User Manual

Autoclave

Cliniklav®25

as of software version 5.15

Dear Dr.

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

As an owner-run and operated family concern founded in 1951, we have a long history of successful specialization in hygiene products for practice-based use. Our focus on innovation, quality and the highest standards of operational reliability has established MELAG as the world's leading manufacturer in the instrument treatment and hygiene field.
You, our customer are justified in your demand for the best products, quality and reliability. Providing **"competence in hygiene"** and **"Quality – made in Germany"**, we guarantee that these demands will be met. Our certified quality management systems is subject to close monitoring: one instrument to this end is our annual multi-day audit conducted in accordance with ISO 13485 and ISO 9001. This guarantees that all MELAG products are manufactured and tested in accordance with strict quality criteria.

The MELAG management and team.

CE 0197

User Manual Cliniklav®25

Valid for Cliniklav®25

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Subjects to technical changes

To ensure the functional effectiveness of this unit and to preserve its value:

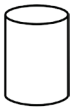
1. Prepare the instruments to be sterilized carefully
2. Take proper care of the autoclave
3. Use only pure distilled or demineralized water

CONTENTS

1 Safety instructions

- When opening the door, particularly after interrupting the drying process, residual steam can escape from the autoclave chamber.
- After opening the door, do not touch any metal surfaces - these will be hot! Danger of burns. Always use the tray lifter to remove trays, or wear suitable hand protectors when taking out other items.
- Do not sterilize any liquids with this autoclave. It is not licensed for the sterilization of fluids. Failure to observe this can result in a delay in boiling, which could result in damage to the autoclave, burns and other injuries e.g. through splintered glass.
- Do not sterilize any liquids with this autoclave. It is not approved for the sterilization of liquids. Failure to observe, these instructions may lead to delayed boiling, damage to the autoclave and burns.
- The autoclave is intended for use outside the patient environment. The minimum distance to the treatment area must have a radius at least 1.5 meters.
- Under current VDE regulations, this autoclave is not suited for use in areas where there are risks of explosion.
- In order to ensure effective sterilization with the autoclave observe the instructions in this User Manual, and in particular ensure that the loading of the autoclave is appropriate for the program selected.
- The autoclave must only be serviced and repaired by MELAG or by its authorised representatives (specialist dealers or customer services) using only original parts and following service instructions.
- Documentation media (computer, CF card reader etc.) must be placed in such a way that they cannot come into contact with liquids.
- Before opening the housing always disconnect from the mains power supply!
- If you intend to install a water treatment unit from another manufacturer, then consult MELAG before you do so.
- We recommend the installation of a water leak detector.

1.1 Symbols on the autoclave

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

2 Description of the unit

2.1 Views of the unit

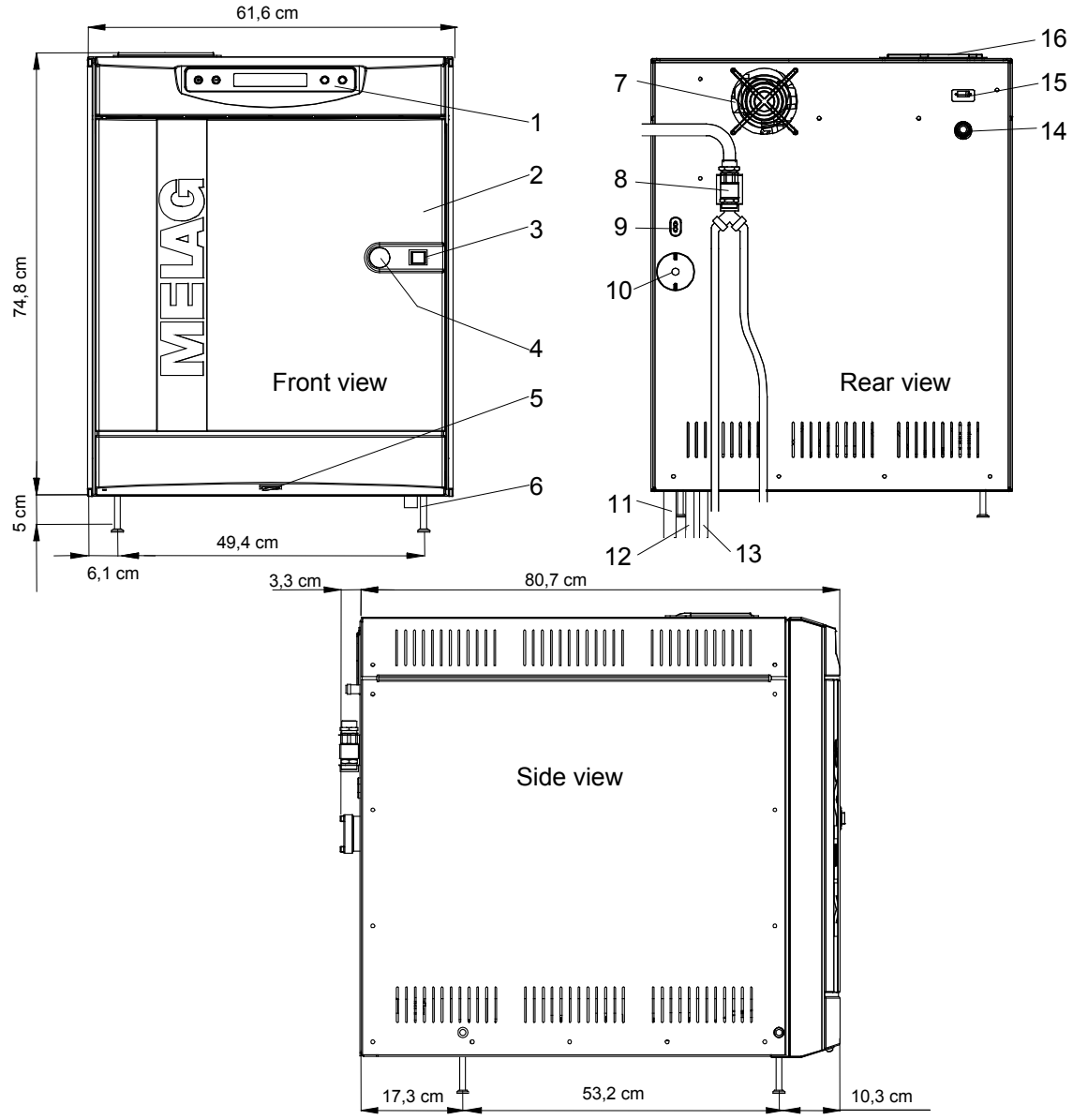
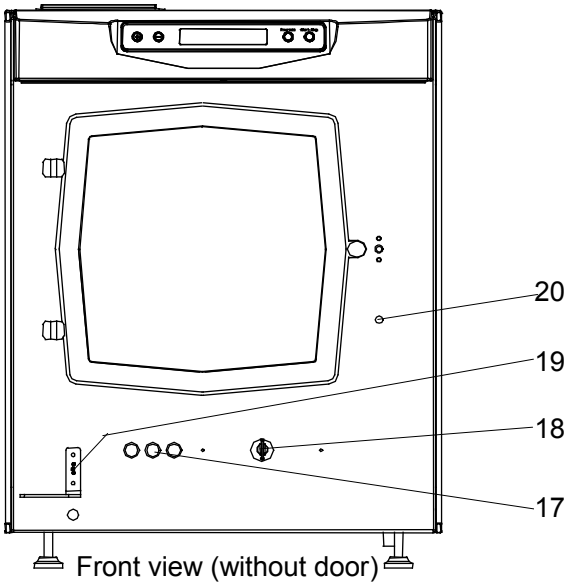


Fig. 1: Views of the Cliniklav®25

1 Control panel
2 Door, opens to the left
3 Door opener
4 Emergency door opening
5 Mains switch
6 Adjustable feet (when delivered without a lower cabinet)
7 Fan
8 Safety combination according to EN1717
9 Emergency pressure release and cavitation outlet
10 Sterile filter
11 Feed water inlet
12 Cooling water outlet (3/4" external thread)
13 Cooling water inlet (3/4" external thread)
14 Safety valve
15 Serial Interface (RS 232)
16 Log-Printer



17 Fuse 3x20 A
18 Protective motor switch
19 Reset for steam generator
20 Door contact switch

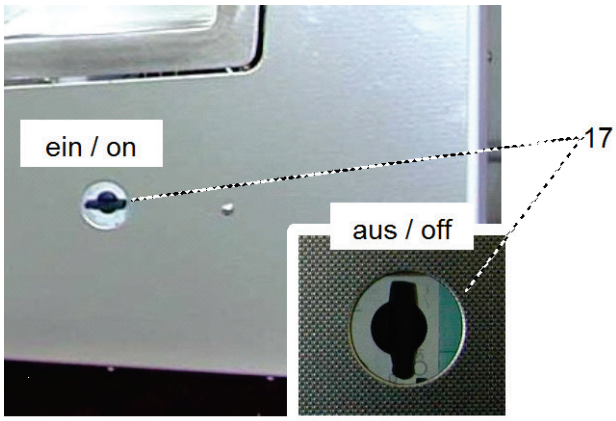


Fig. 1: Front view Cliniklav®25

Fig. 2: Front view of the Cliniklav®25

2.2 Control panel

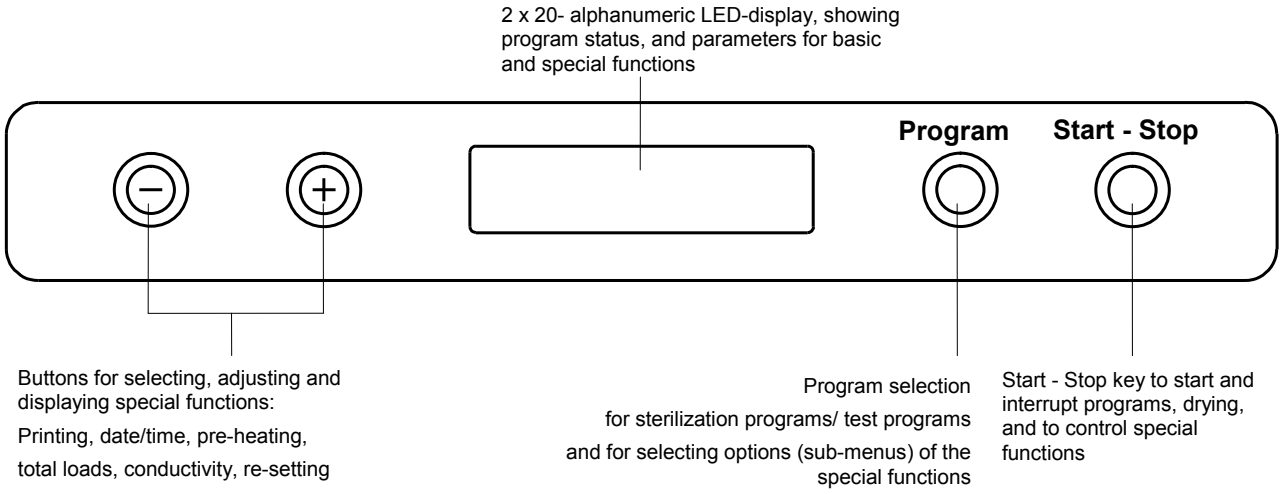


Fig. 3: Control panel of the Cliniklav®25

Technical Data

Chamber space (diameter x depth)	:	32 cm x 32 cm x 65 cm
Electric power supply	:	9000 W/400 V 3N AC/16 A/50/60 Hz
Sterilization pressure/temperature	:	2 bar/134°C; 1 bar/121°C
Maximum load	:	15 kg instruments or 7 kg textiles

For further technical data, please see the Appendix.

2.3 Performance features of this autoclave

2.3.1 Fractionating pulsed vacuum procedure

A fractionating pulsed vacuum method involved the repeated evacuation of the sterilization chamber, alternating with the introduction of steam in order to ensure the necessary penetration of the items undergoing sterilization with superheated steam.
This means that even demanding sterilization tasks, involving for example intricate instruments or large amounts of textiles can be completed quickly and reliably.

2.3.2 Programs for sterilization

The Cliniklav®25 features three sterilization programs for temperatures at 134°C: the “Universal Program” (for wrapped objects), the “Prion-Program” (a special Universal Program), the “Quick-Program” for unwrapped items, and the “Gentle-Program” (a sterilization program for textiles and rubber articles at 121°C). The user can at any time perform additional functional checks of the autoclave by running the Bowie & Dick test for steam penetration, and the Vacuum test for leak testing.

2.3.3 Separate steam generation

The generation of steam by a high-performance unit outside the sterilization chamber makes it possible to sterilize large loads of instruments or textiles quickly. It is not necessary to have any pauses between the sterilization runs, and overheating in the sterilization chamber is impossible.

2.3.4 One-way system/Conductivity measurement/Automatic water supply

The Cliniklav®25 operates with a reliable one-way system, in which all the condensate from a sterilization, including any impurities which this may contain is completely eliminated and purified water used for the next program run.
An integrated conductivity measurement system monitors the quality of the distilled or demineralized water used for the steam generation.
For frequent operations, the larger demand for purified water can be met by a water treatment unit, e.g. MELA*dem*® 55, which can be directly connected to the autoclave.
Provided the instruments to be sterilized are then also prepared carefully, stains on the load and soiling of the autoclave itself can be prevented.

2.3.5 Electronic Parameter Control (EPS)

The microprocessor in the Cliniklav®25 makes it possible to monitor pressure, temperature and time continuously during a program by Electronic Parameter Control. The overall operating time can then be optimised according the load and the temperature of the autoclave.
The process assessment and monitoring system in the program control compare current process parameters with standard process data and monitors the process relative to limit values for temperatures, times and pressures. This makes it possible to identify faults as they occur, and provides quality assurance for the sterilization processes.

2.3.6 Vacuum drying

Vacuum drying ensures the best possible drying results for packed utensils (see also 11.4).

2.3.7 Documentation

The electronic memory stores logs of the previous 40 programs.
For effective hard-copy documentation and for checking purposes, a MELA*print*®42 printer can be connected to print out a log immediately after completion of a program or to print out logs from the memory. If the optional MELAtrace/MELA*view* documentation software is used with this autoclave, a Computer in the doctor’s practice can be used to document the sterilization cycles, and to archive the required data. In this case, the data are transmitted from the autoclave via a serial interface to the Computer in the practice (the serial cable is delivered with the software).

3 Installation and Initial start-up

For preparing the installation and when you are setting-up and installing the autoclave, please consult the separate instructions leaflet "Installing the Cliniklav®25".

