16) now also shows the filter symbol ▩ .

⇨ **Water post-feed**
With the Water post-feed option, water is led within the jacket space not only prior to sterilization, but more water is added as needed from the feed water tank. In this manner, it is possible to implement sterilizing and steaming times of up to 10019 minutes.

⇨ **Batch documentation**
With this option, the sterilizer is additionally equipped with an *integrated printer* for batch documentation. The integrated printer can operate in parallel *with any program*. The printout logs the sterilization process complete with date, batch number and sterilization parameters, as well as any errors that have occurred during program execution.
A possible alternative is using the *VARIOSOFT* PC software for batch documentation.

4.2 Special programs

⇨ **Climatic chamber**
The benchtop sterilizer can be reprogrammed to serve as climatic chamber for long-term ageing tests. This requires the presence of certain expansion options.
The sterilizing time of all available programs must be set to ∞ (infinity). Any program selected and executed must then be terminated manually. The feed water tank (4) level must be checked at regular intervals.

⇨ **Multiple sterilization**
The benchtop sterilizer can be reprogrammed for multiple sterilization for testing. This means that the complete sterilization cycle is executed several times in succession. The number of cycles can be selected. This requires the presence of certain expansion options. The feed water tank (4) level must be checked at regular intervals.

4.3 Safety features

The VARIOKLAV Type 25 T benchtop sterilizer has various safety features, including simple handling thanks to automated program control, which reduces the number of operator errors, and a sophisticated error management system that monitors and reports technical problems or defects. The enclosed diagram gives you an overview over structural and programmed safety features.

4.3.1 Exhaust air filtration (Types FA, FA/FS)

The steam sterilizer may be equipped with a *sterile air filter* (Type FA expansion option) as an additional safety feature. The exhaust air filtration system prevents the escape of micro-organisms from the sterilizer during deaeration. This is necessary for safe and emission-free sterilization of contaminated materials,

especially in maximum-containment laboratories[1)]. The entire filter housing is itself sterilized during each sterilization cycle and is therefore protected from contamination.

If another sterilizer expansion option requires a sterile air filter (Types FS, FL), the sterile air filter will be present in the form of a combination filter Types FA/FS, FA/FL, or FA/FS/FL. This combination filter serves two functions simultaneously: sterile venting and exhaust air filtration. Sterile venting prevents pathogens from entering the sterilizing chamber during pressurized aeration at the end of the sterilization cycle or during aeration at the end of a vacuum drying phase. The combination filter is also itself sterilized during each sterilization cycle.

4.3.2 Thermolock

The steam sterilizer is equipped with a *thermolock*[2)] as safety feature. The thermolock prevents any opening of the sterilizing chamber as long as the reference temperature remains above 90 °C[3)]. The thermolock is effective in all Liquids programs. The current values display (13) shows the reference temperature for checking (instead of the media temperature) during the cooling phase. During sterilization, by contrast, the reference temperature is not shown (- - -).

The sterilizer may be equipped additionally with a flexible temperature sensor (media temperature control expansion option). This flexible temperature sensor has a pressure-sealed entry point through the back wall of the sterilizing chamber. In all Liquids programs, the flexible temperature sensor measures media temperature as the reference temperature. This temperature is the input value for controlling the thermolock. The media temperature is continuously displayed in the current values display (13).

The program steps door locking, heating and automatic deaeration, sterilizing, and cooling are performed automatically. As soon as the liquid temperature drops below 90 °C, the thermolock is turned off. The program is terminated, and the door can be opened.

In case of a power failure or if no electrical outlet is available, the thermolock will always remain switched on. The door is **locked**. It can only be opened when power is restored. The door is also locked when the thermolock is active, but the flexible temperature sensor is defective.

[1)] Genetic Engineering Safety Regulations dated March 21, 1995 (A II 2.): “For all operations during which aerosols could be produced, these must be prevented from reaching the work area.”
[2)] Temperature-controlled safety system for liquids to prevent retardation of boiling in accordance with TRB 402 (3.2.4.), AD instruction A5, DIN 58 950 and DIN 58 951.

5 Preparing for sterilization

DANGER
Only run the sterilizer for correct use.

CAUTION
Take note of all warning signs attached to the sterilizer.

CAUTION
Take care to ensure that the door seal (6) is:
free from dirt, not sticking to the door (2), and not damaged.
The door seal (6) must sit snugly in the groove.

INFORMATION
The sterilizer is equipped with an energy-saving function. If no program is started during the five minutes after turning the device on, the device switches automatically to stand-by mode. By pressing the START/STOP key (19), the sterilizer can be operated as usual.

♦ Push the green START/STOP key (19) to switch on the sterilizer.

The settings of the last sterilizing program selected are shown on the cycle display (16).
The current values display shows:

- The chamber temperature,
- The media temperature (if the Media temperature control expansion option is present),
- The pressure in the sterilizing chamber (absolute pressure),
- The jacket pressure (if the Drying expansion option is present),
- The number of remaining sterilization cycles (if the Multiple sterilization special program is present),
- The remaining sterilization or drying time; the initial time shown is the set time, with the numbers counting down to zero during the sterilization or drying cycle.

5.1 Preparing the sterilizing chamber

CAUTION
Before sterilization, check to see whether there is enough feed water in the feed water tank (4).
Only use deionized or distilled water when topping up the feed water.
Do not use tap water!

- Check the feed water tank filling level (4):
  Minimum water level: Screen is covered.
  Maximum water level: Just below the deaeration nozzle.
- If necessary, fill the feed water tank (4) with deionized or distilled water.

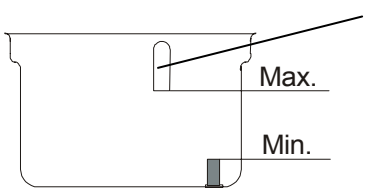


Figure 4: Feed water tank filling level (4)

Feed water supply	Consumption per batch
Approximately 7 litres	Approximately 0.2-1.5 litres

Table 1: Feed water

If the feed water tank (4) runs dry during program execution, the program is automatically terminated and an error message is shown on the cycle display (16) (see Chapter 12, Troubleshooting).

5.2 Preparing the items to be sterilized

5.2.1 Rack system

A rack system with optional trays is available for loading the sterilizing chamber:

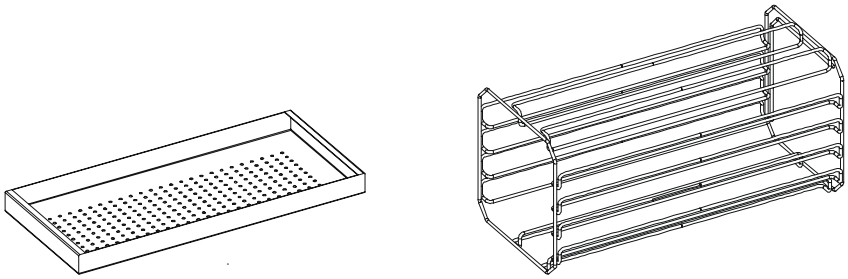


Figure 5: Insert tray (left) and rack system (right)

⇨ **Rack system**
The rack system is designed to accommodate up to 2 or 4 insert trays within the chamber by simple turning by 90°.

⇨ **Insert trays**
Trays are well suited for assembling and transporting the items to be sterilized. The steam easily penetrates the perforated tray floor. No condensate collects in the trays.

5.2.2 Practical tips for different types of items

These practical tips are suggested for different types of items when loading the sterilizing chamber (8):

⇨ **Glassware:**

- First, remove all coarse soiling.
- Place all vessels in baskets so that the openings face downwards.
- Concave and convex parts should be tilted so that condensate can run off.
- Select the **Instruments** program.

⇨ **Pipette tips:**
If anchored boxes are used for storing pipette tips, these must be permeable to steam. Boxes must not be stacked on top of each other. Pipette tips must not be sterilized in closed boxes. Pipette tips will be moist following sterilization.

- Select the **Instruments** program.

⇨ **Destruction (Waste)**

INFORMATION
Only sterilize waste in open vessels (e.g. metal boat with closed bottom).

- Place the waste in open vessels or bags or a metal tray with a solid bottom.

Place open bags additionally into a metal boat with closed bottom. In this way, you can avoid soiling the sterilizing chamber (8) in the event that the bag tears open or leaks.
Do not sterilize waste in large destruction bags. The temperature in the destruction bag can be up to 10 °C lower than the chamber temperature.

You should select the highest possible sterilizing temperature. More heat will result in better sterilization. As a rule, it is sufficient to set a sterilizing time of 20 minutes at 134 °C.

- Select the **Destruction (Waste)** program.

For predominantly liquid waste:

- Select the **Liquids** program.

⇨ **Liquids in open or slightly closed vessels:**
Sterilize liquids in open or slightly closed vessels.

DANGER
Do not sterilize pressure-sealed vessels.
Explosion hazard!
Watch for broken glass!
Scalding hazard!

CAUTION
When sterilizing liquids:
Do not fill the vessels more than two-thirds full, as otherwise liquids may boil over.

Liquid volume may be lost when sterilizing liquids in open vessels.
During the heating phase, the volume of liquid in the vessels will increase. Water vapour will condense off the surface of the vessels. The volume will expand, and bubbles will form during boiling. During the cooling phase, the volume of water will decrease. The loss of liquid will depend on the recooling process, the cooling time, the shape of the vessel and the filling volume. Up to 12 % of the liquid can be lost as a result of “evaporation”, particularly if liquids are held for a long time in the hot sterilizing chamber (8).

The loss involved is reproducible, providing the sterilizing conditions are the same. For this reason, any loss can be compensated when producing culture media by adding the appropriate amount of liquid.

Liquid loss can be reduced by covering vessels with aluminium foil or a cellulose stopper. If you use laboratory flasks made of boron silicate glass (such as DURAN®), you may loosely fit the screw cap or screw it on by **no more than** one turn.

For sterilizing liquids, a reference temperature is determined.

With media temperature control expansion option:

- Measure the media temperature in a reference flask using the flexible temperature sensor (Chapter 5.2.3).
- Select the **Liquids** program.

⇨ **Heat-sensitive culture media:**
Culture media can discolour when subjected for too long to the effects of temperature. There may also be a loss of quality, to the extent that the culture medium becomes unusable. We therefore suggest you take note of the following points to facilitate gentle treatment of culture media:

- Quickly preheat the liquid outside the sterilizer.
- Use small vessel sizes (max. 1,000 ml) and modest filling levels (vessels max. half full).
- Do not make full use of the capacity of the sterilizer.
- Select the **Liquids RM or Liquids RO** program, if present.

This will keep heating time, equilibration time and the cooling phase as short as possible.

Further remedies:
Expansion level with magnetic stirrers integrated into the sterilizing chamber, separate steam generator or sterile steam for fast heating.

5.2.3 Loading the sterilizing chamber

- ♦ Load the items to be sterilized into the sterilizing chamber.
- ♦ Close the door (2) until it touches the sterilizing chamber (8).

Later, the door closes automatically as soon as a program is started.

⇨ **When sterilizing liquids:**
For sterilizing liquids, a reference temperature must be measured. If the sterilizer is not equipped with a flexible temperature sensor, the temperature will be measured automatically.

With **media temperature control expansion option**: The media temperature as the reference temperature is measured using the flexible temperature sensor.

The following points should be observed in connection with the reference flask:

- It must be at least as large as the vessels for the sterilizing articles.
- It must be filled at least as far as the vessels for the sterilizing articles.
- It must be placed in the back of the tray area.

The reference flask is filled with the liquid destined for sterilization. If this is not possible, you may fill the reference flask with deionized water.

- ♦ Insert the flexible temperature sensor into the reference flask. The tip of the temperature sensor must be in the bottom third of the reference flask (minimum insertion depth: 20 mm).
- ♦ Place the reference flask in the back of the tray area.

6 Programs

The program keys are factory preset for complete program cycles. This means that in addition to the process itself, the sterilizing time and temperature and certain options for a sterilizing article are predefined. If you frequently sterilize the same articles, this will be very comfortable.

Program	Sterilization	Cooling
Base model:		
Instruments	121 °C / 20 min	Fast steam release
Destruction (Waste)	134 °C / 15 min	Cyclical steam release
Liquids	121 °C / 20 min	Cyclical steam release up to 100 °C; program end at 90 °C *reference temperature*
With Type RM water recooling system option only:		
Liquids RM	121 °C / 20 min	Water jacket cooling, program end at 90 °C *reference temperature*
With media temperature control expansion option only:		
Liquids / Liquids RM / Liquids RO / Liquids RG	121 °C / 20 min Sterilizing time actuated via media temperature	Depending on program (see above), program end at 90 °C[4] *media temperature*
With Type FA exhaust air filtration (▩) only:		
All programs	Deaeration through sterile air filter	Cyclical steam release via sterile air filter

Table 2: Sterilizing programs

When you select a program, an indicator light in the corner of the selected program key (18) is lit. Sterilizing temperature, multiple sterilization number (special program), sterilizing time and program name appear in the cycle display (Figure 6).

Figure 6: Cycle display

Each additional time the selected program key is pressed, the cycle display shows the available parameters for the sterilization process:

- Sterilizing temperature
- Sterilizing time
- Removal
- Multiple sterilization number (option)
- Batch number

Parameters you can change are marked with the double-arrow symbol (see Figure 7).

If options (acoustic signal or printer) are activated, this is shown by an indicator light in the corner of the selected option key.

The program keys P_1 and P_2 can be configured with the Instruments or Destruction (Waste) programs by the responsible operator using the key-operated switch (17; see Chapter 9). This will make your settings for programs, sterilization parameters and options permanent.

INFORMATION

The program key P_3 is solely designed for activating the Liquids sterilization program. With this program key, a prevacuum of 70 kPa is drawn for deaeration (in the case of devices with a vacuum pump). In comparison to the other program keys, the process is only activated once to ensure that the liquid loss remains low.

In the Liquids program, the sterilization parameters (except the vacuum) and the options may yet be changed.

How you choose a program is described in Chapters 6.1 to 6.6. There you also will find information, which values should be chosen for each kind of sterilizing articles.

How to set the timer, so that a sterilization cycle may automatically start at a later point in time, is described in Chapter 6.7.

6.1 Selecting a sterilizing program

In the basic version, you have a choice of three different programs. Additional programs may be available, depending on which options are present (Table 2).

⇨ **Instruments**
For sterilizing solid items (such as glassware, instruments, pipette tips or filters). After sterilization, a rapid and continuous drop in pressure will take place until the pressure is equal to ambient.

⇨ **Destruction (Waste)**
For sterilizing laboratory waste with a low liquid content, especially used consumables (pipette tips, culture dishes, etc.), and septic or infectious material. After sterilization, the pressure is gradually released until it is equal to ambient.

⇨ **Liquids**
For sterilizing liquids or culture media in open or slightly closed vessels, or for sterilizing liquid laboratory waste to be destroyed.

The thermolock is activated. After sterilization, pressure is reduced step by step in very small increments. There is no danger of overboiling. The vessels will cool in a controlled manner. The sterilizing chamber is pre-aerated between 100 °C and 90 °C. However, no vacuum is created, so that the culture media will not boil in this temperature range. The liquid loss by evaporation is thus reduced considerably. After cooling to a reference temperature (if the media temperature control is present: media temperature) of 90 °C, the program cycle is completed.

With Type RM fast recooling system expansion option:

⇨ **Liquids RM**
For minimizing batch times when sterilizing liquids or culture media in open or slightly closed vessels.
Cooling water flows through the sterilizing chamber in a separate circuit. The sterilized items are quickly and carefully cooled to a reference temperature (if media temperature control is present: media temperature) of 90 °C.

6.2 Setting the sterilizing temperature

The selected set temperature (in °C) is shown on the cycle display (16).
The total available temperature range will depend on the operating data of your sterilizer. The following range is valid for Germany[6)]:

Type 25T: 98 °C to 135 °C.

We recommend the following set temperatures for sterilization and disinfection:

98 °C	for disinfection; for steaming and dissolving agar-agar
103 °C	for thermally instable media
121 °C	for culture media, solutions and other liquids, as well as solids such as glassware or instruments
134 °C	for destructive sterilization

You can set the set temperature on the control panel (5):

- Press the selected program key (18) repeatedly until the sterilizing temperature appears in the cycle display (Figure 7).

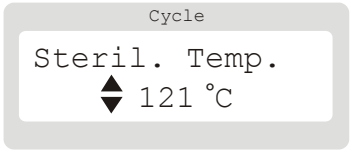


Figure 7: Sterilizing temperature display

- Increase or decrease the sterilizing temperature using the ▲ key (14) or the ▼ key (15).

The set temperature will increase or decrease in one-degree increments with each press of the ▲ key (14) or the ▼ key (15).

6) * In other countries other temperature ranges for setting may be available.

6.3 Setting the sterilizing time

The selected sterilizing time is shown on the cycle display (16).

Setting range: up to 121 °C 1-40 minutes[7)]
from 122 °C 1-30 minutes[7)]

We recommend the following sterilizing times:

20 min for sterilization at 121 °C (liquids: solutions and culture media; solids: glassware and instruments);

20 min for sterilization at 134 °C (destructive sterilization: waste).

Disinfection or steaming times will be governed by the type of articles you want to disinfect or steam.

The feed water supply is limited; it will determine the maximum disinfection or steaming times.

Program	**Maximum disinfection or steaming times**
Liquids / Liquids RM	40 minutes[7)]

Table 3: Maximum disinfection or steaming times

You can set the sterilizing time on the control panel (5):

- Press the selected program key (18) repeatedly until the sterilizing temperature appears in the cycle display (Figure 8).