3.1 Power supply

Switch on the power using the switch on the front of the autoclave (bottom of the door housing cover in the middle). The autoclave is in the initial state:

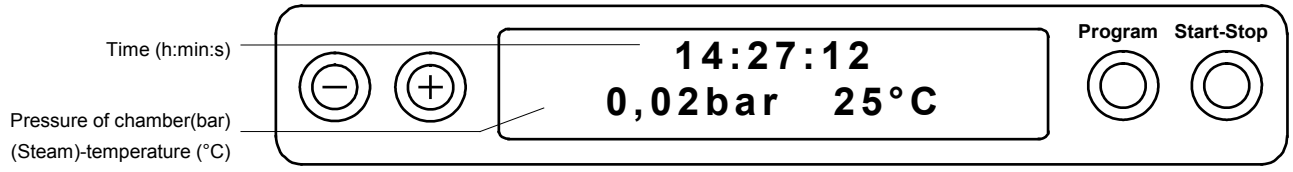


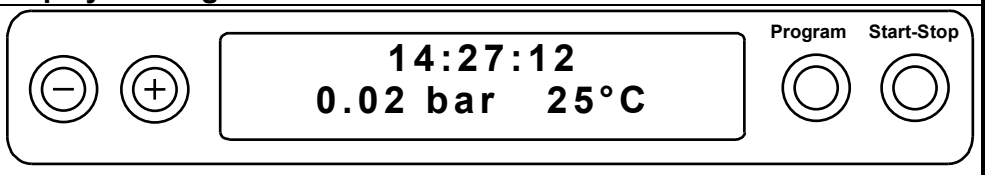
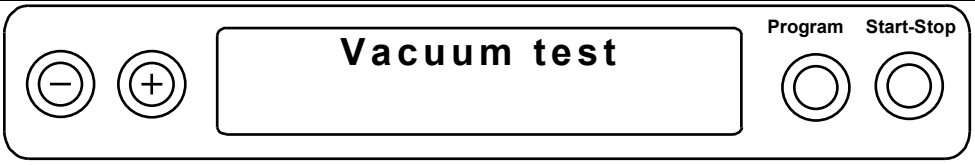
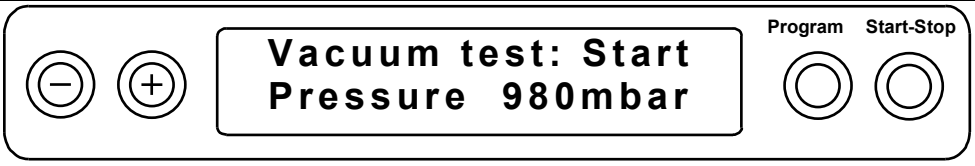
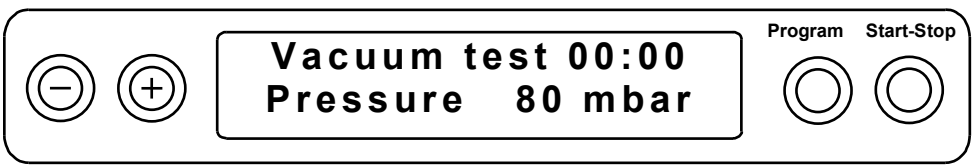
Fig. 4: View of the initial state of display

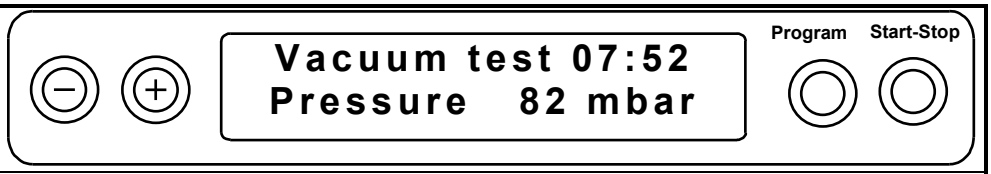
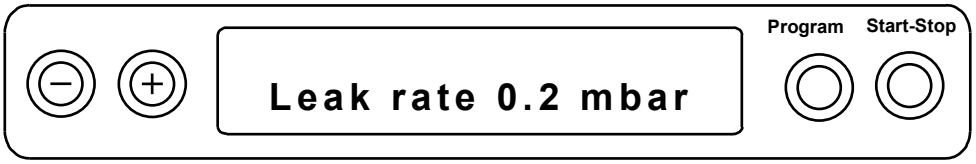
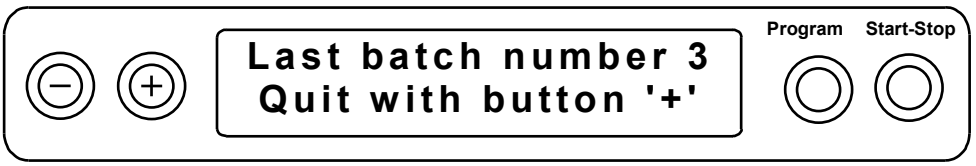
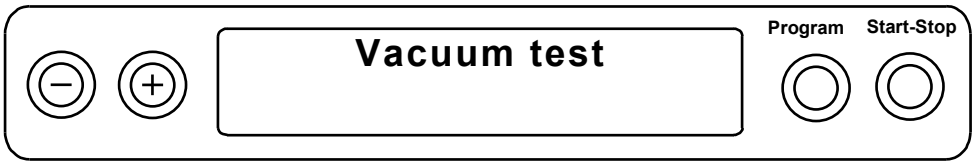
3.2 Connection of a water treatment unit

It is possible to connect a water treatment unit to the autoclave to directly supply it with distilled/demineralized water. Instead of connecting the autoclave to a water storage container, the feed pipe for distilled/demineralized water is directly hooked up to the water treatment unit.
For additional information on the application of the sterilization programs, please refer to section 7.4.
The MELA*dem*® 55 is ideal as choice for the water treatment unit: It has been designed to optimally meet the needs of the Cliniklav®25 with respect to water quality and output. The user manual for the MELA*dem*® 55 contains detailed instructions for installation and operation of this water treatment unit. If you decide, however, to use a water treatment unit made by another manufacturer, make especially sure that the system provides enough water in sufficient quality. We always recommend that you first coordinate with the MELAG company before buying another water treatment unit.

3.3 Vacuum test

In order to check the operation of the autoclave in the course of the initial start-up, after long periods without being used, or after moves, as well as periodically during routine use, a vacuum test should be carried out monthly to check for leaks.
The vacuum test should be carried out as follows, preferably on the cold autoclave:

Operation		Display message
1.	Switch on at mains, then the display will show the basic parameters.	
2.	Press the "Program" key several times until the display shows "Vacuum test" Close the door	
4.	Press the key "Start - Stop"	
5.	The evacuation pressure has been reached. The equilibration period begins	

6.	After waiting for the equilibration (5 min) the measuring period starts (running here e.g. for 7 min 52s)	
7.	After the measuring period (10 min) the chamber is ventilated and …	
	… then the leakage rate is displayed (if the option "Immediate output" is set to "YES" and a printer or another output medium is connected, a log will also be printed) The display shows "Last batch number" in alternation with "Quit with key '+'. By pressing the key '+' the door is unlocked and …	 
	… the door can be opened after the message "Open door please" is displayed.	
8.	The display shows the selected program	

If the leakage rate is above the limit value (> 1.3 mbar/min), then the display (and the log) will also show "Test unsuccessful". In this case, follow the instruction in Section 9.1.

3.4 Bowie & Dick test

The Bowie & Dick test serves as proof of the steam penetration of porous materials such as textiles.
Diverse test systems are offered by specialist dealers for the Bowie & Dick test. Perform the test according to the manufacturer's information to the appropriate test system. We recommend e.g. the Bowie & Dick test packet from 3M No. 1300.
Evaluation is performed following sterilization and removal of the linen test package from the autoclave.

How to start the Bowie & Dick test program:

1. Switch on the autoclave at the mains. The display switches into its initial state.
2. Select the "Bowie & Dick test" program by pressing the "Program" key repeatedly.
3. Press the "Start/Stop" key to start the program.

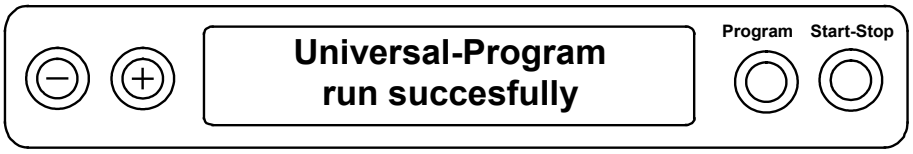
After a successful program run, the last batch number is displayed, alternating with the message "Quit with button '+'." You can open the door after pressing the '+' key.

NOTE

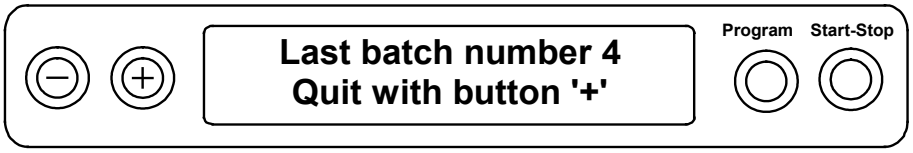
Treatment indicator strips often exhibit differing intensities in the colour change indicating a different length of storage of the manufacturer batches or other influences. Of crucial importance for evaluating the Bowie & Dick test is not the more or less strong contrast of the colour change, rather the even nature of the colour change on the test sheet.
If the treatment strips/treatment indicator sheet indicates an equal distribution of colour change, the ventilation of the sterilization chamber is without fault.
If the treatment indicator strips or the treatment indicator sheets are uncoloured or exhibit less colour in the centre of the star in comparison to the end, ventilation was insufficient. In such a case, please consult the stockist customer services/MELAG customer services.

3.5 Trial run

In order to check the operation of the autoclave under realistic conditions, a test run should be carried out with the "Universal-Program, 134°C wrapped" and a relevant load. After loading the autoclave and selecting the program with the "Program" key, the sterilization is started by pushing the "Start/Stop" key. If the program runs correctly, the following message will appear on the display (see section 4.9).



in alternation with:



If the option "Immediate output YES" has been selected for a log printer or another output medium, a log of the program run will be printed.

3.6 Record of installation and setting up

As documentation that the autoclave has been set-up properly, a record of installation and setting up should be produced by an authorised person and a copy sent to MELAG. This is important in the event that you wish to make claims under warranty provisions.

3.7 Validation

In accordance with EN 17665, the sterilization process should be validated before beginning routine operation with the autoclave.

4 Sterilization

4.1 Supply with fresh purified feed water/cooling water

The autoclave automatically monitors the availability of cooling water and purified water, as well as the quality of the distilled/demineralized water before starting a program.
In order to allow an immediate program start and to avoid malfunction messages or interruptions of programs (see Sections: 9.1 and 9.2):

- Before the first sterilization at the start of the working day, check that the water supply is turned on (water tap),
- If purified feed water is drawn from a storage container, check the water level, and if necessary fill up with purified water of appropriate quality (see section 7.4),
- If the feed water is drawn directly from a MELA*dem*® 55 water treatment unit, check that its water supply is turned on in good time (this may be up to an hour before starting a sterilization program), if the water supply has been turned off over night, for example.
- For routine operation, please refer to the information contained in section 10.

4.2 Preparation of instruments

MELAG non-rusting materials
All parts of the Cliniklav®25 which come into contact with steam are made of non-rusting material. The autoclave chamber and the steam conducting parts are made of stainless steel, the door is made of anodised aluminium and the threaded fittings and solenoid valves are made of brass.
Drag-in rust
The use of non-rusting materials excludes the formation of rust as a result of the components of the autoclave. Where rust forms on the autoclave or the items to be sterilized, investigations have repeatedly shown that this rust has been brought in from other sources. It should be borne in mind that rust can form even on best quality stainless steel instruments, for example as a result of improper treatment with chemical cleaning agents or disinfectant during preparation for sterilization.
Preparations of items for sterilization
The example of drag-in rust shows how important it is to prepare items properly for sterilization, and particularly the following points.:
Handpieces and angles should be cleaned before the sterilization in accordance with the manufacturers instructions and maintained (e.g. oiled). The remaining instruments should be disinfected and cleaned immediately after use in accordance with UVV/VBG 103 with a disinfectant and/or cleaning solution. The solutions should be used in the correct concentration and care should be taken to observe the immersion times precisely!
It is advisable to make use of appropriate cleaning aids such as ultrasonic cleaning units, cleaning and maintenance equipment for handpieces and contra-angles, or thermo-disinfecting systems.
Cleaning the instruments before sterilization is very important in order to avoid introducing contamination which can separate from the instruments under steam pressure during sterilization and block filters, jets and valves of the autoclave. In particular, locks, joints and hinges should be thoroughly cleaned with a brush. Cleaning and disinfecting agents should be washed off the instruments thoroughly in running water, again with a brush. Residues of cleaning and disinfectant chemicals must not find their way into the autoclave, since they can lead to corrosion! Swill finally with demineralized water and then dry the instruments.
Turbines and transfer instruments should be oiled in accordance with manufacturer's instructions in order to ensure a long life for these components.
Brand-new instruments
The cleaning procedures described above are also necessary for brand-new instruments, since these often carry very small amounts of oil, fat and soiling from the manufacturing process.

Note: The instructions of the instrument manufacturers concerning first-time sterilization and re-sterilization should be followed carefully.

4.3 Loading the autoclave

It is of crucial importance for effective sterilization and good drying that the autoclave is loaded properly.
Be sure to observe the following basic instructions when loading the autoclave.

Loading variations

Article	*MELAG Art.-No.*
Mounting for up to 4 trays or 2 instrument baskets	02517
Tray	00250
Instrument basket	00260
Max. 3 mountings for each 6 standard tray cassettes	02518
Standard-tray cassette, perforated with filter sheet	00289

All mountings are also suitable for accommodating the MELAG sterilization containers Type 15K, M, G, Type 17R, K, M, G; Type 23R, M, G, Type 28M, G.
In this case, we recommend using the additionally available chamber floor overlay (MELAG Art.-No. 46890), designed to protect the sterilization chamber from scratching.

Mounting
Normally, the autoclave should be used in conjunction with a mounting, since this ensures that steam penetration and drying are as good as possible. In exceptional situations (e.g. when using sterilization containers from other manufacturers), and after consultation with your specialist dealer or with MELAG, the mounting can be removed and the container can be placed directly in the autoclave chamber.

Trays
Trays for objects which are to be sterilized must be perforated, in order to allow condensate to run away. MELAG trays are recommended. If you use dishes or trays without perforations, then the objects being sterilized will not dry properly.

Closed sterilization containers
Closed sterilization containers must be perforated on at least one side (preferably underneath) or must have valves, in order to ensure that steam can penetrate and condensate can run out. All MELAG sterilization containers meet these requirements with perforations on two sides and filter-cloth-inlays.
Sterilization containers which only have perforations on the top only allow limited drying.
If sterilization containers are stacked in the autoclave, it is important to ensure that the perforations are not blocked.

Transparent sterilization packaging
If you use transparent sterilization packaging, such as MELA*fol*®, then the items should if possible be stood vertically on the tray, or sterilized in foil holders (MELAG Art. no. 22420). They should never be laid flat one on top of the other.
If seals split open during sterilization it may be necessary to increase the length of the sealing impulse or to use a double-seal.
Standard tray-cassettes sealed in MELA*fol*® (250 mm wide) must be taped and clasped additionally to ensure that the side-seals do not split open.

Multiple wrapping
The pulsed vacuum method means it is possible to use multiple wrapping.

Maximum loads
Loads should not exceed 15 kg of instruments or 7 kg of textiles.

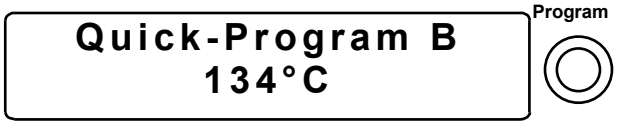
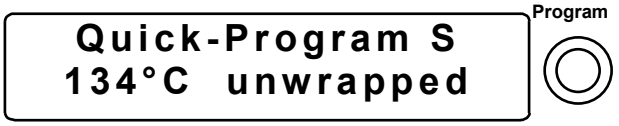
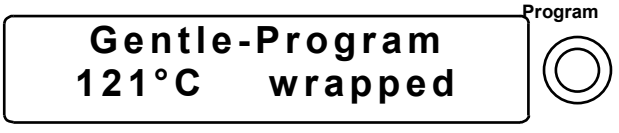
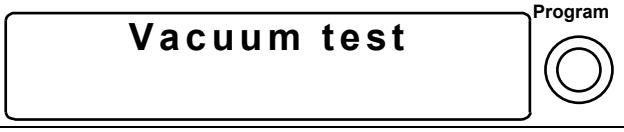
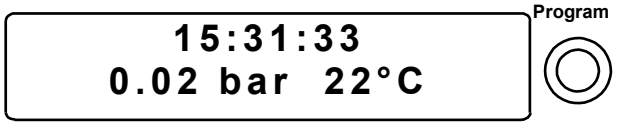
Mixed loads
If mixed loads of textiles and instruments are to be sterilized, then as far as possible the textiles should be above the instruments and direct contact with the instruments should be avoided.
Inclusion of textiles and instruments in the same sterilization container is not desirable.
Textiles should never come into direct contact with the walls of the chamber.
If different types of packaging are included in a load, then:

- Instruments and sterilization containers should be at the bottom
- Transparent and paper sterilization packaging should be at the top (but lower than textiles)

Suitability for sterilization
Relevant information provided by manufacturers of instruments and textiles about sterilization should be strictly observed.

4.4 Program selection

A program should be selected which is appropriate for the physical properties of the items being sterilized (and in particular their heat resistance) and the type of packaging (if any part of the load is wrapped, then either the "Universal-Program" or the "Gentle-Program" must be used).
By pressing the "Program" selection key it is possible to review the display of the following programs for selection:

Program name/Display message	Parameter/Application
	**Universal-Program.** at 134°C, 2 bar, and a sterilization time of 5.5 min Sterilization of all types of wrapped items, in particular instruments, or mixed loads (unwrapped/wrapped)
	**Quick-Program B** at 134°C, 2 bar and a sterilization time of 5.5 min. Sterilization for unwrapped items, simple wrapped (5.5 kg) instruments or porous load (4 kg) for rapid re-use.
	**Quick-Program S** at 134°C, 2 bar and a sterilization time of 3.5 min Sterilization **only of unwrapped instruments** (no textiles) for rapid re-use (drying can be interrupted manually)
	**Gentle-Program** at 121°C, 1 bar and a sterilization time of 20.5 min. Sterilization of all types of wrapped items, in particular large amounts of textiles or thermosensitive materials (plastic, rubber), or mixed loads (wrapped/unwrapped)
	**Prion-Program** (a special Universal-Program) at 134°C, 2 bar, and with sterilization time extended to 20.5 min, for sterilization of wrapped items, especially instruments and/or mixed loads (i.e., packed and unpacked). This program is recommended for sterilization of instruments used in situations in which the danger of infection by pathologically modified proteins is suspected: for example, Creutzfeld-Jacob and BSE).
	**Bowie&Dick Test** at 134°C, 2 bar and a sterilization time of 3.5 min Used to check the operation of the autoclave (Steam penetration of special indicators)
	**Vacuum test** Used to check the autoclave for leaks, from a cold start
	**Basic display** (no program selected)

4.5 Pre-heating

Operate the Cliniklav®25 only after it has been pre-heated. This will reduce the condensation of water on the wall of the sterilization chamber: which shortens the cycle times and greatly improves drying. When you start the Quick-Program S with an empty sterilization chamber, the cold autoclave chamber will be pre-heated. DIN EN 285 (for steam sterilizers) recommends preheating before beginning the actual sterilization cycle.

4.6 Selecting extra drying

The standard drying times for the various programs provide adequate drying if the autoclave has been loaded correctly (see section 4.3). Nevertheless, with certain loads residual moisture may remain. By selecting the "Additional drying" function, the drying time can be extended by 50%:

Operation	Display message
At the start of the program, press the "+" key. The display shows a message confirming the extra drying, and then the program runs as described in section 4.9 but with 50 % longer drying time.	

4.7 Opening and closing the autoclave door

To close the autoclave door, lightly press it closed, then press the door opener to position 2 shown below. The door is properly closed when the door opener remains depressed until the motor sound in the door stops.

Position 1: OPEN
Position 2: CLOSE

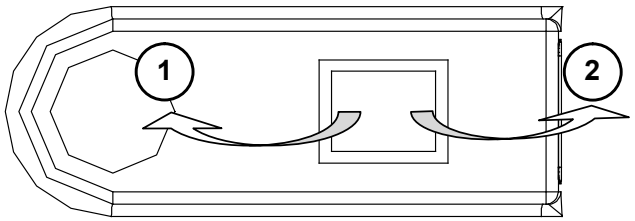


Fig. 5: Door opener

4.8 Program start

Press the "Start-Stop" key once the desired program is shown on the display. The availability of cooling water and feed water will be checked automatically, with a conductivity measurement.

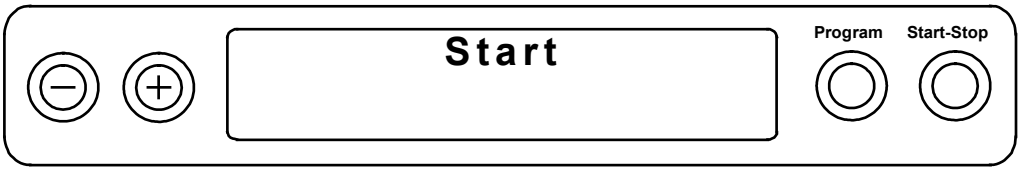
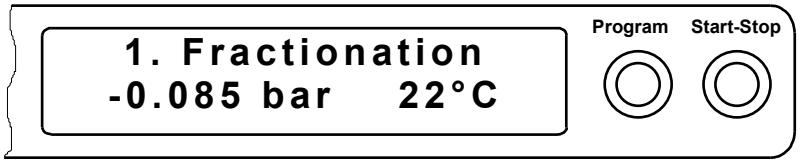
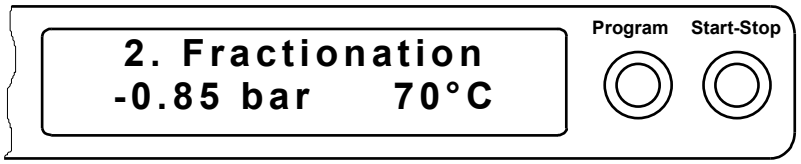
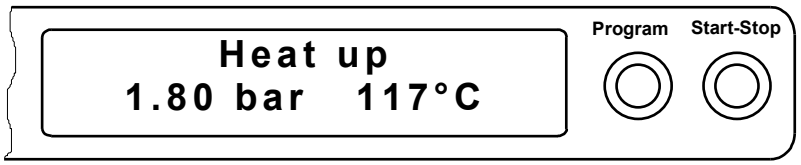
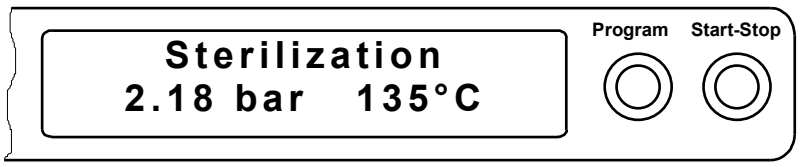
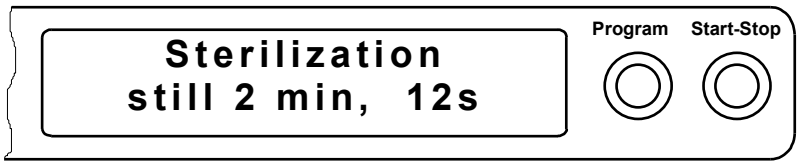
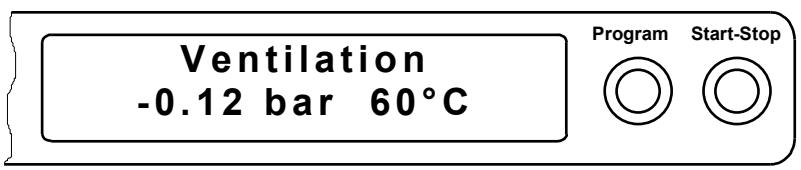


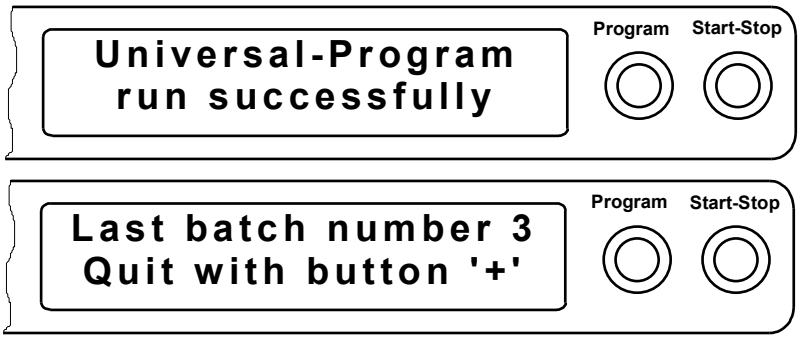
Fig. 6: Program start message

At the start of the Quick-Program S there will be an additional message "Warning! Only unwrapped instruments“. This message must be acknowledged by pressing "Start“ again.

4.9 Program progress

After starting the program, it will then progress automatically. The display shows the current program status as follows:

	Program status	Display message
1.	**1. Fractionation** consisting of evacuation (removal of air) until the appropriate evacuation pressure is reached, followed by steam introduction up to slightly above atmospheric pressure. Display show pressure in chamber and steam temperature	
2.	**Phase 2 and following** Depending on the program chosen and the temperature of the chamber at the start of the temperature, additional cycles may be necessary to ensure that air is evacuated and superheated steam enters the items being sterilized.	
3.	**Heating phase** A heating-up phase follows. The continuous introduction of steam raises pressure and temperature in chamber to the values needed for the program.	
4.	**Sterilization phase** When the required pressure and temperature have been reached the sterilization proper then begins. The display shows alternately the pressure and temperature and the time remaining.	 
5.	**Pressure release** After completion of the sterilization time, the pressure is released and the steam generator emptied. Pressure and temperature fall.	
6.	**Drying phase** After pressure release the drying phase begins. At this point it is possible to stop the program without this leading to a fault being reported, since the sterilization itself is now completed. However, with the exception of the "Quick-Program S", the drying phase should be allowed to run to completion.	 
7.	**Ventilation** After the drying, the chamber is ventilated, with pressure equilibration.	

8.	**Program end** After ventilation of the chamber the program is completed. If a printer or another output medium is attached and option "Immediate output" is set to "YES" , the log will be printed-out immediately. After pressing the '+' key the door is unlocked and …	
9.	**Open the door** … can be opened after the display message "Please open door" is displayed.	

4.10 Manual termination of program

4.10.1 Terminate before beginning of drying

A program can be terminated at any time by pressing the "Start-Stop" key. If the program has not yet reached the drying phase then the items will be **non-sterile** (or for some programs **non-disinfected**)**!**

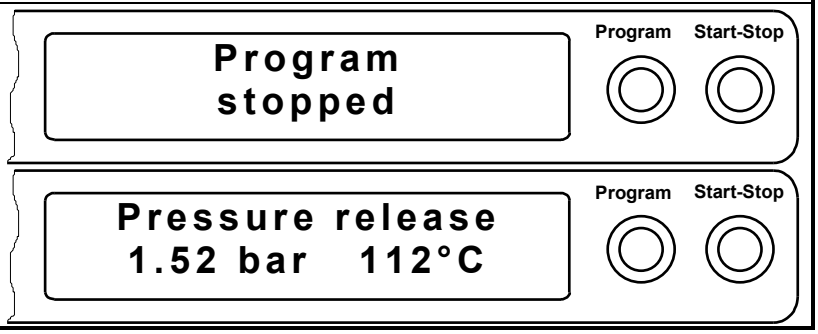
Warning

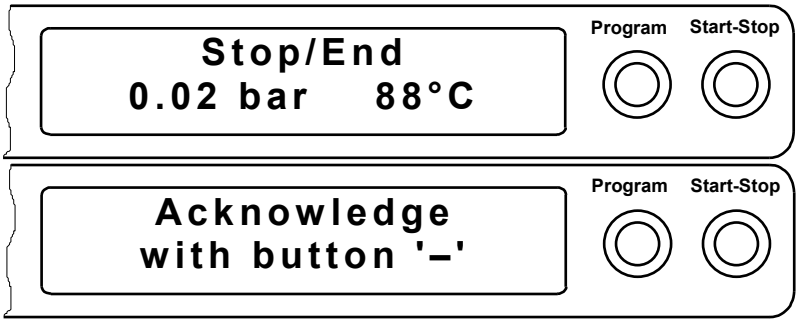
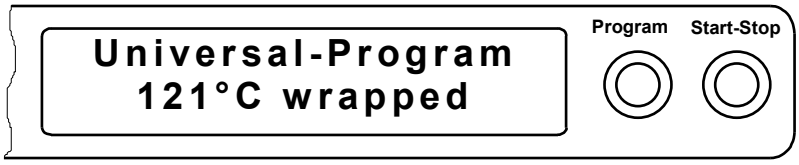
The standard DIN EN 285 prescribes very good drying (residual dampness < 1% for textiles/ 0.2 % for metals), which cannot be guaranteed upon program abort (see above). In such a case, the requirements placed on sterilization by DIN EN 285 are not met.
When using "Quick-Program S", you can perform an early drying abort, effecting immediate renewed availability. The unwrapped instruments are to be removed following program end and left to dry through their own heat during cooling.

Warning

Depending on the previous operation of the autoclave steam may be released, when the door of the autoclave is opened. Steam may escape when the autoclave door is opened.

If the sterilization phase of the program had not been completed, then it is advisable to carry out an empty sterilization run before re-using the autoclave.

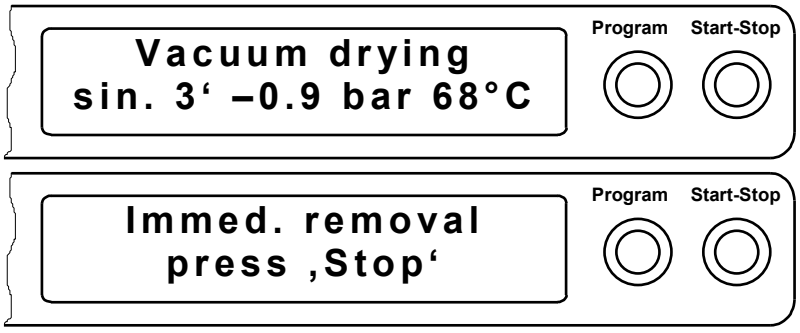
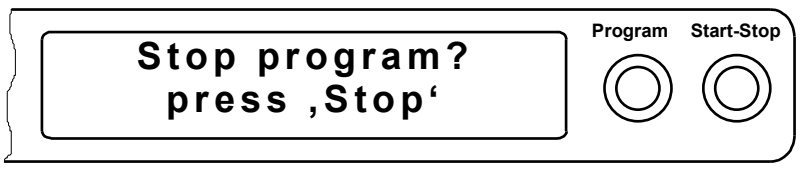
Operation	Display message
1. **Press the "Start-Stop" key** To confirm, press the "Start-Stop" once again within 5 seconds. If no confirmation is given then the program resumes normally.	
2. If confirmation is given then the program stops. The pressure inside the autoclave will then be equilibrated, either by pressure release, or by ventilation (if vacuum inside).	

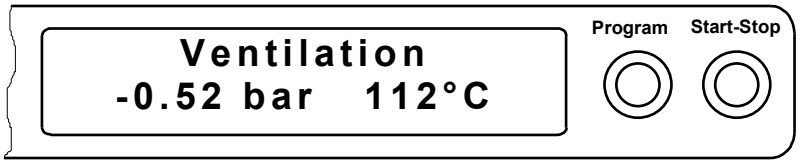
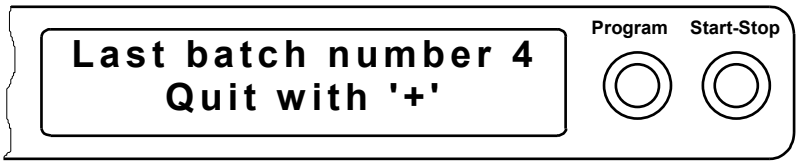
3.	After pressure equilibration, the display will alternately show the messages "Program stopped" and an offer to quit the program termination.	
4.	To undo the program termination, press the " – " button. - Otherwise, the display for the selected program reappears.	

4.10.2 Terminate during drying

A program can also be terminated during the drying phase. Since in this case the sterilization has been completed, the items in this case can be treated as sterilized.
However, depending on the state at which the drying program is terminated, the load may not have dried sufficiently, and wrapped items in particular may not be dry enough for sterile storage. We therefore recommend that you do not interrupt the drying process for wrapped items in the "Universal-Program" and "Gentle-Program".
With the "Quick-Program S" it may be desirable to interrupt the drying program so that items can be used again. The unwrapped items will dry as they are cooling down.

Warning! If the drying process is interrupted than steam may be released when the door of the autoclave is opened.

Operation		Display message
1.	The autoclave is in the drying phase. The display shows the drying time … … alternately with the option to terminate the drying phase.	
2.	Press the "Start-Stop" key. To confirm, press the "Start-Stop" once again within 5 sec. If no confirmation is given then the program resumes normally.	
3.	If the "Start-Stop" key has been pressed again to confirm then the program terminates.	

4.	This is followed by ventilation of the autoclave chamber.	
	After the ventilation of the chamber the display shows that the program has been successfully completed … … in alternation with "Last batch number 4 - Quit with '+' ". If a printer or another output medium is connected and the option "Immediate output" is set to "YES" a log with confirmation that the drying process has been terminated is printed out.	 
	By pressing the key '+' the door is unlocked … … and can be opened after the message "Open door please" is displayed.	 

4.11 Removing the sterilized items

Warning

Be careful when removing the sterilized items! **Touching the metal surfaces can lead to burns**. Always use the appropriate aids to lift the trays or wear suitable hand protection.

4.12 Sterile storage

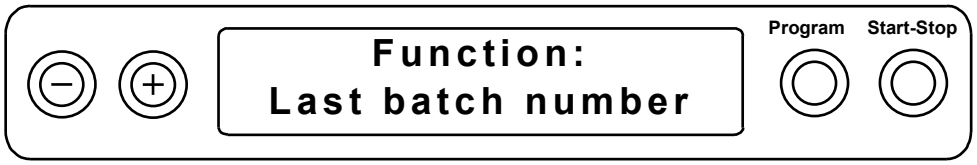
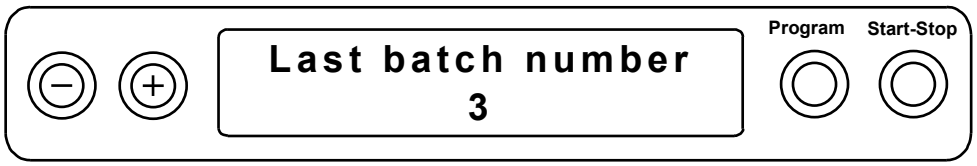
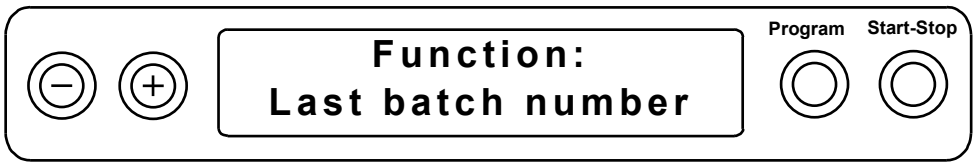
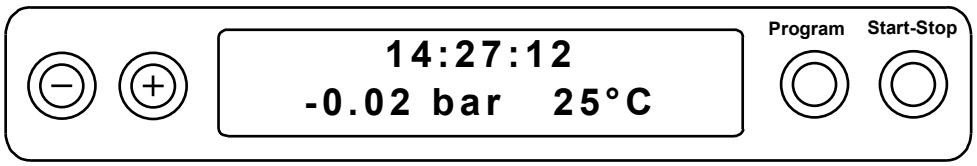
After removing wrapped sterile items, the wrapping should be checked for any signs of damage. If it is defective (e.g. split seals) then the sterilization of the items must be repeated after the items have been re-wrapped.