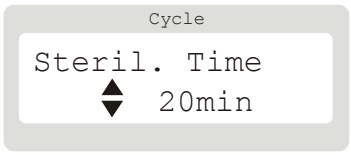


Figure 8: Sterilizing time display

- Increase or decrease the sterilizing time using the ▲ key (14) or the ▼ key (15).

The sterilizing time will increase or decrease in one-minute increments with each press of the ▲ key (14) or the ▼ key (15).
When decreasing sterilizing time, the display will change from the minimum selectable to the maximum selectable sterilizing times (30/40 min, 999 min or ∞). This makes it easy to select long sterilizing times.

6.4 Setting the multiple sterilization number

The multiple sterilization program is a special program. The selected multiple sterilization number is shown on the cycle display (16).
Setting range: from 1 to 99 sterilization cycles.

[7)] To facilitate longer sterilizing times, the steam sterilizer can be equipped with the water post-feed expansion option. In this manner, it is possible to implement sterilizing and steaming times of up to 999 minutes (∞ for the climatic chamber design). The feed water tank level must be checked at regular intervals.

It is recommended to set the multiple sterilization number very low in the Liquids program, as otherwise a very high liquid loss by evaporation is the result.
If you want to transport the VARIOKLAV Type 25T sterilizer and therefore must empty the jacket space with the Empty Jacket program, you should select 1 as the multiple sterilization number.

You can set the multiple sterilization number on the control panel (5):

- Press the selected program key (18) repeatedly until the multiple sterilization cycle appears in the cycle display (Figure 10).

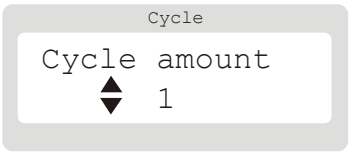


Figure 9: Multiple sterilization cycle display

- Increase or decrease the multiple sterilization number using the ▲ key (14) or the ▼ key (15).

The set multiple sterilization number will increase or decrease in one-degree increments with each press of the ▲ key (14) or the ▼ key (15).

6.5 Selecting or deselecting options (acoustic signal or integrated printer)

⇨ **Acoustic signal**

The acoustic program end signal (buzzer) is active in all programs; the indicator in the Acoustic signal key (21) is lit. You may turn off the acoustic signal before starting the program.

- Press the Acoustic signal key (21).

The signal is turned off; the indicator in the Acoustic signal key (21) is off.

⇨ **Batch documentation**

If the benchtop sterilizer is equipped with an integrated printer, this printer can operate in parallel with any program.
First you should check the date and time given by the program control. The sterilization start time cannot be logged correctly if these times do not exactly correspond to the actual date and time.

- Press the Timer key (23).

The timer display (Figure 11) appears, with the current date and time appearing on the first line (U). The second line (T, Timer) displays the current date and time as the standard value (U).
If necessary, set the current date and time (see Chapter 9).

- To turn off the timer again, press the Timer key (23).
- Check to see if the printer has enough paper. No red lines must be visible on the paper. Insert a new paper roll if required (see Chapter 11.3).
- Press the Printer ON/OFF key (26).

The indicator light of the Printer ON/OFF key (26) will be lit. The printer prints the complete log of the program as it is executed.

6.6 Setting the timer

If you do not want to start sterilization right away, you may set the timer.
When the timer is set, the acoustic signal is automatically deactivated. You can thus perform sterilization overnight or over the weekend. When you start work the next (working) day, your sterilized items are ready and waiting for you.

⇨ **Setting the starting time and turning on the timer**
To set the starting time on the timer, you must observe the current values for date and time. Chapter 9 describes how you can set the date and time.
Select the desired starting time, and the date if required:

- Press and hold the Timer key (23).
- Press the START/STOP key (19).
- Release both keys (23, 19).

The cycle display (16) now shows the timer date or the timer time, initially preset with the current time and date. Using the ▲ key (14) and the ▼ key (15), you can switch between date and time displays.
To change the settings for day / month / year or hours / minutes / seconds, press the program key below and change the value using the ▲ key (14) or the ▼ key (15).

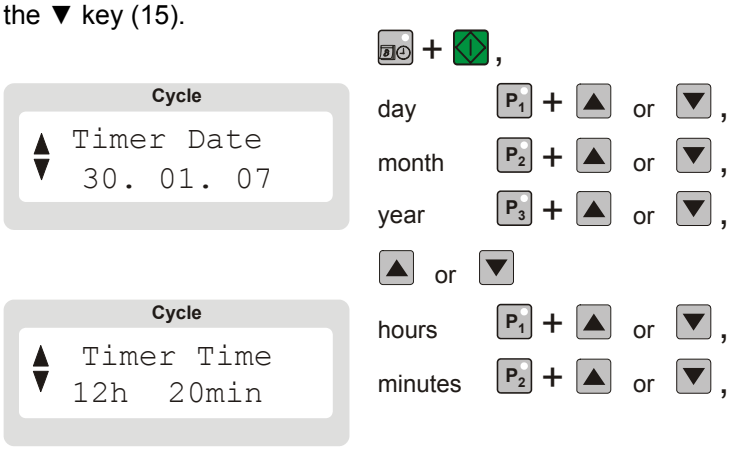


Figure 10: Setting the timer, with corresponding display

Example: Setting the hours

- Use the ▲ key (14) or the ▼ key (15) to change to the Timer display.
- Press and hold the P_1 program key (18).
- Press the ▲ key (14) or the ▼ key (15) until the desired hour is set.
- Release both keys (18 and 14 or 15).

Proceed in the same way to set the minutes and, if required, the date.
When you are done setting the timer, you must confirm your setting by pressing the Timer key (23). This also activates the timer:

- Press the Timer key (23).

The cycle display (16) now shows the timer setting (Figure 12) with the current time and date on the first line (U) and the timer setting on the second line (T).
The timer is active when the indicator in the Timer key (24) is lit.

Sterilization does not start immediately when the START/STOP key (20) is pressed, but on the day and at the time selected.

Figure 11: Timer display

7 Starting and running a program

- Check the sterilization parameters of the selected sterilizing program (program, sterilizing temperature, sterilizing time and options).
- Check to see that the sealing surface on the door (2) and the door seal (6) are clean.
- Close the door (2) until it touches the sterilizing chamber (8).
- Press the green START/STOP key (19).

The door is locked automatically (door indicator, 20). If the door cannot be locked, the “Lock open” error message is displayed (see Chapter 12). Once the door is locked, the sterilizing program starts.

If the timer is set and active, the indicator in the Timer key (23) will be lit. The program cycle starts when the time set on the timer is reached.

If there is pressure in the jacket space, the feed water cannot be transported from the feed water tank to the jacket space, unless the automatic feed water option is present. This situation may occur if a program with a drying phase has been completed immediately before or if a sterilization cycle has been interrupted. The cycle display (16) will show a notice indicating that the system is waiting for the proper jacket temperature (“Warten auf Manteltemp.”). Program execution will start as soon as the jacket space has cooled and the pressure subsided.

The sterilizing chamber (8) is automatically heated and deaerated. The various phases of the program are shown in the sterilization phase display (24) during execution.

Assuming normal loading of the sterilizing chamber (8) with liquid sterilizing articles, you will need a heating time of approximately 25 to 35 minutes. The sterilizing chamber (8) will then have reached a temperature of 121 °C. While the heater heats, the ▲ symbol is shown next to the chamber temperature in the current values display (13).

Liquid sterilization requires an additional equilibration time of no more than 5 minutes until the medium has reached the sterilizing temperature. The length of the equilibration time depends on the quantity of the liquid.

The actual sterilizing time will start once the sterilizing temperature has been reached. If the media temperature control option is present, the sterilizing time in the Liquids program does not start until the media temperature is equal to the sterilizing temperature. The progress of the sterilizing time is indicated in the current values display by the ▼ symbol next to the sterilizing time: The sterilizing time counts down to zero in one-minute increments. If the media temperature drops below the sterilizing temperature during the sterilizing phase, the sterilizing time will be interrupted briefly.

When the sterilizing time is over, the sterilizing chamber (8) is automatically cooled down through controlled release of steam.

In the case of the Multiple sterilization special program, the program cycle of heating, sterilizing, cooling and drying (optional) repeats itself according to the selected multiple sterilization number.

In the **Liquids** programs, the thermolock will unlock the door (2) as soon as the reference temperature drops below 90 °C.