It is important for sterile storage that the items have been properly dried. The Cliniklav®25 provides very good drying if the program has not been interrupted before its completion and the autoclave has been properly loaded (see Section 4.3). Directly after sterilization there may still be residual condensation on the items or the container. Because the items are hot on removal, this will usually evaporate quickly. The German industrial standard DIN 58953 Part 7 Section 7 contains the following comment about residual moisture on paper wrapping or transparent sterilization paper after sterilization: "...small amounts of water on the wrapping are unproblematic, provided they have evaporated within 30 minutes after removal from the steam sterilizer....."

After cooling, wrapped sterilized objects should be stored in a place where they are **protected from dust** (e.g. instrument cupboard). Given proper storage, the sterilized objects can be stored up to 6 months according to DIN .8953-8:2003.

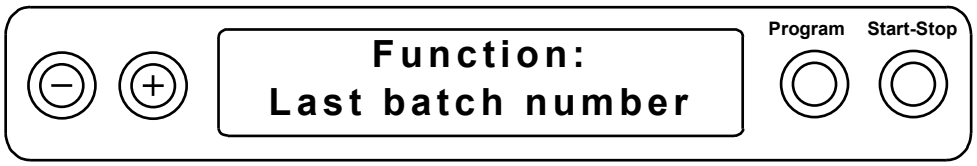
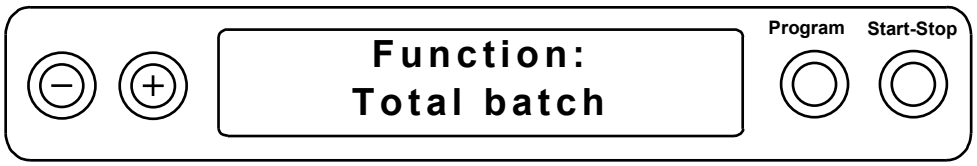
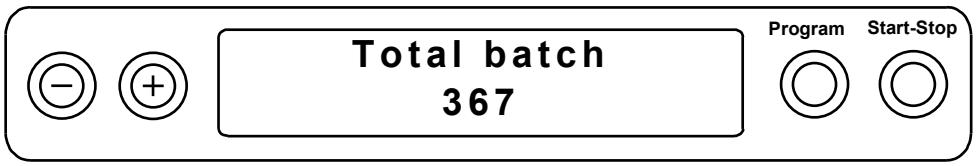
4.13 Display batch number

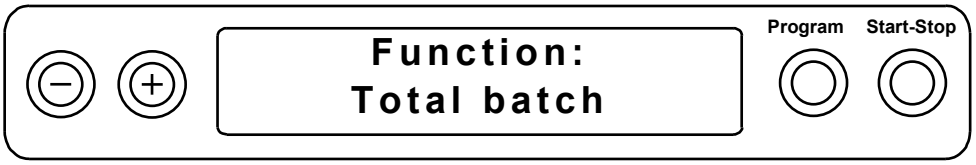
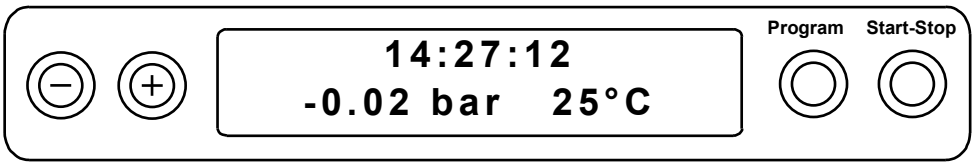
After every completed program you automatically see on the display the last batch number of the day.
You can also allow the display of the last batch number whenever necessary:

Operation		Display message
1.	Hold down "+" key and also press "-", Select "Function" menu, submenu "Last batch number".	
2.	Press key "Program". The display shows the submenu "Last batch number".	
4.	Close by pressing "Start-Stop", and return to the "Function" menu, then …	
5.	… press "Start-Stop" again to return to the starting point	

4.14 Display total batch number

The Cliniklav®25 keeps a running count of the total number of batches sterilized, and this is displayed as follows:

Operation		Display message
1.	Hold down "+" key and also press "-", Select "Function" menu, submenu "Last batch number".	
2.	Press "+" until the display shows the submenu "Total batch".	
3.	Press "Program", the display shows the current total batch number, e.g.:	

Operation		Display message
4.	Close by pressing "Start-Stop", and return to the "Function" menu, then	
5.	Press "Start-Stop" again to return to the starting point	

5 Logging

The European standard DIN EN 285 regulates the existence of an analogue or a digital register equipment for the batch documentation. In order to sterilize with the Cliniklav®25 in compliance with the standards it is necessary to connect a log printer, e. g. MELA*print*®42., or a Computer , e.g. with the documentation software MELA*trace*/MELA*view*.
In order to document the progress of the sterilization programs, then the processor memory stores logs of the last 40 programs.
These logs can be downloaded subsequently via the serial data and printer connection (RS232).
When the memory is full (40 program runs) then before the start of the next run the oldest log will automatically be overwritten. If an external printer or another output medium is connected (and operable) and the option "Immed. output? NO" has been selected, then confirmation will be requested before the oldest log is overwritten (see Section 9.1).

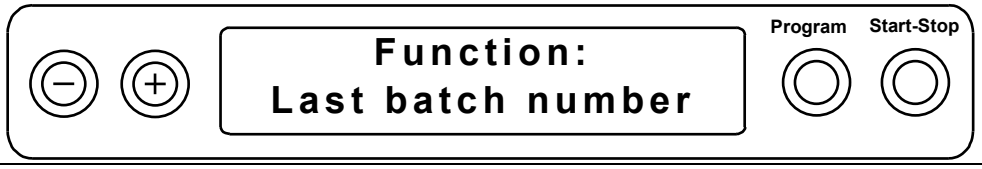
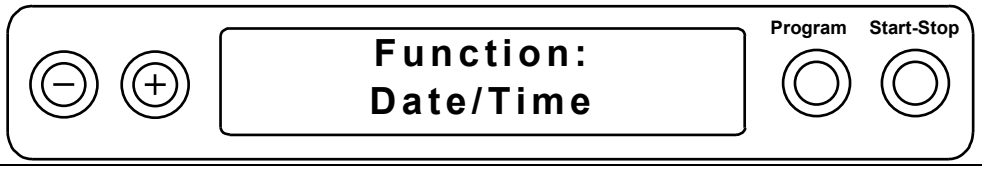
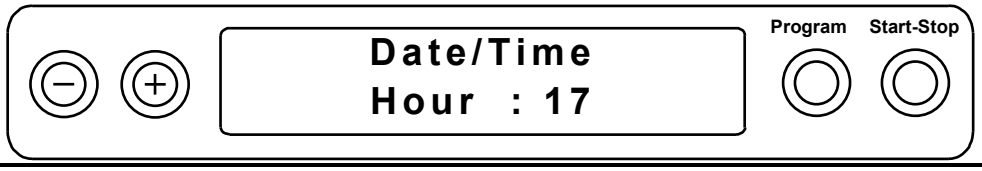
You can use the following listed devices for the batch documentation:

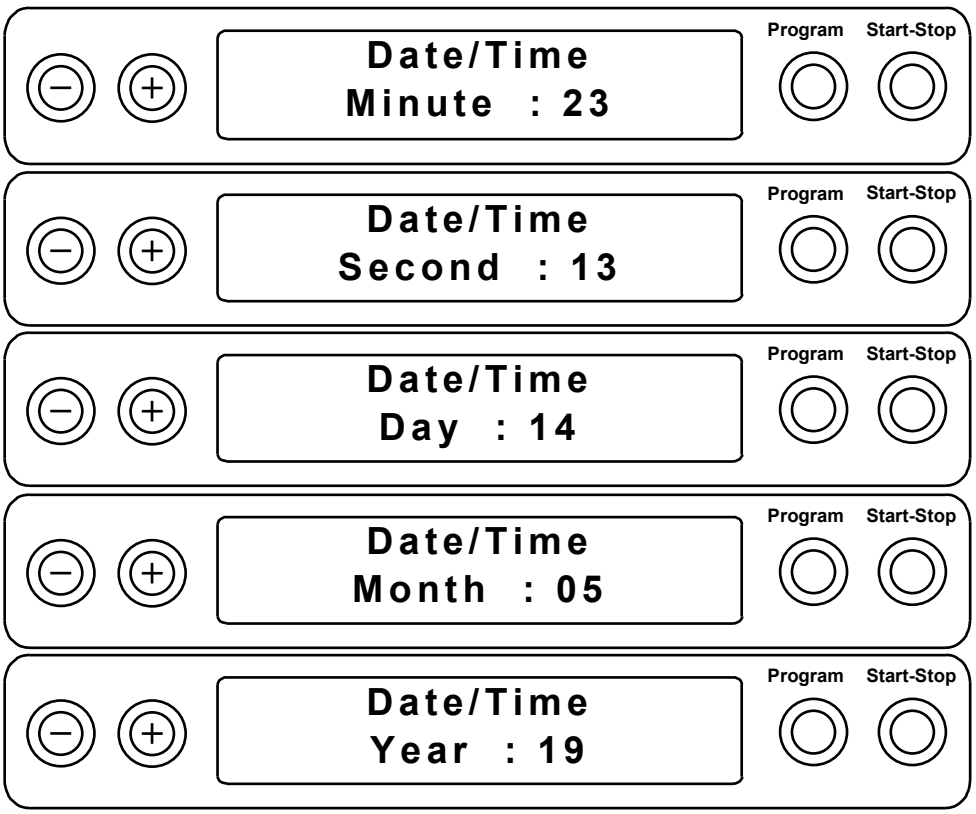
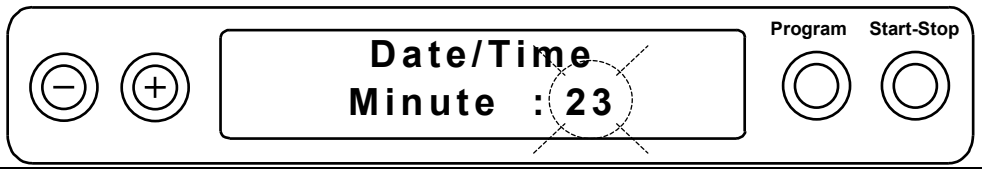
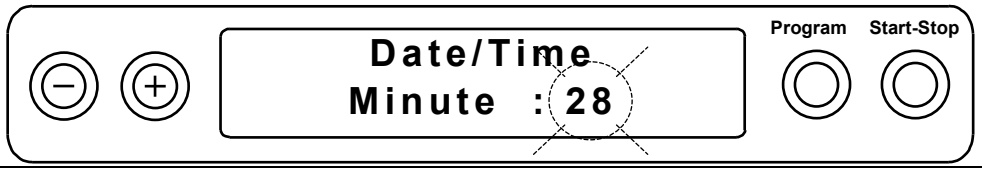
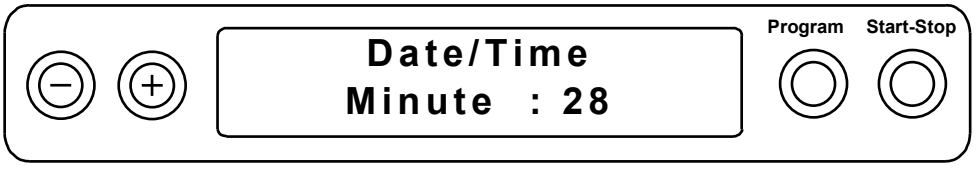
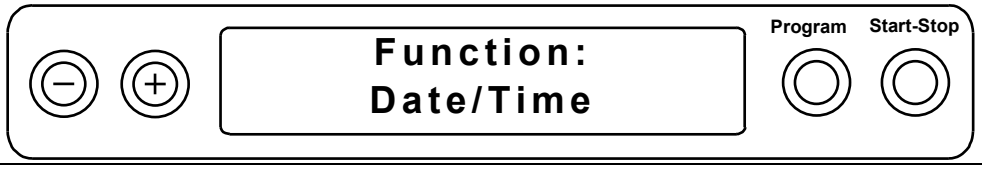
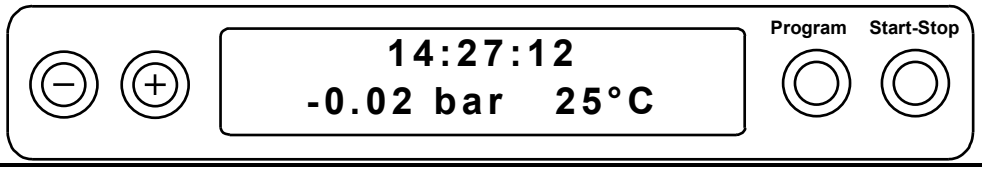
- Computer, e.g. with MELA*trace*/MELA*view*
- Log printer MELA*print*®42
- MELA*flash* CF-Card-Printer
- MELA*net* Box
- Modem

Hardware details and the nature of the batch documentation are provided in the following sub sections.

5.1 Setting date and time

The date and time can be reset if necessary (e.g. winter time/summer time) as follows:

Operation		Display message
1.	Hold down "+" button and also press "-" key. Select "Function" menu, submenu "Last batch number"	
2.	Press "+" (or "-"), until the display shows the submenu "Date/Time".	
3.	Press "Program", the display shows the current hour (24-hour clock) (here for example 17.00)	

Operation		Display message
4.	By pressing the "+" (or "-") key the following options can be selected:	
5.	After finding the required option, e.g. "Minute", press the "Program" key and the current value flashes.	
6.	Press "+" or "-" to increase or reduce the value:	
7.	Press "Program" to confirm the new value, which then stops flashing. If more adjustment are necessary, return to point 4 and begin again …	
8.	...or press "Start-Stop" to return to the "Function" menu and …	
9.	… press "Start-Stop" again to return to the starting point.	

5.2 Log printer MELA*print*®42 as output medium

If you have purchased a Cliniklav®25 with pre-installed log printer, and if you still cannot print out, then please continue below with Section 5.2.2.

5.2.1 Connecting the log printer MELA*print*®42

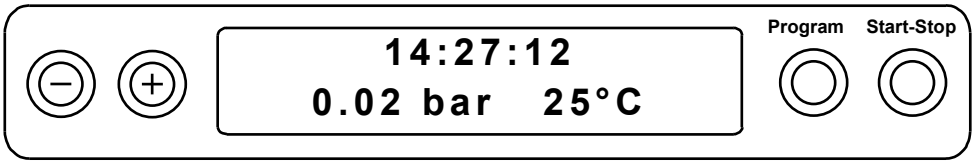
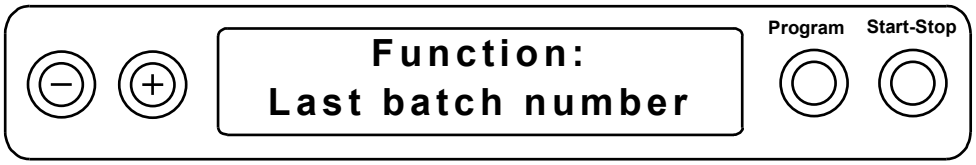
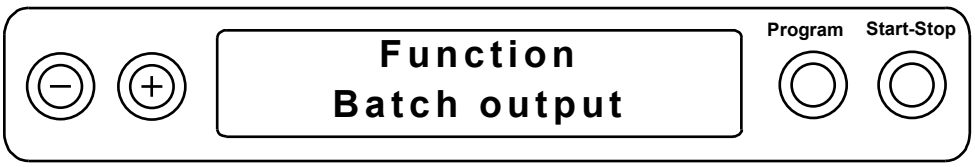
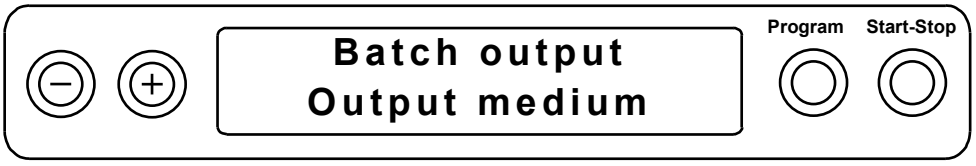
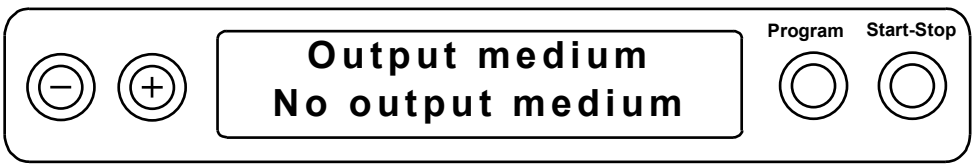
To connect a log printer (or another output medium) to the autoclave, you must hook up one end of the serial data- and printer cable to the 9-pin jack on the top of the autoclave (see section 2.1, Fig. 1, pos. 3), and the other end to the 25-pin connection jack on the rear of the printer. Securely insert the cable ends into the jacks, and screw down the threaded connections finger-tight.