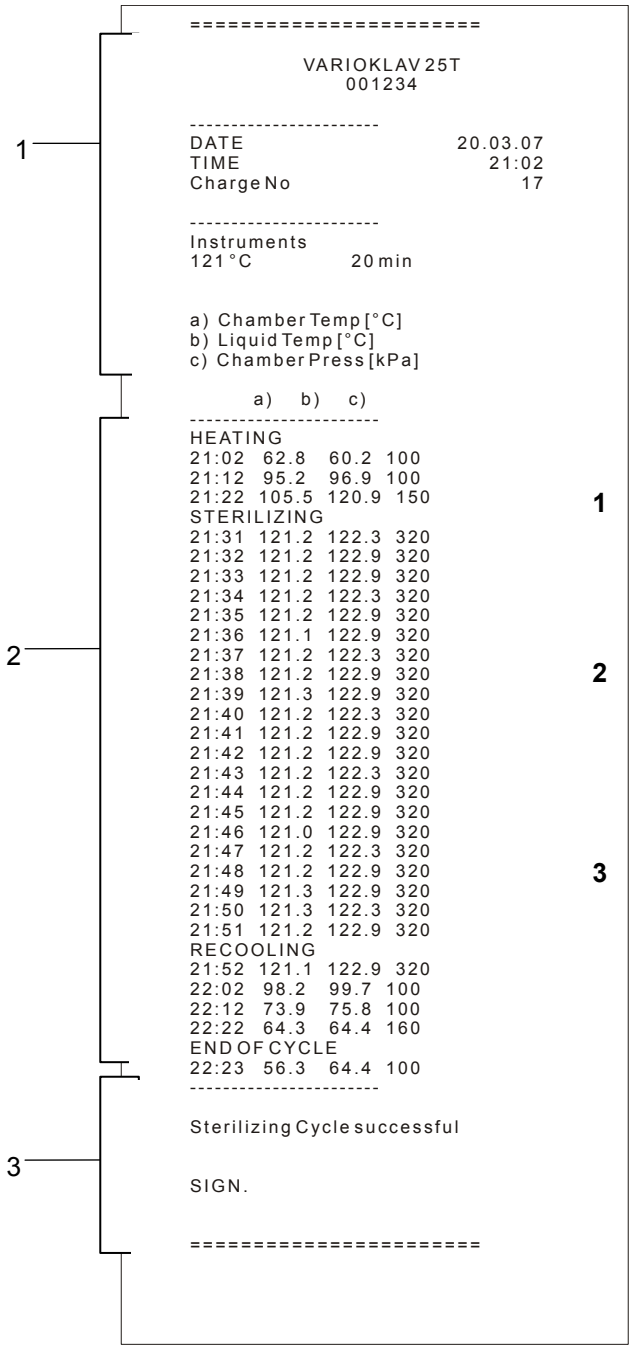
By pressing the START/STOP key (19), you can interrupt the program cycle at any time. The sterilizer always returns to a safe state before unlocking the door.

If the program is followed by a drying phase, the current values display (13) shows the drying time and the ▼ symbol. The drying time counts down to zero.

7.1 Batch documentation (option)

⇨ **Integrated printer**

The integrated printer (if present) logs sterilization process data. The printout is tamper-proof. The log header (1) is printed out as soon as the program is started. Chamber temperature, media temperature and chamber pressure are continuously measured during program execution. The log shows the measured values of the sterilization phase in increments of one minute. Values are logged every 10 minutes during the heating and cooling phases.
Errors occurring during sterilization are printed immediately.



1 Log header : Device ID and batch information (date, time, batch number) and program parameters.

2 Values : Temperature and pressure values for the various program phases at the time indicated (first column)

3 Log footer : Successful sterilization notice, signature field.

Figure 12: Sterilization log (example)

⇨ SEGOSOFT

The SEGO®Soft software lets you log measurements on a PC.

SEGO®Soft displays the readings of all temperature sensors and the chamber pressure sensor in graphic mode. Measurements may be stored and archived.

Usable PC interfaces: serial interface (RS232), network (Ethernet)

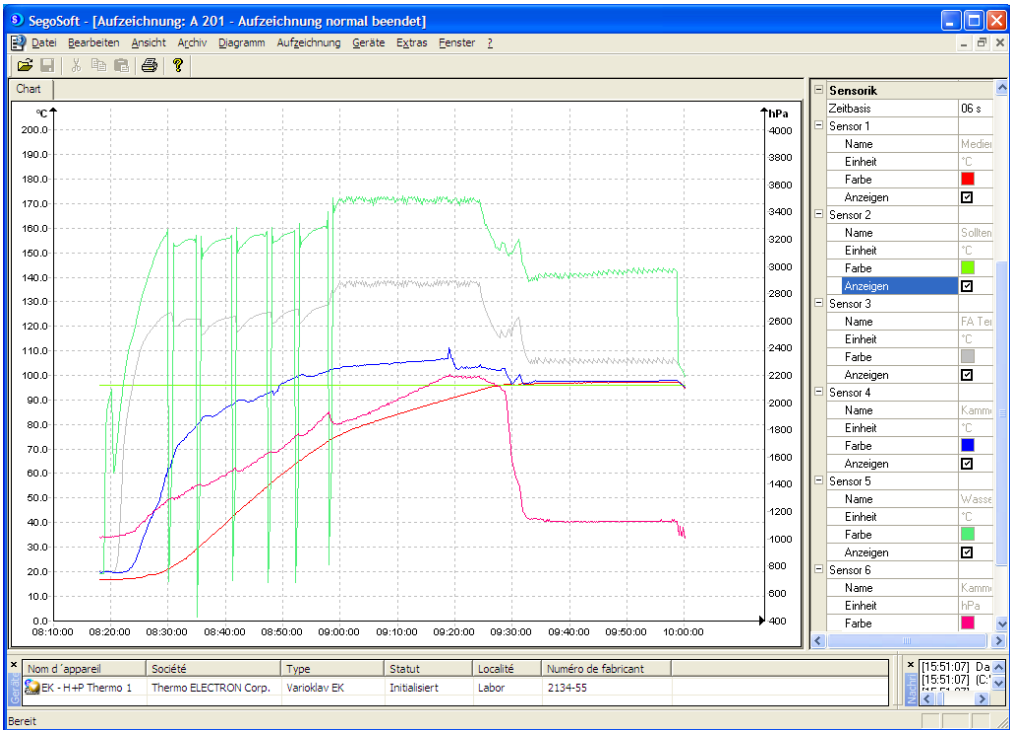


Figure 13: SEGO®Soft screen

8 Program end and removal

DANGER
Do not open the sterilizing chamber (8) until removal is signalled.
Watch for hot steam and hot water!
Scalding hazard!
Follow the specified operating steps to the letter.

DANGER
When pressure-sealed flasks or bags are *accidentally* sterilized:
Watch for broken glass and splitter!
Watch for hot water spray!
Allow at least 4 hours to elapse at the end of sterilization.
Always wear protective clothing, heat-insulated gloves and eye protectors.
Do not remove flasks or bags until the reference temperature has dropped below 70 °C.

The end of the program is signalled both acoustically and visually: a buzzer will sound, and the green START/STOP key (19) will flash. This indicates that all phases of the sterilization cycle have been completed. The sterilization phase display (24) shows the indicator lights for all completed phases.

DANGER
You must wear the following protective items when opening the sterilizing chamber (8) and removing the sterilized articles:
- **Apron,**
- **Eye protectors,**
- **Heat-insulated gloves.**

Watch for hot surfaces and hot steam!

CAUTION
Before opening, check to see if the indicated pressure has dropped below the set removal pressure (factory setting: 110 kPa).

♦ Press the green START/STOP key (19).

The acoustic signal will be switched off. The door (2) is released. The pressure in the sterilizing chamber (8) will adjust automatically to the outside pressure (pressure compensation).
The displays of the control panel (5) will turn off automatically after 10 minutes.

- Open the door a crack. When doing so, hold the door by the lower third of its right edge. Do not put your fingers behind the door.

DANGER
Hot steam may escape when the door is opened.
Scalding hazard!
Step back when opening the sterilizer.

- Wait one minute.
- Now, rotate the door to the side.

DANGER
After drying in the sterile air stream, the sterilizing chamber and the sterilized items will be very hot!

INFORMATION
Without the use of additional drying equipment, filters, fabric, or cotton wool will not dry properly after sterilization.

INFORMATION
After sterilization while using a flexible temperature sensor: Remove the flexible temperature sensor from the reference flask of leave the reference flask in the sterilizing chamber (8).

- Remove sterilized items.

The sterilizer is ready for a new cycle immediately after the sterilized items have been removed and the feed water tank has been filled up (if required) with deionized water.

INFORMATION
The door (2) should always be left open when the sterilizer is not in use so that remaining moisture may disappear.

9 Configuring programs

As delivered by the factory, each control panel program key (18) is pre-set with one program each. Depending on which programs are present, the microprocessor control may offer additional programs. Authorized operators can use the key-operated switch to change the configuration of the programs permanently within the technical limits of the unit and to reprogram program keys.

INFORMATION

The sterilizer is protected from inadvertent changes in configuration by a key-operated switch (17).
Remove the key from the key-operated switch while the sterilizer is in operation.
Carefully store the key in a safe place.

INFORMATION

The program key P_3 is solely designed for activating the Liquids sterilization program.

Authorized operators can thus define individually configured programs for the program keys P_1 or P_2.

⇨ **Starting configuration**

- ♦ Insert the key into the key-operated switch (17).

⇨ **Reprogramming a program key**

- ♦ Select the one of the both program keys (18) P_1 or P_2 for which you wish to choose an individual program.
- ♦ Turn the key-operated switch (17) to the configuration position (“Konfig.”).

Each time the selected program key is pressed, the cycle display shows the available parameters for the sterilization process:

- Program
- Sterilizing temperature
- Sterilizing time
- Drying time (option)
- Vacuum (option)
- Removal
- Multiple sterilization number (option)
- Batch number

Parameters you can change are marked with the double-arrow symbol. You can program the selected program key for a different program. For instance, if all you ever sterilize is either solids or liquids, but never waste, you might use one of the program keys for a second Solid sterilization program.

- Press the ▲ key (14) or the ▼ key (15) repeatedly until the cycle display (16) shows the desired program.

You can now configure this program as usual, by changing the sterilizing time and temperature and by activating or deactivating options.

⇨ **Changing the sterilizing temperature**

- Increase or decrease the sterilizing temperature using the ▲ key (14) or the ▼ key (15).

⇨ **Changing the sterilizing time**

- Increase or decrease the sterilizing time using the ▲ key (14) or the ▼ key (15).

⇨ **Setting the removal pressure**

INFORMATION

The removal pressure must be assimilated to the ambient pressure of the installation site.

If the selected removal pressure is too high, steam may escape out of the lid at program end.

If the selected removal pressure is too low, the necessary criteria for ending the sterilizing program can not be achieved.

- Using the ▲ key (14) or the ▼ key (15), select a value approximately 10 kPa to 15 kPa over the average ambient pressure.
  By default, the sterilizer is set to 110 kPa.

⇨ **Changing the multiple sterilization number**

- Increase or decrease the multiple sterilization number using the ▲ key (14) or the ▼ key (15).

⇨ **Changing the removal temperature for the program key P_3, preset with a Liquids program**

Each time the program key P_3 is pressed, the cycle display shows the available parameters for the sterilization process:

- Program
- Sterilizing temperature
- Sterilizing time
- Removal temperature (in °C)
- Removal pressure (in kPa)
- Multiple sterilization number (option)

- Press the program key P_3 repeatedly until the cycle display shows the removal temperature (in °C).
- Increase or decrease the sterilizing temperature using the ▲ key (14) or the ▼ key (15).

⇨ **Activating or deactivating options**

You may, for instance, turn off the acoustic signal for the selected program permanently.

- Turn the key-operated switch (17) to the configuration position (“Konfig.”).
- Press the Acoustic signal key (21):

When the indicator of the respective key is lit, the corresponding function is activated.

You can also elect to have the integrated printer activated each time the program is selected.

⇨ **Setting date and time**

To use the timer or the timer for batch documentation (integrated printer option), you must first set the current date and time:

- Turn the key-operated switch (17) to the configuration position (“Konfig.”).
- Press and hold the Timer key (23).
- Press the START/STOP key (19).
- Release both keys (23, 19).

The cycle display (16) now shows the time or date as currently set. Using the ▲ key (14) and the ▼ key (15), you can switch between date and time displays.
To change the settings for day / month / year or hours / minutes / seconds, press the program key below and change the value using the ▲ key (14) or the ▼ key (15).
Example:
Changing over to daylight saving time (summer time; moving the clock ahead one hour).

- Change to the Time display using the ▲ key (14) or the ▼ key (15).
- Press and hold the program key P_2 (18).
- Press the ▲ key (14) .
- Release both keys (18, 14).

The values last selected are stored.

⇨ **Inspecting the device configuration**

Here you can check which software and hardware version is installed in the benchtop sterilizer and which expansion options (e.g. PC protocol using VARIOSOFT 2.4, sterile filtration, refilling = water post-feed, climatic chamber) are activated.

- Turn the key-operated switch (17) to the configuration position (“Konfig.”).
- Press the START/STOP key (19).

The cycle display first indicates the current software version. Each additional time the START/STOP key (19) is pressed, the display proceeds to show the next parameter.
The following abbreviations are used:
M: Media temperature control (Liquids RM or RO program)
R: Water recooling system (Program RM)

S: Type ST supporting pressure (Program RO)
T: Sterile air stream drying (Instruments DR / Destruction (Waste) DR programs)
V: Vacuum and drying with vacuum
F: Type FA exhaust air filtration
Z: Multiple sterilization
C: Batch documentation
K: Climatic chamber
E: External steam

⇨ **Ending configuration**

- Turn the key-operated switch (17) to the operation position
- Remove the key from the key-operated switch.

10 Initial commissioning

DANGER
The supply voltage and supply frequency must be the same as given on the type plate.
Only connect the sterilizer to the specified socket.

CAUTION
Only use deionized or distilled water when topping up feed water. Do not use tap water!

CAUTION
During the heating phase, contaminated exhaust air or waste water may be emitted from the sterilizer to the on-site disposal system.
Remedy: Expansion option Type FA exhaust air filtration.

INFORMATION
The central lock with thermolock is electro-mechanically locked during delivery.
Connect to mains to unlock.

INFORMATION
The removal pressure the sterilizer is set to must be assimilated to the ambient pressure of the installation site. (See Chapter 9.)

If the selected removal pressure is too high, steam may escape out of the lid at program end.

If the selected removal pressure is too low, the necessary criteria for program end can not be achieved.

INFORMATION
Only use the condensate collector, if you just utilize the sterilizer occasionally. When the collector overflows, water damage may arise.
Especially in case of contaminated exhaust air, the water in the collector as well as the collector itself may be infected with germs. This factor is to be considered when disposing of the collector content.

The steam sterilizer is marked with the name of the manufacturing company and a type plate. All operating parts, such as valves, etc., are marked. A spare-parts store for this instrument is maintained at the manufacturer's factory. Availability of parts is guaranteed for 10 years.

All VARIOKLAV steam sterilizers are **CE-marked** based on the European Pressure Equipment Directive 97/23/EC and the Low-Voltage Directive as well as the EMC Directive.
Since January 1st, 1996, the Council Directive 89/336/EEC on electromagnetic compatibility (EMC) has been in force and binding for all units with electrical or electronic components. It requires adequate resistance to jamming and limited emitted disturbance radiation of units operated electrically or electronically. Units must be CE-marked.
The electrical control system for VARIOKLAV steam sterilizers is designed as a low voltage system; the heating system operates with 230 V. They are therefore covered by the Council Low-Voltage Directive[8)]. Since January 2nd, 1997, units have to be CE-marked in accordance with this Directive (and with its amendment 93/68/EEC).
As the VARIOKLAV steam sterilizers are not machinery[9)] as defined by the Machinery Directive 89/392/EEC (pressure vessels being explicitly excluded from its scope), they cannot be CE-marked in accordance with this Directive.
Furthermore, the EU Medical Products Guideline has been in effect since January 1st, 1995, and the transition period stipulated in the Guideline ended on June 14th, 1998. This Guideline, however, is relevant only for those steam sterilizers that are used for sterilizing medical devices.
The following operating documents are supplied with the delivery (as invoiced):

- Declaration of Conformity for the unit pursuant to the Pressure Equipment Directive DGRL 97/23/EC.
- Certificate for the thermal safety system to prevent retarded boiling (Thermolock according to TRB 402)

The unit comes with the following documentation:

- Operating Manual with commissioning, maintenance and care instructions
- Short Operating Manual
- Checklist for Routine Care and Maintenance

10.1 Scope of delivery

In addition to the documents already mentioned, a 1 m silicon hose with connector is included with the sterilizer. This hose is used for emptying the feed water tank. (See Checklist for Routine Care and Maintenance.)

8) Excerpt from the **Council Directive "Electrical equipment designed for use within certain voltage limits" 73/23/EEC**:
Article 1
For the purposes of this Directive, "electrical equipment" means any equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current (...).

9) Excerpt from the **Council Directive "Machinery" 89/392/EEC**:
Article 1
(...)
(2) For the purposes of this directive, "machinery" means an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material.
The term "machinery" also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.
(3) The following are excluded from the scope of this Directive: (...)
(...)
steam boilers, tanks and pressure vessels,
(...)

10.2 Warranty periods

1-year warranty for all electrical and mechanical parts.
5 years warranty for stainless steel pressure vessel.

10.3 Legal regulations

10.3.1 Free movement pursuant to European Pressure Equipment Directive 97/23/EC

Starting on 30 May 2002, the VARIOKLAV Type 25 T steam sterilizers have been manufactured serially pursuant to the Pressure Equipment Directive PED 97/23/EC. The units have been assigned to Category I pursuant to Section 9 of the Pressure Equipment Directive 97/23/EC and subjected to the conformity evaluation procedure pursuant to Section 10 of the Pressure Equipment Directive 97/23/EC Module A.
Each steam sterilizer is CE-marked. A written Declaration of Conformity is enclosed with each unit.
This means that the conditions for placing pressure vessels on the market or putting them into service pursuant to the Pressure Equipment Directive 97/23/EC Article 4 (1) 1.1[10)] are met.