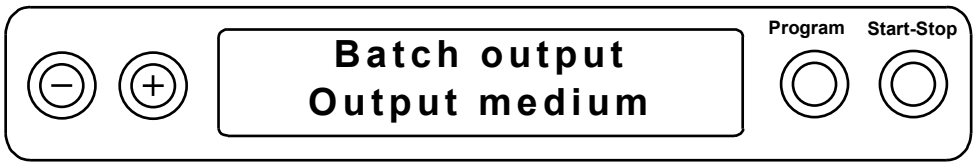
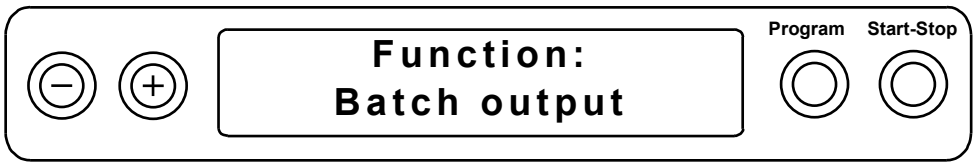
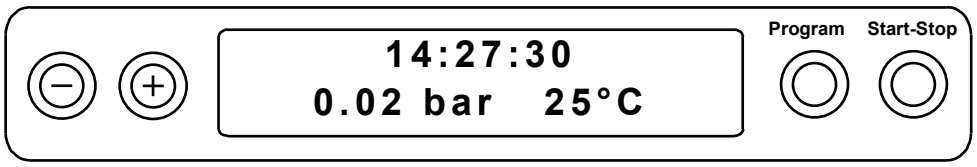
To provide power to the printer, plug the supplied power supply unit into the socket under the enclosure hood of the Cliniklav®25. Then insert the plug (low-voltage output of the power supply unit) into the power-supply jack on the rear of the printer.

For operation of the printer, please consult the instructions in its user manual.

5.2.2 Initialising the log printer MELA*print*®42

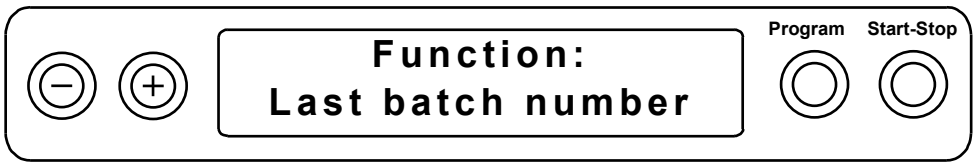
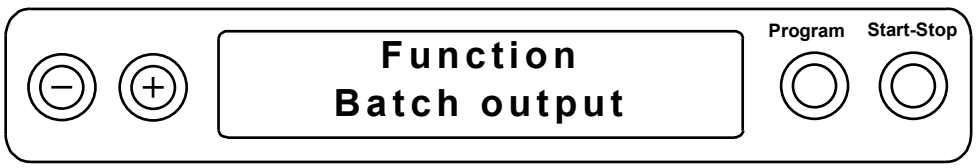
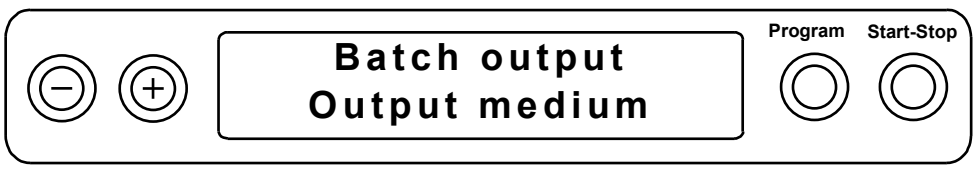
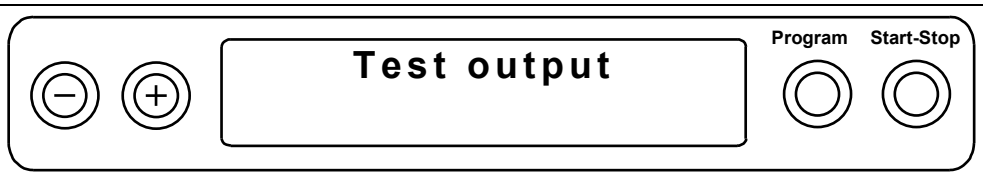
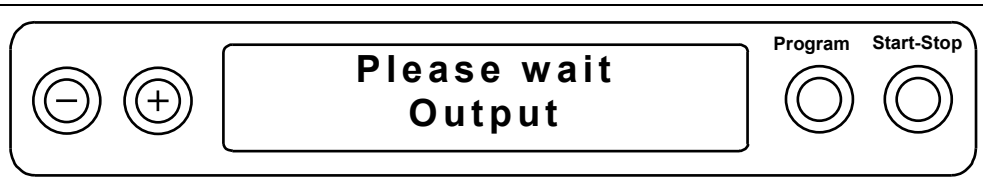
After connecting the printer to the autoclave it must be registered with the autoclave processing unit (initialised). Proceed as follows:

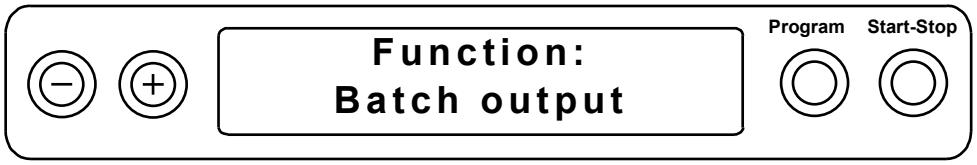
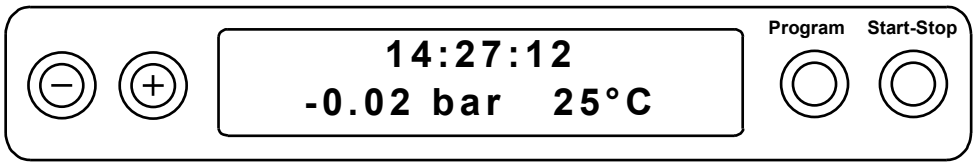
Operation		Display message
1.	Switch on autoclave. Display shows time, pressure and temperature.	
2.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Last batch number".	
3.	Navigate with key '+' (or "-') to the submenu "Batch output".	
4.	Press "Program" key, select "Batch output, submenu "output medium".	
5.	Press "Program" again, display shows current status e.g. "No output medium".	
6.	Press "+" (or "-") key until display shows "MELAprint".	

7.	Press "Program" key, confirm the setting, return to "Batch output" menu.	
8.	Press "Start-Stop" key, return to the "Function" menu.	
9.	Press "Start-Stop" key. Quit the "Function" menu and return to the initial display.	

5.3 Test output

In order to check the printer and its connection to the autoclave, a test log output can be made as follows:

Operation		Display message
1.	Hold down "+" key and also press "-" , Select "Function" menu, submenu "Print".	
2.	Navigate with key '+' (or "-') to the submenu "Batch output".	
3.	Press "Program" key, the display shows the menu "Batch output", submenu "output medium".	
4.	Press "+" (or "-") until the display shows "Test output".	
5.	Then press the "Program" key for a test output (or press "Start-Stop" to terminate)	

Operation		Display message
6.	Then press "Start-Stop" to return to the "Function" menu …	
7.	… and press "Start-Stop" again to return to the starting display.	

5.4 Computer as output medium

Logs and archives can also be kept by using a Computer. This requires a suitable connection between the serial port of the Computer and the serial data and printer connection of the autoclave.
For data transfer and data processing then you can install the documentation software MELA*trace*/ MELA*view* on your Computer.

5.5 Employing other devices as output medium

For installation and operation of other output devices (e.g. MELA*flash* CF-Card-Printer, MELA*net* Box) you find detailed information in the operating manual for the devices themselves.
In order to initialise the devices proceed as described in section 5.2.2, under step 6 select "MELAflash" or "MELAnet" as output medium.

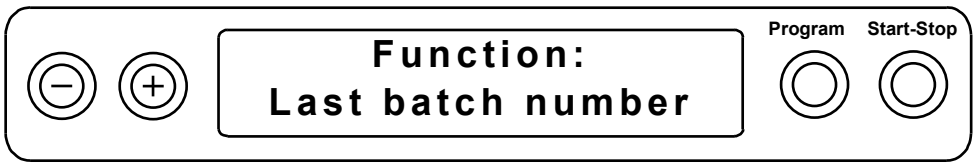
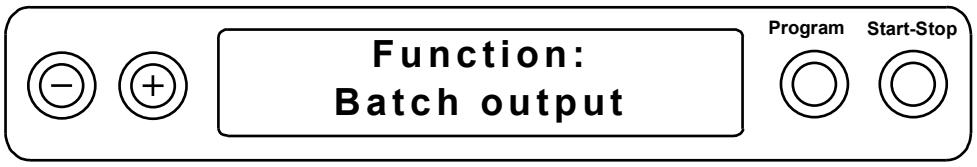
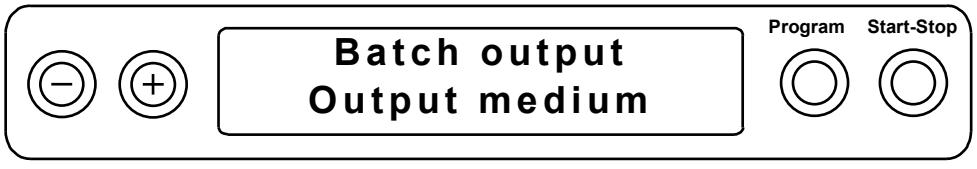
5.6 No output medium

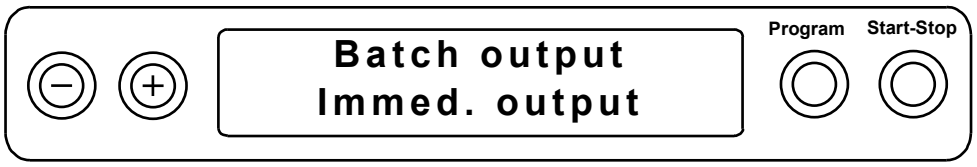
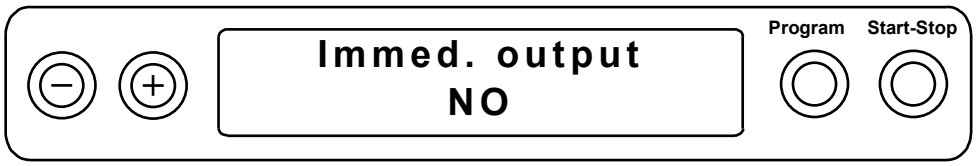
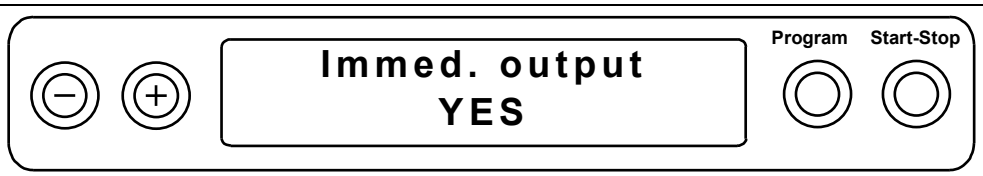
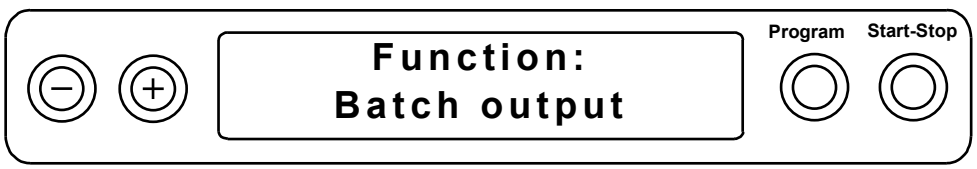
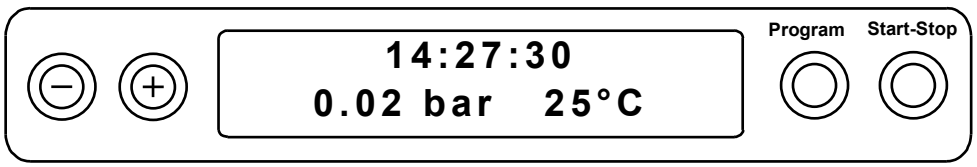
In order to select the option "No output medium" proceed as described as in section 5.2.2. Under point 6, however, use the "+" or "-" key to reach the setting "No output medium".

5.7 Output of the logs

5.7.1 Automatic immediate log output

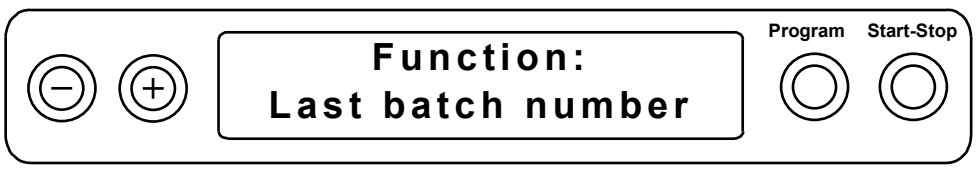
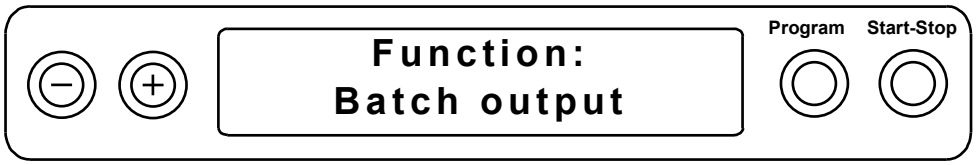
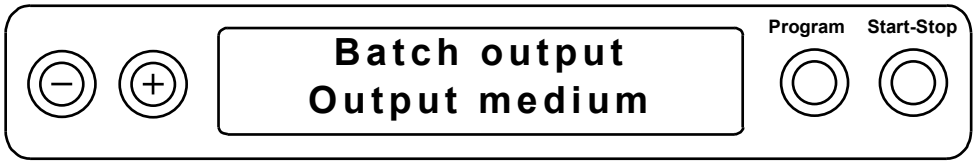
When a log printer or another output medium is fully installed, a log output can be produced automatically at the end of each program run by selecting the following options after switching on the autoclave:

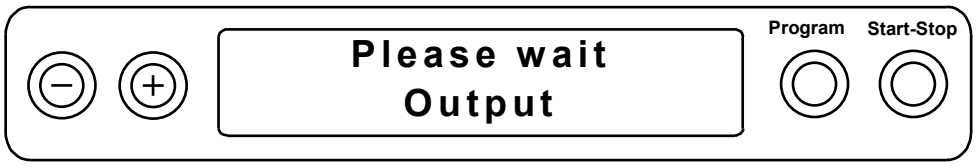
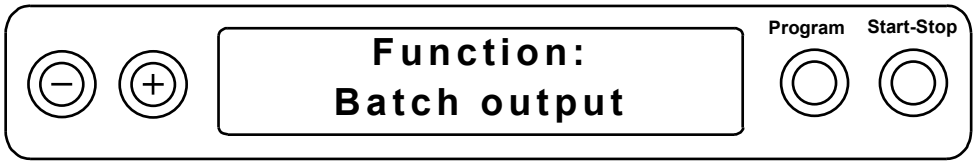
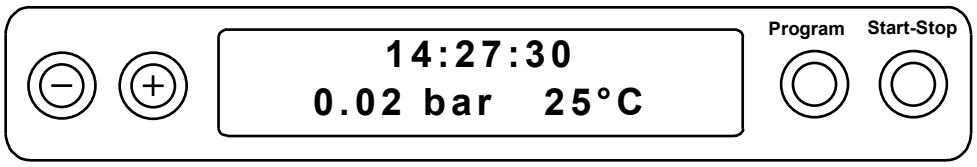
Operation		Display message
1.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Last batch number".	
2.	Navigate with key '+' (or "-') to the submenu "Batch output".	
3.	Press "Program" key, select "Batch output" menu ,submenu "Output medium".	