10.3.2 Operating the device according to the German Operating Safety Regulation

When operating the VARIOKLAV Type 25 T steam sterilizer, please refer to the national regulations. In Germany, operators please refer to the German Operating Safety Regulation.

10.4 Installation

The VARIOKLAV Type 25 T bench-top sterilizer can be installed without any special installation requirements to be met on the building site. The amount of space needed can be seen in Figure 15. The minimum footprint is 580 mm x 620 mm
(W x D).

[10)] Excerpt from the **Pressure Equipment Directive PED 97/23/EC**
Article 4 Free movement
(1) 1.1. Member States shall not, on grounds of the hazards due to pressure, prohibit, restrict or impede the placing on the market or putting into service under the conditions specified by the manufacturer of pressure equipment or assemblies referred to in Article 1 which comply with this Directive and bear the CE marking indicating that they have undergone conformity assessment in accordance with Article 10.

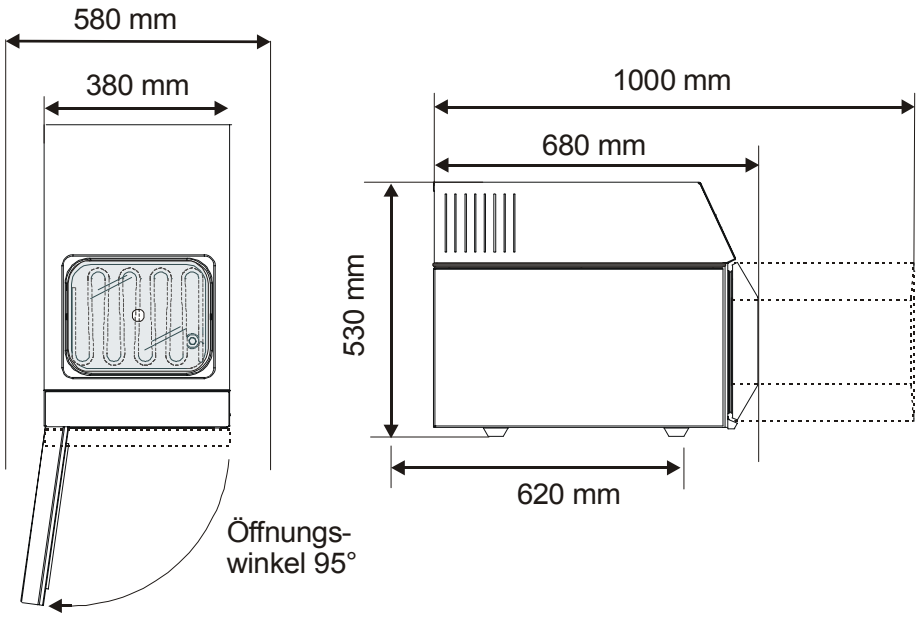


Figure 14: Footprint and dimensions, VARIOKLAV 25T, seen from above and from the side

- Choose a stable and level area for deploying the sterilizer (e.g. a table or workbench). Make sure that this area is exactly level in all directions.
- When installing the sterilizer, keep a distance of at least 100 mm from the wall and from other devices on all sides. The unit must be freely accessible from above (open to the top).
- Place the insertion tray and, if necessary, the rack system inside the sterilizer.

10.4.1 Connecting the steam sterilizer to the *disposal system*:

CAUTION
During the heating phase, contaminated exhaust air or waste water may be emitted from the sterilizer to the on-site disposal system.
Remedy: Expansion option Type FA exhaust air filtration.

Exhaust air, spent steam, condensate (approximately 0.5 to 1 litres per batch) and waste water are generated during the whole sterilization process.

The outlets situated at the back of the sterilizer must be connected with a disposal system.

Disposal system: Minimum requirements
The disposal line must be designed for taking in steam or for high temperatures. Hot water (approximately 100 °C) can flow a short way through the waste-water channel. (The plastic pipes and channels found on-site are usually not suitable for this temperature range.)

The required disposal lines for emitting steam and condensate must be laid with a gradient towards the drain. A minimum diameter of 10 mm is necessary; the lines must not exceed a length of 2 m. The lines must be free of kinks and crushes. It should also not be laid in tight bends. The line outlets have to be free. They are to be mounted fixedly to the drain (Figure 16). The lines should be equipped with a vacuum breaker and swing type check valve each, otherwise waste water may be sucked back into the container by negative pressure.

Produced condensate: approximately 0.5 to 1 litres per batch.

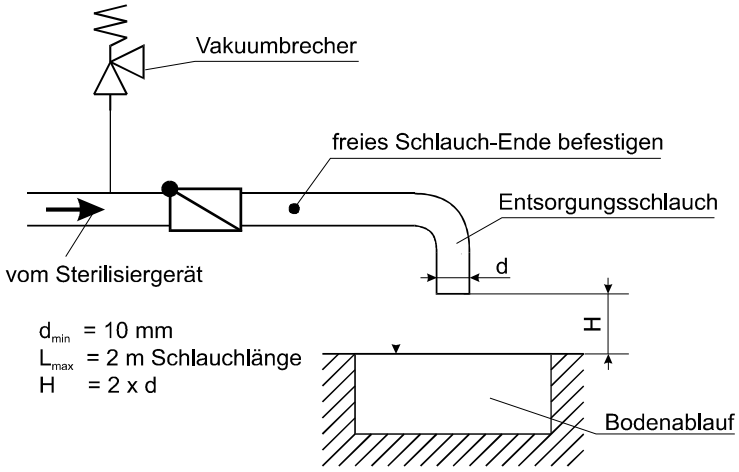


Figure 15: Free outlet, diagram

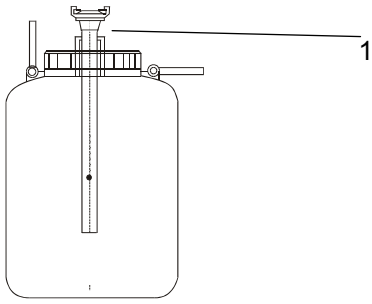
⇨ **Condensate collector**

The condensate collector is a simple device for collecting the condensate emitted from the sterilizer at a favourable price. It is used for liquefying spent steam and cooling exhaust air. In this case, an on-site disposal line is not necessary. Even in safety laboratories, the condensate collector can be used to good advantage as the on-site disposal system will remain uncontaminated.
Plastic container made of temperature-resistant PEHD, rectangular, with two handles.
Dimensions (L x W x H): 275 x 235 x 405 mm
20 litres volume.
Large cleaning hole (Ø 140 mm) with screw lid and stainless-steel immersion tube, quick-release coupling for hose connection.
Steam disposal hose, R ½", male thread and quick-release coupling, 1 m long, blue.

INFORMATION

Only use the condensate collector, if you just utilize the sterilizer occasionally. When the collector overflows, water damage may arise.
Especially in case of contaminated exhaust air, the water in the collector as well as the collector itself may be infected with germs. This factor is to be considered when disposing of the collector content.

- Fill the container with approximately 5-6 litres tap water.
- Connect the temperature-resistant steam disposal hose to the quick-release coupling.



1 Quick-release coupling

Figure 16: Condensate collector

Please observe the Commissioning and Operating Manual “Condensate Collector” . There you find detailed information regarding the required connections, maintenance information, important safety warning and much more.

If you wish to use your own container, please note the following:

- The plastic container (e.g. PEHD) must be temperature-resistant and able to contain approximately 20-30 litres.
- The lid opening of the container must be large enough to facilitate easy internal cleaning.

⇨ **Automatic spent-steam condenser, water-cooled)**

Disposing of the condensate:
By gully, siphon of washbasin or sink, waste-water line or condensate collector (makeshift or used in safety laboratories for collecting and subsequently disinfecting or sterilizing the condensate).
Disposing of tap water:
Heated cooling water does not come into contact with the condensate. Connection to on-site cooling circuit is possible.
Cooling water: approximately 5 to 10 litres per batch.
Please observe our Installation and Maintenance Manual “Automatic spent-steam condenser, water-cooled” . They include detailed information regarding the required connections, maintenance information and important safety warnings.

⇨ **Integrated spent-steam condenser with condensate return**

When on-site disposal systems are completely missing or when operated in safety laboratories, the sterilizer may be equipped with a condensate return system. Condensate produced during sterilization is returned to the feed water tank, resulting in a closed circuit system.