Operation		Display message
4.	Navigate with key '+' (or "-') to the submenu "Immed. output".	
5.	Press "Program", display shows current option, here e.g. "NO"	
6.	The key "Program" can be used to switch between "YES" and "NO". Press "Program" key, select "YES" option.	
7.	Press "Start-Stop" key, confirm the setting and return to "Function" menu, submenu "Batch output".	
8.	Press "Start-Stop" key, quit the "Function" menu and return to the initial display.	

5.7.2 Output selected logs subsequently

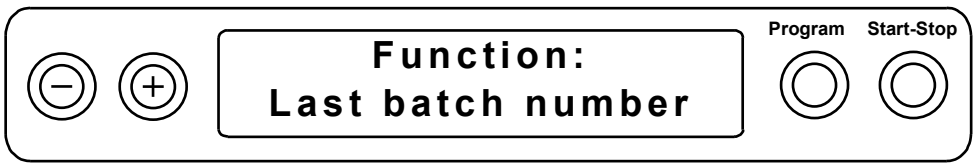
In order to output a log subsequently and independently from the time of the end of a program (an output medium is connected and initialised) proceed as follows:

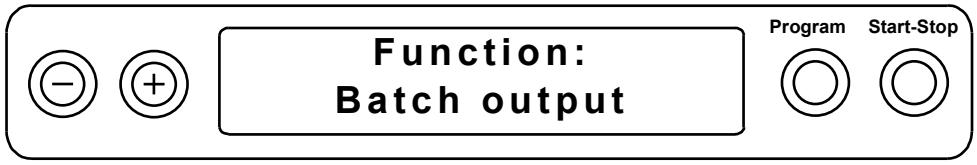
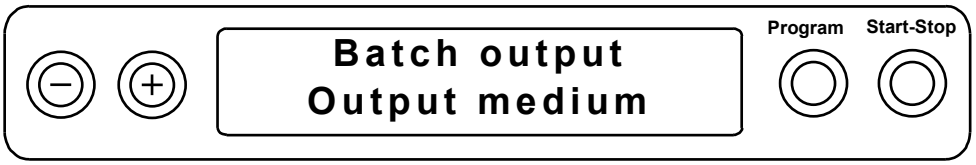
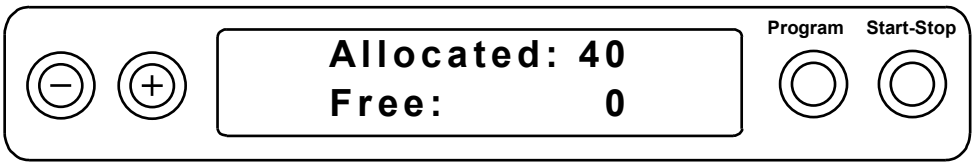
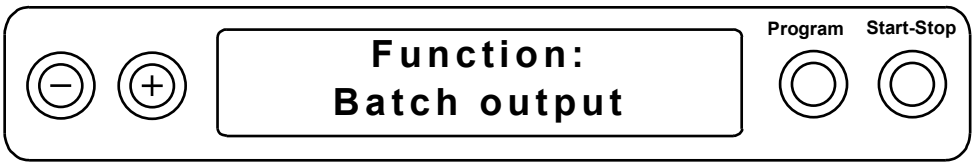
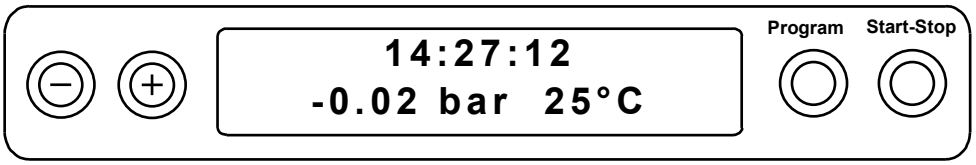
Operation		Display message
1.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Print".	
2.	Navigate with key '+' (or "-') to the submenu "Batch output".	
3.	Press "Program" key, select "Batch output" menu, submenu "Output medium".	

Operation		Display message
4.	Press "+" (or "-") until the submenu "Output last cycle" appears on the display.	
5.	Press "Program" key, the cycle log number flashes.	
6.	To select another number, press the "-" or "+" key until the right number is reached, e.g. here No. 25.	
7.	Press "Program" key to start the output of the selected cycle, (or to terminate press "Start-Stop" and return to the "Function" menu).	
8.	If you wish to output further cycles then return to point 4. or...	
9.	... to terminate press "Start-Stop" and return to the "Function" menu.	
10.	Press the "Start-Stop" key to return to the initial display.	

5.7.3 Display protocol memory

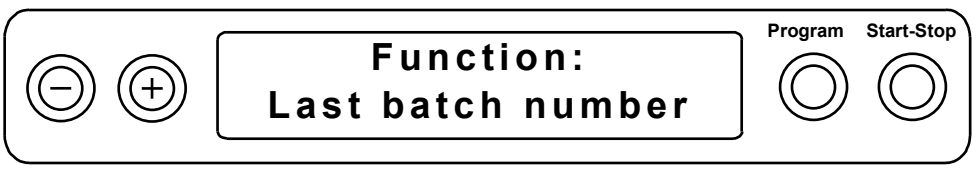
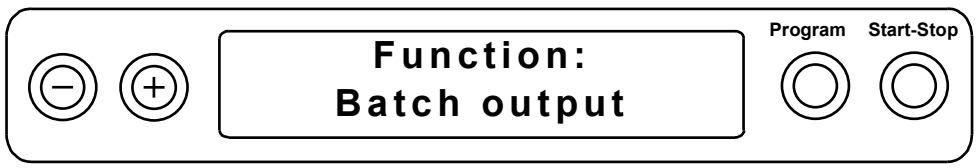
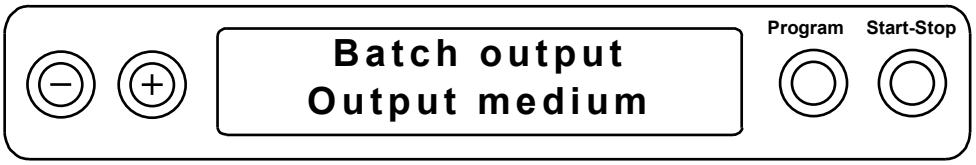
With a connected and initialised printer (or another output medium), the status of the protocol memory can be displayed as follows:

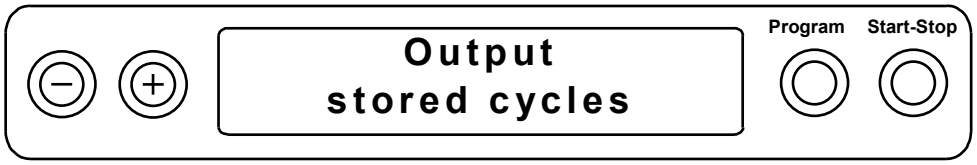
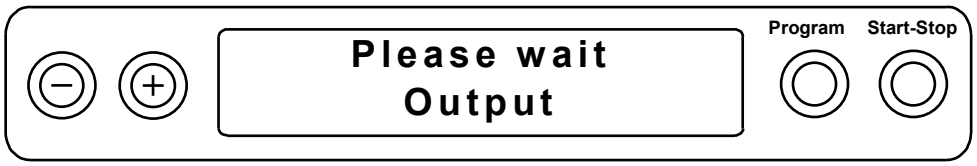
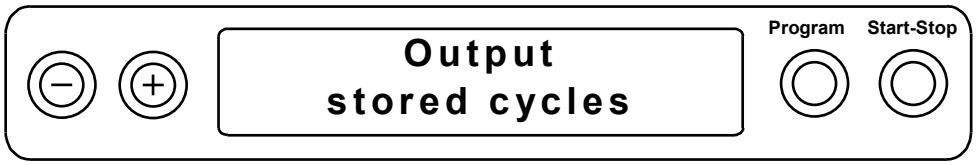
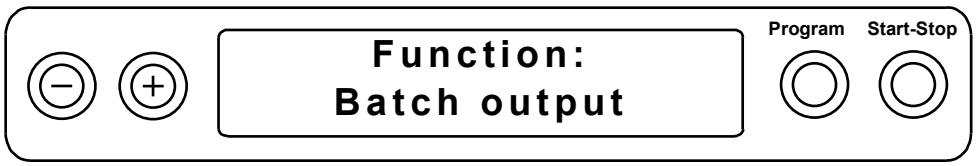
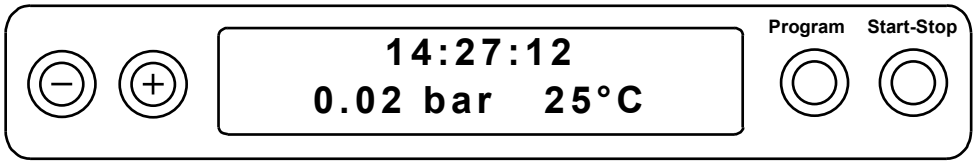
Operation		Display message
1.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Last batch number.	

Operation		Display message
	Navigate with key '+' (or "-') to the submenu "Batch output".	
2.	Press "Program" key, select "Batch output" menu, submenu "Output medium"	
3.	Press "+" (or "-") key until the display shows the memory status, e.g.:	
4.	Press the "Start-Stop" to return to the "Function" menu …	
5.	… and press "Start-Stop" again to return to the starting display.	

5.7.4 Output all stored logs

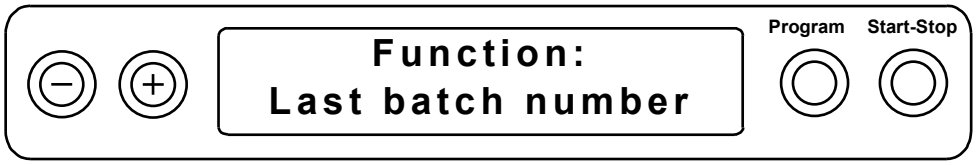
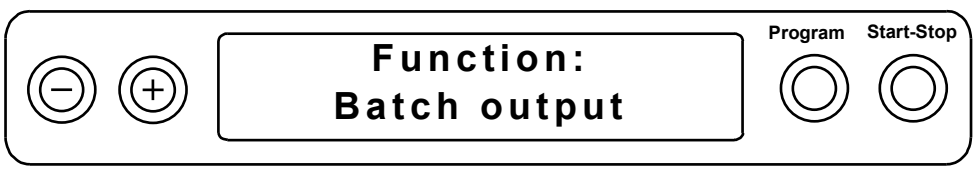
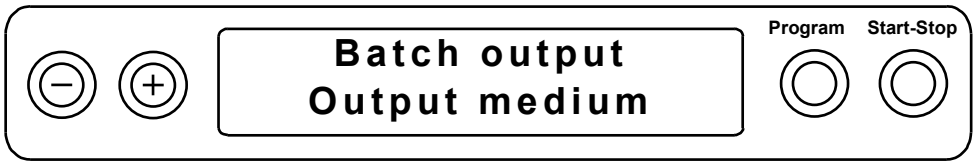
In order to output all stored cycle logs (with a connected and initialised printer or another output medium) then select the following options after switching on the autoclave:

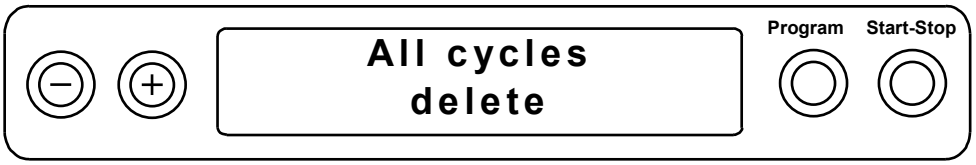
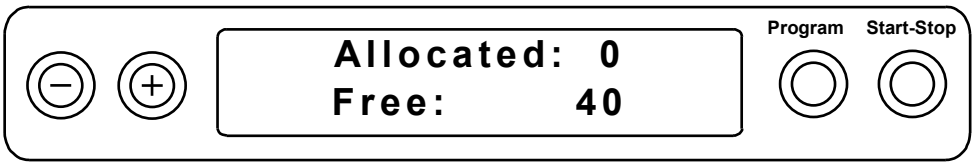
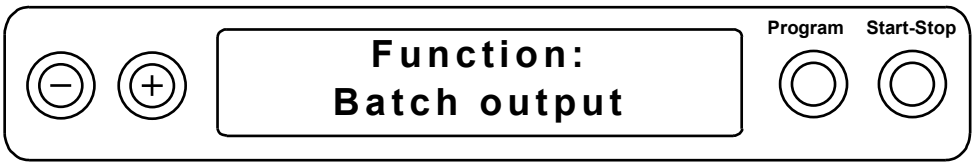
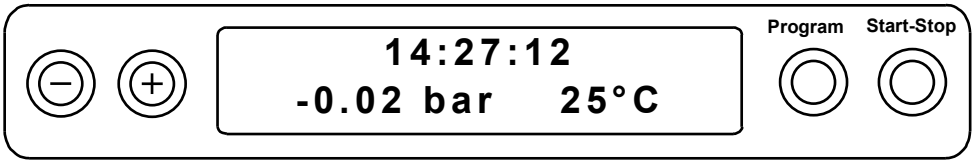
Operation		Display message
1.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Print".	
	Navigate with key '+' (or "-') to the submenu "Batch output".	
2.	Press "Program" key, select "Batch output" menu, submenu "Output medium".	

Operation		Display message
3.	Press "+" (or "-") until the submenu "Output stored cycles" appears on the display.	
4.	Press "Program" key to start the output of all the stored logs (up to 40!), or to terminate press "Start-Stop" and return to the "Function" menu (Once printing has started termination is only possibly by switching off the power!)	
5.	When the output is complete, the display again shows the submenu :	
6.	Press the "Start-Stop" key to return to the "Function" menu …	
7.	… and then press "Start-Stop" again to return to the initial display.	

5.7.5 Delete all stored logs

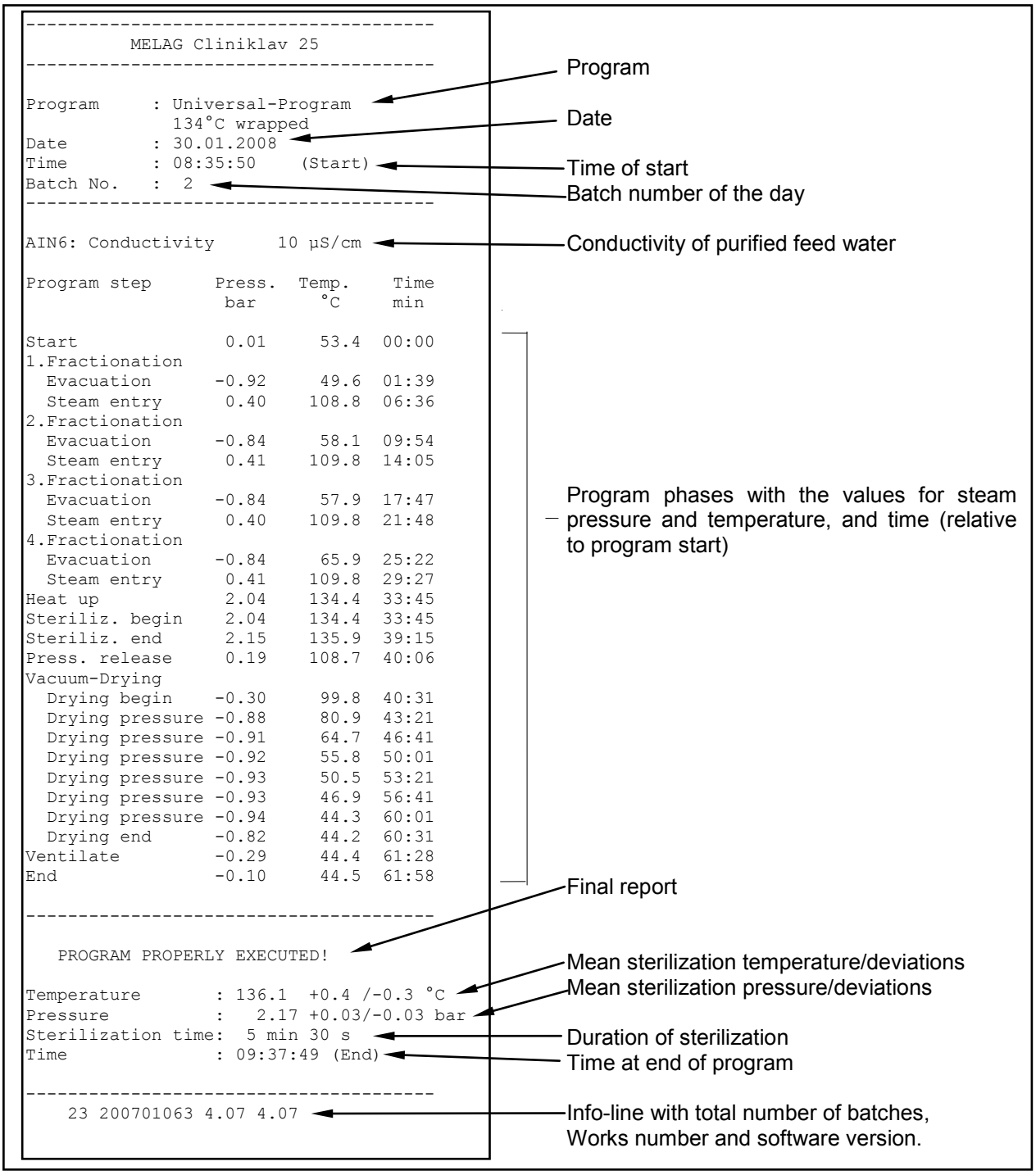
In order to delete all stored logs (e.g. in the event of the warning message "Protocol memory full", with the option "Immed. output? NO", selected (see section 5.7.1), then after switching on the autoclave proceed as follows:

Operation		Display message
1.	Hold down "+" key and also press "-" key. Select "Function" menu, submenu "Print".	
	Navigate with key '+' (or "-') to the submenu "Batch output".	
2.	Press "Program" key, select "Batch output" menu, submenu "Output medium" and press key "Program".	

Operation		Display message
3.	Press "+" (or "-") until the display shows "Delete all cycles".	
4.	Press the "Program" key to delete all stored logs (or press "Start-Stop" to terminate).	
5.	Then press "Start-Stop" to return to "Function" menu …	
6.	… and press "Start-Stop" again to return to the starting display.	

5.8 Read log files correctly

The log file contains the following information:



6 Operating pauses

In general, the door should only be leant to during operational pauses in order to reduce wear on the door seal and to avoid premature failure or sticking.
In the event of longer breaks, such as during vacations, the cooling water supply should be turned off (and the feed water supply from the water treatment unit if one is connected). We recommend that you do not disconnect the power supply.
If you allow the autoclave to remain unused for a lengthy period of time, we recommend to perform a sterilization cycle with an empty sterilization chamber, before normal use again.

6.1 Sterilization frequency

After completing or terminating the drying phase, the autoclave can be reloaded and started immediately. No pauses in operation are necessary.

6.2 Shut-down/Transport

When closing down and transporting the autoclave you should proceed as follows:

- Switch off the power.
- Disconnect from the mains; allow the autoclave to cool down.
- Turn off cooling water and feed water supplies.
- Disconnect pipes at rear of autoclave.
- If transporting the autoclave with trays and mounting in place, then protect the inside surface of the door by including a sheet of foam or similar material.
- When setting the autoclave up for re-use after transport or repairs then proceed in accordance with section 3.

7 Maintenance

7.1 Cleaning

The tray assembly and the autoclave chamber including the contact area of the door gasket and the door opening should be inspected thoroughly at least once a week for signs of damage or soiling. If necessary, wipe out the autoclave chamber using a **lint-free cloth** and surgical spirits. This involves withdrawing the trays and mounting. Stubborn spots can be removed using small amounts of a mild commercial steel cleaning agent (pH-levels from 5 to 8). Care must be taken to ensure that cleaning agent does not get into the pipes attached to the autoclave chamber. The cleaning agent must not contain chlorine and should not be alkaline. Do not use abrasive cleaning pads, steel wool, or brushes.
Inspect the door seal every week for signs of damage and soiling, and if necessary clean it with a mild commercial liquid cleaning agent (pH-levels from 5 to 8) or with surgical spirits. If necessary, the seal can be removed.
The bolt of the door lock (right side) and the door hinge (left side) must be regularly lubricated with silicone grease, in order to ensure that the door can easily be locked and unlocked, without unnecessary wear.
The outer parts of the autoclave can be cleaned with a mild commercial cleaning agent or with surgical spirits.
If the feed water is not provided directly but is stored in a container then this should be inspected every time it is refilled to make sure it is clean. If necessary it should be cleaned before refilling. If you have a MELAG storage container then please note the instruction on the label.

7.2 Preparation of instruments

MELAG non-rusting materials
All parts of the Cliniklav®25 which come into contact with steam are made of non-rusting material. The autoclave chamber and the steam conducting parts are made of stainless steel, the door is made of anodised aluminium and the threaded fittings and solenoid valves are made of brass.
Drag-in rust
The use of non-rusting materials excludes the formation of rust as a result of the components of the autoclave. Where rust forms on the autoclave or the items to be sterilized, investigations have repeatedly shown that this rust has been brought in from other sources. It should be borne in mind that rust can form even on best quality stainless steel instruments, for example as a result of improper treatment with chemical cleaning agents or disinfectant during preparation for sterilization.
Preparations of items for sterilization
The example of drag-in rust shows how important it is to prepare items properly for sterilization, and particularly the following points:
hand pieces and angles should be cleaned before the sterilization in accordance with the manufacturers instructions and maintained (e.g. oiled). The remaining instruments should be disinfected and cleaned immediately after use in accordance with UVV/VBG 103 with a disinfectant and/or cleaning solution. The solutions should be used in the correct concentration and care should be taken to observe the immersion times precisely!

It is advisable to make use of appropriate cleaning aids such as ultrasonic cleaning units, cleaning and maintenance equipment for hand pieces and contra-angles, or thermo-disinfecting systems.
Cleaning the instruments before sterilization is very important in order to avoid introducing contamination which can separate from the instruments under steam pressure during sterilization and block filters, jets and valves of the autoclave. In particular, locks, joints and hinges should be thoroughly cleaned with a brush. Cleaning and disinfecting agents should be washed off the instruments thoroughly in running water, again with a brush. Residues of cleaning and disinfectant chemicals must not find their way into the autoclave, since they can lead to corrosion! Swill finally with demineralized water and then dry the instruments.
Turbines and transfer instruments should be oiled in accordance with manufacturer's instructions in order to ensure a long life for these components.

Brand-new instruments

The cleaning procedures described above are also necessary for brand-new instruments, since these often carry very small amounts of oil, fat and soiling from the manufacturing process.

Note: The instructions of the instrument manufacturers concerning first-time sterilization and re-sterilization should be followed carefully.

7.3 Rust formation = Drag-in rust

As already explained, the non-rusting materials used in the autoclave cannot cause rust formation in the autoclave!
Where rust forms this is "drag-in rust". This originates from instruments or other metal items carrying traces of rust, even though they are made of stainless steel, or which are made of normal steel but which have a damaged galvanic coating. Often, a single rusty instrument is enough to pass rust on to other instruments or to lead to film rust forming in the autoclave resulting to corrosion damage. Drag-in rust must be removed from the affected instruments or from the autoclave and mounting using a mild commercial cleaning agent for stainless steel. Do not use steel wool, a wire brush or other abrasive cleaners! Spots can be removed with a damp, lint-free cloth or a cloth with surgical spirits or alcohol.

7.4 Use qualitatively high-grade feed water

Quality requirements

For steam sterilization it is necessary to use high quality distilled or demineralized water.
The DIN EN 285:2009 recommends to notice the guide values for water quality in accordance with the appendix B, table B.1.

Guide values for water quality in accordance with the CEN standard DIN EN 285:2009, Appendix B

Table B.1 – impurities in the feed water for an assigned steam generator

Substance/properties	***Feed water***
Evaporation residue	≤ 10 mg/l
Silicates	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Residues of heavy metals apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 2 mg/l
Phosphate	≤ 0.5 mg/l
Conductivity (at 25 °C)	≤ 5 µS/cm *)
pH value	5 - 7
Appearance	without colour, without residue
Hardness	≤ 0.02 mmol/l

*) µ *) µS/cm = micro-Siemens per centimetre

Table B2 - Impurities in the condensate of a sterilizer steam supply, measured in the feed line.

Substance/properties	*Condensate*
Silicates	≤ 0.1 mg/l
Iron	≤ 0.1 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metals apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 0.1 mg/l
Phosphate	≤ 0.1 mg/l
Conductivity	≤ 3 µS/cm *)
pH value	≤ 5 - 7
Appearance	without colour, no deposits
Hardness	0.02 mmol/l

The special construction of the steam generator and the procedure employed to generate the steam (integrated gas venting) makes higher conductivity values permissible.
As a result, the value of 5 recommenced in accordance with DIN EN 285:2009 in table 1 can be exceeded. At 15 S/cm, the water treatment unit mixed-bed resin cartridge should be replaced. Once conductivity has reached 20 S/cm the display issues a warning message. At this point at the latest, the mixed-bed resin cartridge should be replaced/the unit should be checked.

7.5 Avoid formation of spots

Formation of spots on instruments
The extent to which spots form on instruments depends on the quality of the water used to produce the steam.

7.6 Renewed Qualification

DIN EN 17665 recommends a new qualification at regular intervals.
A new standard DIN 58946-7 is currently in preparation. This will make concrete proposals for the initial validation, the renewed qualification as well as daily routine operation.

7.7 Maintenance recommendations

Regular maintenance of the autoclave is important if it is to have a long life and remain in good working order. MELAG recommends that the Cliniklav®25 be serviced annually by a trained technician in accordance with maintenance instructions for this autoclave. The annual service includes a visual inspection and a test of operational functions. As well as all essential components and electrical elements, parts are also inspected for wear and replaced as necessary.
A maintenance reminder appears on the display every two years or after 1000 sterilizations.
Consult your dealer of the MELAG Customer service if you have any questions relating to servicing and maintenance.

Notice
National pressure vessel requirements may ask the user of pressure vessel, such as autoclaves, to carry out safety inspections. Please check the download area from our website and find our recommendation in accordance with German requirements. For more information ask your local authorities.

8 Function test

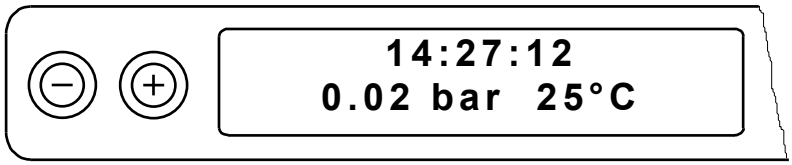
8.1 Water quality (conductivity)

The conductivity should be checked every day before starting routine operation.

NOTE

If the autoclave is continued operating even if the warning message is issued as soon as the conductivity value has reached 20 µS/cm a Helix test body should be added to each sterilization cycle to check the steam for non-condensable gases (see next section). Once the conductivity has reached 35 µS/cm the display issues a malfunction message. A program start is then no longer possible.

By repeatedly pressing the "**-**" key then the preheating temperature of the chamber and the conductivity of the purified feed water used for steam generation can be displayed alternately.

Operation		Display message
1.	Press down the "-" key to display the conductivity of the feed water in µS/cm.	
	Release the "-" key to return to the basic display (as shown here) or the program status	

8.2 Helix test body system MELA*control*®/PRO

The test body system MELA*control*®/MELA*control*®PRO is an indicator and batch control system fulfilling the requirements of DIN EN 867-5. It consists of a test body, the Helix and an indicator strip. If sterilizing category "critical B‘‘ instruments, you should add the MELA*control*®/PRO test body to every sterilization cycle as a batch control. Regardless of this, you can perform a steam penetration test at any time using MELA*control*®/PRO in the Universal-Program. Specified use of the Helix test body can result in the colouration of the plastic surface. This colouration exercises no influence on the functionality of the Helix test body.

8.3 Continuous monitoring of sterilization process

The electronic parameter control means that all relevant parameters are constantly monitored a compared with standard process data, so that error reports can be made immediately. If a program is completed without problems then on its completion there is an "End" message. The log output contains a corresponding report.

The operator of the autoclave can check the progress of the program at any time by means of the values shown on the display (or after its completion by means of the log output).

9 Operational errors/Malfunctions

If the autoclave does not seem to be working properly (e.g. poor drying, warnings, or error reports) then follow these instructions in order to exclude possible operational errors.
Following these instructions continue to work with the autoclave. If the malfunction occurs repeatedly then contact your dealer, and authorised MELAG customer service or contact MELAG directly. You should describe the problem precisely and include the works number of your autoclave.

9.1 Warning messages

For the following warning messages, please observe the comments made and restart the program in question. If the warning occurs repeatedly please consult your specialist dealer.

Warning message	Cause/Remedy
WARNING! **Door open** **No start possible** **Acknowledge with button '-'**	Door contact (see section 2.1, Fig. 2, pos. 19) is not closed when the autoclave is started: • The door is not correctly closed. • Hold down the door opener until the message “Door closed” appears in the display (see section 4.7).
WARNING! **No cooling water** **Check Tap water** **Acknowledge with button '-'** **Stop/ end 0.02 bar 35°C**	Cooling water switch has not opened: • Check water inlet, open water tap • Check pressure of mains water supply pressure (if too low it may be necessary to install a pressure booster) • Check if the motor protection switch has tripped (Fig. 2, pos. 17) (no sound from vacuum pump). Press button of protection switch back down.

WARNING!
No feed water
Feed water Check supply
No start possible
Acknowledge with button '-'
	Float switch for the supply of distilled or demineralized water has not closed (when filling the steam generator):
	• If you have a water storage container:
	  • Check the water level in the container. If necessary refill with purified water.
	  • Check that the intake tube is free from twists or kinks
	  • Check that the height difference between autoclave and water level is not too great (max. 1.5 metres)
	• If you have a MELA*dem*® 55 water treatment unit:
	  • Check the water treatment unit. If necessary open the water intake tap. If the pressure water storage unit is empty wait approximately 1 hour before restarting the program. If the message reappears repeatedly, have the water treatment unit serviced.
	If the autoclave is being used for the first time or is being restarted after a break then this message may simply be caused by the fact that the tubes were initially empty - just repeat the start procedure.

Warning message	Cause/Remedy
Feed water quality bad **Feed water check quality** **Feed water check quality**	Conductivity of the demineralized or distilled water is above the first limit value of 20 µS/cm, a start is possible by pressing the "Start" key once more: • If water is from a storage container, then empty the container, clean it thoroughly with distilled or demineralized water, and refill with water which meets the purity specifications. • If water is from a MELA*dem*® 55 water treatment unit: The demineralization cartridge in the reverse osmosis unit may be exhausted. Exchange in accordance with the operating manual. • Water from other water treatment units: Exchange the demineralization/deionisation unit in accordance with the manufacturer's instructions. After taking the appropriate steps, carry out the program start. When starting for the first time after exchanging the purified water container, or after maintenance of the water purification equipment, there may be another report because at first the supply tube and/or measuring cell will not have been washed out with fresh, pure water. ☞ If the mixed-bed resin cannot be replaced immediately a Helix test body, e.g. MELA*control*®/PRO should be added to each sterilization cycle.
Feed water quality insufficient **No start possible** **Acknowledge with button '-'**	Conductivity of the demineralized or distilled water exceeds the second limit value of 35 µS/cm - a program start is no longer possible: • Proceed as above for "Water quality bad".
WARNING! **Sterile filter Replace** **Acknowledge with button '-'**	The pressure for the ventilation drying lies outside the permitted range. The meassage comes at the end of the program, and as the last line of the log file: • The sterile filter may be clogged or torn. Exchange the sterile filter (MELAG Art. No. 20160).
Output medium not ready	Communication with the log printer via the serial data and printer connection or another output medium been interrupted. This message appears when a log cannot be printed out. It is displayed for 20 seconds. If the output medium becomes operational during this period the cycle log is printed out: • The autoclave may be operated without an output medium. Check under the menu "Function" → Batch output → Output medium that the option "No output medium" has been selected. (see section 5.6) • Check the cable connection between the printer and the autoclave. • Check the power supply to the printer. In the

Warning message	Cause/Remedy
	MELA*print*®42 the red light should indicate 'power on' • The printer may be "Offline". Select "online" (MELA*print*®42, press "SEL" button, green LED "SEL" should shine)
Protocol memory full	The internal protocol memory is full (40 cycles), a output medium is registered, and in the menu Function → Batch output → the option "Immed. output? NO" is selected. The message is displayed when a program is started. Pressing the "Start/Stop" key again deleted the message and the program starts: • You can continue operations simply by pressing the "Start/Stop" key twice when you start a program. • Select "Immed. output? YES" (see section 5.7.1) • Delete stored logs (see section 5.7.5), if necessary print-out all stored cycle logs first (see section 5.7.4) In the menu Function → "Batch output" → "Output medium", select the "No output" option (see section 5.6)
Excecute service please	The service message is activated after a certain number of batches or a set operating period, when a service is due. The message appears before the start of every program. If you press the "Start/Stop" key again the message is deleted and the program starts. • You can continue operations, by simply pressing the "Start/Stop" key twice when you start a program. • Have a service carried out as recommended by an authorised MELAG servicing company or your specialist dealer. The cycle counter for servicing should be reset during the service.
Test unsuccessful Leak rate: 3.2	The leak rate during the vacuum test exceeds the limit value: • Check and if necessary clean the door seal and the rim of the chamber • Repeat the vacuum test with a completely cold autoclave If no other malfunction messages occur during operation, you can continue to use the autoclave until the regular service, when the cause of the leak will be identified.