10.4.2 Connecting the steam sterilizer to the *supply system*:

Type	Heating System	Mains connection	Socket / Fuse
25T	3.0 kW	230 VAC / 50 Hz	Socket outlet with grounding contact 16 AT

Table 4: Power supply requirements on the building site

The power cable is located at the back and underneath the sterilizer. The mains socket must be located in the immediate vicinity of the sterilizer. The mains cable is 2.5 m long.

♦ Plug the power cable into a socket outlet.

INFORMATION
The mains plug socket of the sterilizer must be freely accessible. In case of failures, it is used to disconnect the sterilizer from mains.

Actuation of a current-operated e.l.c.b. system:
After long shutdown periods, the resistance of the ceramic insulation in the heating elements can drop because of condensation, with the result that the actuation of a current-operated e.l.c.b. system is possible.

Remedy:

- **Supervised by an expert** (electrician, service technician) conduct a sterilization cycle or test cycle on mains connection which is not protected by a current-operated e.l.c.b. system.
- Fill the feed water tank with feed water. Use only deionized or distilled water.

The steam sterilizer is now ready for use. The first sterilization cycle will use approximately two litres of feed water.

The heat emanation of the sterilizer to the environment during the heating phase depends on the heating power: approximately 25 % to 35% of the nominal heating capacity.

10.5 Commissioning of the options

The Media temperature control, Exhaust air filtration, Water post-feed and Batch documentation expansion options do not need to be commissioned separately. They are ready for use when the benchtop sterilizer is delivered.

10.5.1 Type RM fast recooling system

Required connections
Decalcified cooling water or deionized water (or very soft tap water of no more than 5° dH (German hardness)), 0.5 bar minimum supply pressure, max. 6 bar, R ½" on-site connection, max. 2 m away from unit, R ½" cooling water inlet at sterilizer. Maximum demand 1.5 l/min, R ½" on-site stop valve and strainer required.

- Connect the enclosed pressurized water hose (2 m, R ½") to the cooling water inlet at the sterilizer.
- Check if the on-site cooling water supply is secured with a R ½" stop valve and a strainer.
- Connect the pressurized water hose to the on-site cooling water supply.
- Connect the disposal hose to the cooling water outlet of the sterilizer.
- Connect the disposal hose to the on-site disposal system.

To protect the tap water system, it may be necessary to install a return flow inhibitor or system disconnector just upstream of the softening or deionizing facility according to the regulations of the local public utility company (DIN 1988, Part 4 / Technical Rules for Tap Water Installations, TRWI).
Please observe the maintenance and functioning controls pursuant to DIN 1988, Part 8.

10.6 Calibration, qualification, validation

The operator's quality assurance system may require that the temperature and pressure measuring points and the value displays of the sterilizer be calibrated. This can be required before commissioning or at regular intervals. In addition, it may be required that the sterilizing process be qualified or validated at regular intervals.[11)]

Sterilization processes can be **validated** only by the operator. By qualification and the possibility of batch documentation, THERMO Labortechnik AG assists you in performing this validation.

Within the framework of pre-acceptance testing, each sterilizer is **qualified** in a standard program (121 °C, 20 minutes). This means that an independent, calibrated measuring system is used to determine whether or not the sterilization process actually uses the predetermined parameters. Qualification is documented by affixing a "Qualified" test sticker to the sterilizer.

We recommend that qualification be repeated annually by one of our after-sales services. The next test date is written on the test sticker. Ask for a qualification or an annual safety check including qualification.

If desired, the temperature measuring points, displays and printers can be **calibrated** at the factory prior to delivery. You will be given a test and adjustment report for every position, which will show the error in measurement at the temperature measuring point, of the indicating instrument, or of the printer relative to a reference temperature. Calibration may also be performed by our after-sales service at the operation site at a later point in time.

Monitoring sterilization parameters (batch documentation)
Within the framework of quality assurance during production or in safety laboratories, sterilization data may have to be monitored.
Several fixed and flexible sensors are available for measuring media temperature, local chamber temperature(s) and chamber pressure. Measured values are logged using the integrated printer or a PC.

Integrated printer
The integrated printer logs the entire sterilization process: Process data (time, reference temperature and chamber pressure) are printed in one-minute intervals. In addition, it documents the date and time of sterilization, the batch number and the sterilizing program including the selected sterilizing temperature and sterilizing time.

Monitoring sterilization parameters on the PC

The sterilizer is equipped with a RS 232 port. This allows you to monitor and document program execution (temperature, pressure, sterilizing time) from your

[11)] Definition, translated from DIN 58 950-1: 1995-08
(Steam sterilizers for pharmaceutical sterilizing articles)
Adjusting
Adjustment means setting or balancing a measuring instrument so that the differences between the measured values for the parameters relevant to the process and the value considered to be correct do not exceed the given limits of error.
Calibration
Determining and documenting the differences, for the measuring instrument, between the measured values for the parameters relevant to the process and the value considered to be correct.
Qualification
Formal and systematic proof of the functionality and suitability of the steam sterilizer for its intended purpose. Qualifying includes calibrating and, if necessary, adjusting the parameters of the measuring and controlling instruments relevant to the process.
Validation
Proof in accordance with Good Manufacturing Practice that procedures, processes, equipment, materials, working steps, or systems really yield the expected results. Validation includes qualification.

PC, and to perform validations. It also facilitates batch documentation (date, sterilization data, etc.).

We recommend the SEGOsoft software by Comcotec Messtechnik GmbH for analyzing the sterilization data.

Users may also control the RS 232 port to run their own programs for process control.

11 Maintenance and cleaning

DANGER
Repairs and interventions may only be carried out by our authorized after-sales service.

DANGER
If the safety valve does not react to a higher pressure than the set nominal pressure, cease using the sterilizer immediately. Do not use it again until a new and fully functional safety valve is installed.

DANGER
When a fault occurs and for maintenance purposes, disconnect the steam sterilizer from the mains supply. Pull the mains plug or neutralise the fuse.

INFORMATION
When introducing “Deodorant Pearls” into the sterilizing chamber (8) in order to avoid unpleasant odours: Some ingredients of the “Deodorant Pearls” may rapidly disintegrate the door seal (6)

INFORMATION
Only original seals made by the manufacturer may be used.

INFORMATION
We highly recommend you to have the sterilizer serviced regularly by our authorized after-sales service. We also recommend to enter into a contract for maintenance or for annual safety checks. Repeat testing of the pressure vessel must only be carried out by an authorized person fulfilling the requirements stated in the German Operating Safety Regulation.

11.1 After-sales service and maintenance

Observe the manufacturer's recommendations on service intervals for the sterilizer and periodic inspections for the pressure vessel in line with regulations covering pressure vessels. Please, check also the electrical safety of your equipment (VDE test pursuant to VBG 4, Section 5) in accordance with the regulations.
We recommend service of the sterilizer by our service engineers at least once a year (annual inspection). In addition, maintenance contracts are available to assure continual safety checks.

11.2 Important notes

All parts of the pressure vessel that may be exposed to sterilized items are made from stainless steel (Material No. 1.4571 DIN 17440). This quality has proved to be suitable for most sterilizing goods. However, it is known that this material may corrode in certain circumstances.

When sterilizing vessels, instruments or parts **made of steel or iron** (e.g. screw caps), the sterilizing chamber (8) or the door (2) may exhibit a rust film despite their stainless-steel material. This film may occur if iron dust is deposited on the door (2) or on the walls or floor of the sterilizing chamber (8).

If the sterilizing chamber (8) comes in contact with **inorganic acids**, either when cold or when hot, the surface of the pressure vessel may be corroded. Even plaques such as sometimes occur on the walls of the pressure vessel may cause corrosion under certain circumstances.

Substances containing chlorine ions, especially 0.9% NaCl solution, cause a special type of corrosion, pitting. Pitting increases with

- increasing chlorine ion concentrations
- increasing temperature

It is not only the composition and concentration of the corroding agent, but also the temperature, the pH value, and other influences that have to be taken into consideration. Minimal additional quantities of e.g. oxidising or reducing substances may attenuate or aggravate the process.

CAUTION
In order to guarantee smooth operation and prevent corrosion damage, please follow the checklists for regular maintenance and care and the maintenance manual to the letter!

11.3 Inserting paper rolls into the integrated printer

INFORMATION
Do not pull the paper out of the printer. Use the Paper feed key for this purpose.
Never pull the paper backward, because this may damage the printer.

On commissioning the sterilizer, you need to insert a paper roll into the integrated printer.
In addition, you must change the paper roll when there is almost no paper left. You can tell that this is the case when a wide red line appears on the paper.

- Cut the end of the new paper roll as shown in Figure 18.

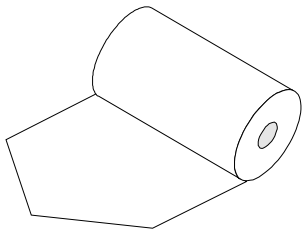


Figure 17: Cutting the end of the paper roll

- Press both the Printer ON/OFF key (26) and the Paper feed key (27) concurrently.
  The printer cover (25) opens.
- Remove the printer cover (25).
- Cut the paper strip off the old paper roll.
- Press the Paper feed key (27) until the remaining paper has been removed from the printer head.
- Remove the old paper roll from the paper roll compartment.
- Insert the new paper roll into the paper roll compartment so the end of the paper roll is below the roll.
- Insert the end of the paper roll into the paper feeder.
- Press the Paper feed key (27).

The paper is now pulled into the printer head (Figure 19, right). It will curl slightly upward.

- Replace the printer cover (25). Guide the paper through the slot of the printer cover (25).

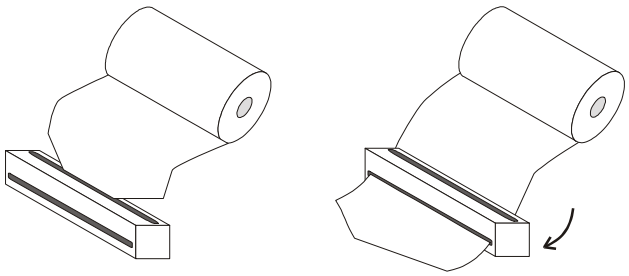


Figure 18: Inserting paper into the paper feeder (note direction, arrow)

11.4 Changing the ribbon of the integrated printer

If the printout starts to appear faded after a longer period of use, the printer ribbon should be replaced.

INFORMATION
Do not pull the paper out of the printer. Use the Paper feed key for this purpose.
Never pull the paper backward, because this may damage the printer.

- Press both the Printer ON/OFF key (26) and the Paper feed key (27) concurrently.
  The printer cover (25) opens.
- Remove the printer cover (25).
- Hold the left end of the ribbon cartridge with your left hand.
- Press on the right end of the cartridge.
  This will lift the left end of the cartridge.
- Remove the cartridge.
- Take a new cartridge.
- Insert the left end of the new cartridge in the left corner of the printer head.
  Make sure that the cartridge is parallel to the ribbon guide.
- Press the right end of the cartridge down into the right corner of the printer head.
- Replace the printer cover (25). Guide the paper through the slot of the printer cover (25).

12 Troubleshooting

The program control is equipped with a sophisticated error management system. If an error occurs during program execution, an error message is shown in the cycle display (16) or the current values display (13).
If an error occurs:

- Memorize or write down the error message.
- Press the START/STOP key (19).

This will interrupt the program cycle. The sterilizer is returned to a safe state.

- Before restarting the program, troubleshoot the problem (see Table 5).

Message in the cycle display	**Meaning**	**Remedy**
Error 2 Lock open	Locking levers do not attain their maximum closing positions.	Open and close door; if necessary, contact after-sales service
Error 3 No p.- buildup	Door seal cannot build pressure: Compressor missing or defective, or pressure line missing or interrupted, or door seal missing	Contact after-sales service.
Error 4 Seal defective	Door seal builds but cannot keep pressure: Seal leaking, or pressure tank leaking, or pressure line leaking.	Contact after-sales service: Have leaking part replaced
Error 6 Compressor	Door seal loses pressure during sterilization: Compressor defective.	Contact after-sales service.
Error 9 Running dry	The heater has overheated because the jacket space has run dry. Or the overtemperature limiter was set too low (required setting: 170 °C) and was therefore activated.	Contact after-sales service.
Error 10 Control error	Internal program control error.	Turn off and restart the sterilizer; contact after-sales service.
Error 12 Water low	Feed water tank empty, or valves (Y3, Y6.1, Y6.2) defective, or external water supply (option) defective.	Fill feed water tank or contact after-sales service; check external water supply where applicable.

Message in the cycle display	**Meaning**	**Remedy**
Error 17 Overheating	Heating system does not turn off. Heating system relay defective or program control error.	Contact after-sales service.
Error 20 Microheating	Microheating system (heatable temperature sensor) cannot regulate water feed to jacket. Microheating system defective.	Contact after-sales service.
Error 22 No heater	Heating coils are defective, or the heating system control is defective.	Contact after-sales service.
Error 23 Partial heater	One heating coil is defective.	Contact after-sales service.
Err1 *in the Chamber field:* in the Media field:	Sensor broken *Chamber temperature sensor is affected.* Flexible temperature sensor (reference temperature sensor) is affected[12].	Have technician replace sensor or contact after-sales service.
Err2 *in the Chamber field:* in the Media field:	Sensor shorted *Chamber temperature sensor* *Flexible temperature sensor [12)2)2)] (reference temperature sensor).*	Have technician replace sensor or contact after-sales service.
Err3 *in the Chamber field:* *in the Jacket field: below the Jacket field:*	Pressure sensor defective *Pressure sensor in sterilizing chamber* *Pressure sensor in jacket[12)]* *Pressure sensor in seal[12)]*	Contact after-sales service.

Table 5: Error codes and their meanings

[12)] If present

13 Technical specifications

VARIOKLAV steam sterilizer	**25 T**
Dimensions (W × H × D)	380 × 530 × 680
Chamber dimensions Ø × T (mm)	255 × 500
Usable volume (dm^3)	25
Weight (kg)	approximately 70
Rated heating capacity (Nominal heating capacity) (kW)	3.2
Heat emanation	approximately 25 % to 35 % of the nominal heating capacity
Current type	AC ~
Nominal current rating (A)	16
Mains connection	230 V / 50 Hz
Socket / Fuse	Socket outlet with grounding contact 16 AT
Permissible operating conditions: Ambient temperature Relative humidity Barometric pressure	 +5 °C to +40 °C 30 % to 80 % 900 hPa to 1,060 hPa
Permissible storage conditions (empty): Ambient temperature Relative humidity Barometric pressure	 -40 °C to +70 °C 10 % to 95 % 500 hPa to 1,060 hPa
Protective class IP type of protection (control)	I
EMC (electromagnetic compatibility): Integrity test:	pursuant to DIN EN 50081 Part 1 pursuant to DIN EN 50082 Part 1

The sterilizer must not be operated in an environment where an explosion hazard exists.

Any changes to the steam sterilizer must be approved and confirmed by the manufacturer and must be entered in the data sheet.

14 Glossary

A	
Actual temperature	Effective temperature
B	
Bench-top sterilizer	Steam sterilizer to be placed on a table
C	
Chamber	That part of the sterilizing chamber designated to receive the sterilizing articles
Chamber temperature	Temperature in the sterilizing chamber
Condensate	Water vapour, which has precipitated onto a surface and liquefied
To configure programs	To change permanently
Control system	Electronic unit controlling program execution
Cycle	Sequence of sterilization phases
D	
Deaeration time	Time period until air has been removed from the sterilizer
Disinfection	Destruction of disease-causing agents
Distilled water	Water free of minerals and salts
Drying time	Time needed for drying
E	
Exhaust air filtration	Filtration system for safe sterilization of infectious material (with pathogen bioburden). Cleanses the exhaust air from the sterilizer during the heating and sterilizing phases.
Equilibration time	Time period until all sterilizing articles have reached the chamber temperature
F	
Feed water	Deionized water in the sterilizing chamber which is heated to provide the sterilizing steam
FRVV	Fractionated prevacuum
Fully deionized water	Water from which all minerals and salts have been removed by ion exchange (anions for OH^-, cations for H^+) or reverse osmosis; not the same as softened water
I	
Infectious	Catching
M	
Mechanical locking stop	Safety feature which prevents the door from being opened under pressure

Metering equipment	Equipment for measuring a specific quantity
R	
Recooling	Cooling the sterilizing chamber and the sterilized articles after sterilization
Reference flask	Liquid-filled flask, in which the temperature of the liquid is measured with a temperature sensor
Reference temperature	Temperature at the reference point (e.g. reference flask) in the sterilizer
To reproduce	To repeat
S	
Septic	Non-sterile, causing disease
Safety Valve	Valve which automatically releases steam or air when the pressure in the sterilizing chamber becomes too high
Set temperature	The temperature which has to be reached
Steam pot	Device for heating liquids, for maintaining the temperature of liquids, and for dissolving agar.
Steam release	Removal of steam from the sterilizing chamber
Steam sterilizer	Equipment for carrying out degerming under the effect of steam
Sterile venting	Venting with decontaminated (sterile) air
To sterilize	To degerm, to eliminate all micro-organisms
Sterilizer	Equipment used for sterilizing
Sterilizing articles	Liquids or solids destined for degerming
Sterilization phases	Parts of a sterilization cycle
Sterilizing temperature	Temperature needed for sterilization
Sterilizing time	Time needed for sterilization
T	
Temperature sensor	Thermometer
Thermally instable	Not stable when heated
Thermolock	Safety feature preventing premature opening of the door. It is controlled via the reference temperature. The temperature of the liquid must be below 90 °C before the sterilizing chamber can be opened.
Toxic	Poisonous
V	
Vacuum	Negative pressure