9.2 Malfunction messages

Malfunctions are generally reported by an "Error" on the display with the number of the error and its short name.
Malfunction messages may occur without a program start (when the power is switched on or soon after), or during a program.
If errors are reported during a program, then in addition to the error report the program will also be stopped. This may be accompanied by the equilibration of the pressure in the autoclave, and in this case the error message will alternate with the messages "Pressure release", or "Ventilation", and "End".
After the termination, the display will alternately show the error message and "Acknowledge with button '-' " and then "Stop/End ". Pressing "-" deleted the error message (if the error is not permanent). Until you have quit the malfunction message the autoclave door cannot be opened. If a program has been prematurely terminated in this way the autoclave load must always be regarded as being **not sterilized**. We recommend that you unload the autoclave, carry out a sterilization cycle without any load (the drying may be impaired for this first cycle) and then reload the autoclave and repeat the interrupted operation cycle.
If an output medium is connected and "Immed. output? YES" is selected, a log will automatically be printed out at the end of the termination.
The log output shows the full name of the error, and if a program has been interrupted before completion it will also show "Load not sterile". The following list gives malfunction messages, the cause and possible remedies.

Error messages	Causes/Remedy
Malfunction 1: Vacuum system	The monitoring time for reaching the evacuation pressure for the individual pressure cycles, pressure release, or for reaching the minimum drying pressure has been exceeded: • Check that the door seal and the lip of the opening to the pressure chamber are intact and clean. • Check that the outflow of condensate is not obstructed by fallen instruments, pieces of filter paper, etc. on the floor of the pressure chamber. • Check for leaks using the "Vacuum test" program. If this occurs repeatedly, inform your specialist dealer.
Malfunction 2: Steam generator	The monitoring time for a heating phase or for reaching the sterilization pressure has been exceeded: • Maximum load exceeded • Voltage of mains power supply is too low; check mains supply; try autoclave on different power circuit. If this occurs repeatedly, inform your specialist dealer.
Malfunction 4: Pressure release	The monitoring time for pressure release was exceeded: • Check that the cooling water outflow allows steady drainage, without kinks. If this occurs repeatedly, inform your specialist dealer.
Malfunction 6: Ventilation	The monitoring time for the ventilation of the pressure chamber was exceeded. • The sterile filter is clogged, there will have been an earlier warning message (see section 9.1). • Exchange filter.
Malfunction 8: Time base	Maximum difference between the program duration and the internal clock exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 9: Door open	Door not closed properly • Press grip down until contact is made (display should then show "Door closed")! If this occurs repeatedly, inform your specialist dealer.
Malfunction 10: Overh. steam gener.	The capillary tube level regulator is open at the start of the program (error report immediately after start), or the monitoring time until refilling with demineralized or distilled water during the program (until the end of sterilization) is exceeded: • This problem can arise because after stopping a program and immediately restarting - wait for two minutes and try starting again. • If this occurs repeatedly, inform your specialist dealer.
Malfunction 13: No cooling water	The cooling water pressure switch has closed during the program (see message "**Warning! No cooling water**" - page 37).
Malfunction 14: No feed water	The flow monitor for the demineralized/distilled water supply does not close during the program (see message "**Warning! No feed water**" - page 37).

Malfunction 18: Sensor: ... Input: ...	The internal testing of the sensors for temperature, pressure or conductivity showed an excessive deviation, the malfunction can be reported on switching on the autoclave or in the course of a program: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 26: A/D-Converter	The limit deviation for internal analogue/digital signal conversion has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 27: Temp.Sens.def 1,2	The limit deviation between the two sensors for the steam temperature has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 31: System leak	During the Vacuum test program the pressure was too high (very large leak): • Repeat the vacuum test, and if there is another malfunction message inform your specialist dealer.
Malfunction 32: Power failure **Sterile filter sterilize**	After starting the program there was a loss of power. The error report is received when the electricity supply is restored: • Check the mains power supply installation, if no errors can be found, inform the service agent. If there is a loss of power when the chamber is under pressure, then there will be an additional reminder to sterilize the sterile filter, since this may have become moist and non-sterile: • Remove the sterile filter at the rear of the autoclave. • Sterilize the filter using the Quick-Program S. • Then replace the filter.
Malfunction 33: Press. release	The time limit for the steam generator to reach the necessary pressure has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 34: Sterilization TU1	The minimum sterilization temperature has not been reached: • Reduce the size of the load. • If this occurs repeatedly, inform your specialist dealer.
Malfunction 35: Sterilization TO1	The maximum sterilization temperature has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 36: Sterilization DU	Sterilization pressure falls below the minimum level: • Reduce the size of the load. • If this occurs repeatedly, inform your specialist dealer.
Malfunction 37: Sterilization DO	The maximum sterilization pressure has been exceeded: • If this occurs repeatedly, inform your specialist dealer.
Malfunction 38: Sterilization TD1	The difference between measured and theoretical temperature is too large: • If this occurs repeatedly, inform your specialist dealer.

WARNING! **Overtemp. display**	Defective cooling fan, defective temperature sensor (Input 4), air supply to the cooling fan at the back plane is covered or hindered e.g. by extreme soiling or dust • Check if the vent opening at the back plane of the autoclave is covered or hindered • Let the autoclave cool down for 30 – 60 min, then restart the autoclave If this occurs repeatedly, inform your specialist dealer or After-sales Service
Malfunction 50: **Motor protect. V-pump**	The message is displayed at the start of a program, if the protective motor switch (DIN 7) triggers –Start of a program not possible. An error log is putted out. Possible causes: stiff vacuum pump poss. because of calcification • Actuate motor protecting switch (see page 8, Fig. 2) • If necessary exchange the device fuses 16A/FF If this occurs repeatedly, inform your specialist dealer or After-sales Service
Malfunction 51: **TU2**	The minimum sterilization temperature has not been reached (at temperature sensor 2): • Reduce the size of the load. • See malfunction 34 If this occurs repeatedly, inform your specialist dealer or After-sales Service
Malfunction 52: **TO2**	The maximum sterilization temperature (temperature sensor 2) has been exceeded: If this occurs repeatedly, inform your specialist dealer or After-sales Service. • Also see malfunction 35
Malfunction 53: **TD2**	The difference between the theoretical temperature , quoted from the pressure sensor signal, and the temperature measured at temperature sensor 2 is too large: If this occurs repeatedly, inform your specialist dealer or After-sales Service. Also see malfunction 38

9.3 Reaction to warnings/error messages

The Cliniklav®25 has a number of safety features and an extensive integrated control and monitoring system, in order to ensure the greatest possible level of safety for the sterilization process, and to eliminate risks for the patients and operators.
Various aspects of the operation of the autoclave, such as pressure and temperature sensors are automatically checked when the autoclave is switched on.
The power supply, and the quantity and quality of the feed water and cooling water are checked before a program can start.
A successful program start is followed in the next stages by the monitoring of all parameters of relevance for the sterilization. If any limit values for the individual program phases are exceeded then there is a malfunction report and the program is automatically interrupted.
In addition to messages, warnings or malfunction messages on the display, if a printer or another output medium is connected then a log output will provide details of the type of malfunction and when it occurred.
If any such warning message occurs then you should consult section 9, which provides detailed advice and possible operational errors.

9.4 No display on the screen

After switching on the autoclave, the display should show the initial setting (see section 8).
If there is no display, check:

1. Is the cable plugged into the mains?
2. Is the mains supply O.K:(if necessary check with another appliance)?
3. Check the three mains fuses. These fuses are installed behind the door. Since the electric door opening function may in such a case also no longer function, then please proceed as described under section 9.5.

   Disconnect the power cable and remove the screw caps over the fuses using a screwdriver or a coin. Exchange the fuses (three reserve fuses are delivered with the autoclave) then replace the screw cap and reconnect the autoclave to the power supply. If there is still no display when the autoclave is switched on, or if the display blacks out repeatedly, please inform your specialist dealer. If you exchange the fuses, order two new spare fuses through your dealer (MELAG Art.-No. 57590).

9.5 Emergency measure if the electric door release button fails

In the unlikely event that the electric door system should fail: In such a case, you can use the crank handle delivered with the autoclave to open the door as follows:
12.1 Remove the cap (12) from the emergency door-opening socket.
12.2 Insert the crank handle into the socket that is now open.
To **open** the door, turn the crank to the left (counter-clockwise, or anti-clockwise): see Fig. 7 below.
To **close** the door, turn the crank to the right (clockwise).

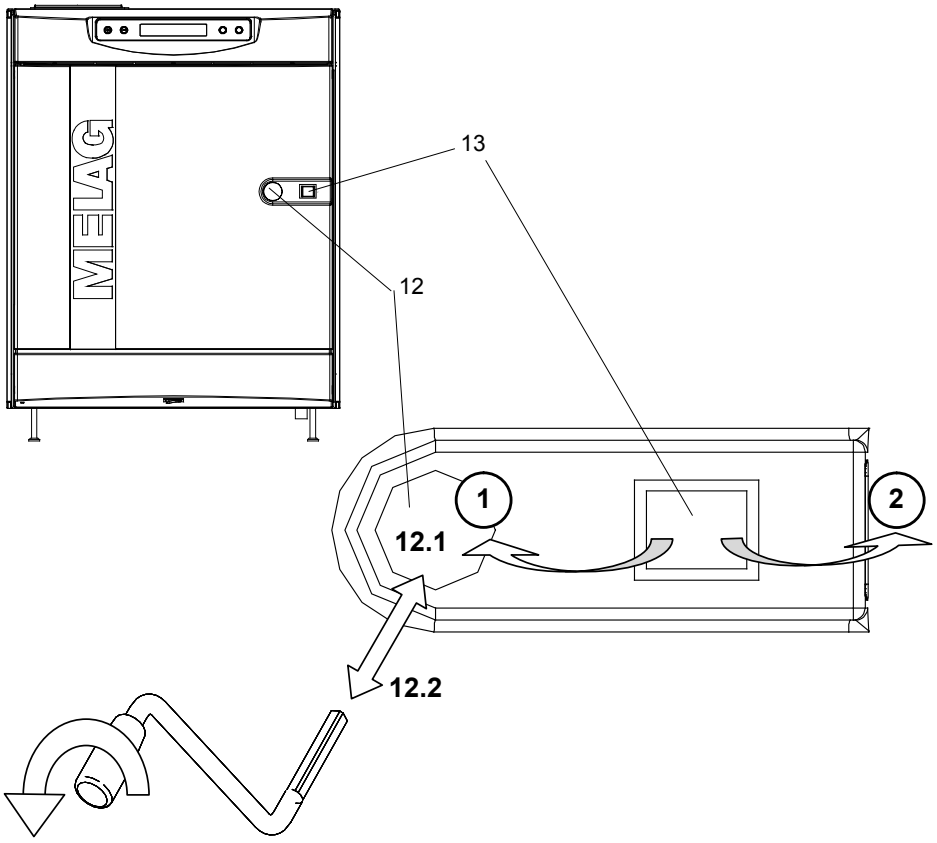


Fig. 7: Emergency operation of the door latch

WARNING: If you use the crank handle to open the door, it is very important to pull out the crank **BEFORE** the door is completely open. If you open the door completely before pulling out the crank handle, this will damage the plastic door.

9.6 Too large feed water consumption

The consumption of distilled or demineralized water will vary depending on the program and the load in the autoclave. If much more water is consumed than the amount specified in the appendix (see section 0), then you should:

1. Check to make sure that you have loaded the sterilization chamber correctly (for example, you may have loaded too much material that soaks up a great deal of water).
2. Check that the condensate outflow is not blocked by dropped, instruments, filter paper, etc. on the floor of the pressure chamber.
3. If neither of these measures help to reduce water consumption, please inform your specialist dealer.

4. Bad drying results

Good drying not only depends on the correct operation of the autoclave, but also on the way the autoclave is loaded. If drying is not satisfactory:

1. Check to make sure that the condensate can flow out properly: check to ensure that the autoclave is correctly connected (for example, make sure that there are no kinks in the drain hose).
2. Check that the condensate outflow is not blocked by dropped, instruments, filter paper, etc. on the floor of the pressure chamber.
3. Check that the maximum load has not been exceeded (particularly for textiles), that the autoclave has been loaded properly (no direct contact with the walls of the pressure chamber), and that the appropriate mounting has been used (see section: 4.3 and 11.4)
4. Only start the autoclave when the chamber is heated up.
5. Start with "Additional drying" (see section 4.6)
6. If none of these measures help to reduce water consumption, please inform your specialist dealer.

9.7 Program modifications

The standard programs are designed to meet most practical operational needs (subatmospheric pulsing, heating, sterilization, pressure release, drying, and ventilation) and to display the parameters of most interest (pressure, temperature, time).
The operator is responsible for ensuring that the autoclave is not overloaded, and that the load is arranged properly to ensure good drying. There is the standard option "Additional drying".
Any further program modification to suit specific individual requirements should only be carried out by authorised personnel, after consultation with your dealer or with the experts at MELAG.

10 Important information regarding routine operation

The former DIN 58946-6 and future DIN 58946-7 both prescribe the following fundamental procedures for routine operation the autoclave:

Time of test	Nature of test
Before starting routine operation	Installation Qualification (IQ) Operational Qualification (OQ) Performance Qualification (PQ)
Daily	Visual inspection • Check of the sterilization chamber and seal for its correct condition, see section 7.1 • Check of the operating materials, see section 4.1. • Check of the operation readiness of the recording equipment, see section 5.3. Feed water quality: • see section 7.4 and 8.1 Bowie & Dick test (steam penetration): • Also see section 3.4
Monthly	Vacuum test
Annually or following 1000 cycles	Maintenance
After changes to the autoclave and its maintenance	Operational Qualification (OQ)
After changes to the configuration	Renewed performance qualification (PQ) for a particular reason
In regular intervals (in accordance with DIN EN 17665, section 12.4)	Renewed performance qualification (PQ)

11 Appendix

11.1 Technical Data

Device type	**Cliniklav®25**	
	Table-top device	**with floor unit**
Device dimensions (HxWxD)	80 x 62 x 80[1)] (84) cm	150 x 62 x 80 (84) cm
Sterilization chamber (HxWxD)	32 x32 x 65 cm	
Effective capacity	30 x 30 x 60 cm	
Volume of the sterilization chamber	1 StU	
Weight (empty)	157 kg (	197 kg
Electrical connection	400 V 3N ~/AC, 50/60 Hz ~ 16 A separate fuse, FI protection 30 mA	
Electrical operating level	9000 W	
Max. sound power	< 70 dB(A)	
Heat emission	ca. 4 MJ	
Max. altitute	2000 m	
Ambient temperature	5-40 °C (recommended max. 25 °C)	
Relative humidity	80% at 31 °C, decreasing in a linear fashion up to a relative humidity of 50% at 40 °C	
CE marking	CE 0197, CE 0035	
Degree of protection (following IEC 60529)	IP20	
Cold water connection		
Min. Flow pressure	2.5 bar at 7 l/min	
Qualiy	Drinking water, water hardness 4-12° dH (in accordance with DIN EN 285)	
Feed water		
Flow pressure	min. 2.5 bar	
Consumption per cycle	2.6-6.5 l	
Volume of water storage container	15 L	
Quality	Distilled or demineralized water in accordance with DIN EN 285, Appendix C (with central demineralization system max. conductivity 5 µS/cm)	

1) incl. device feet

11.2 Additional technical data

Dimensions:	Depth	Width	Height	The unit holds:
Tray	60 cm	30 cm	5 cm	4 each
Standard-tray cassette	29 cm	19 cm	4 cm	18 each
Sterilizing container 1 STE				1 each
Sterilizing container 1/2 STE				2 each
Sterilizing container 1/4 STE				4 each

Maximum load:	15 kg instruments
	7 kg Textiles

Program differences:			
Type of loading: Program:	**Instruments wrapped**	**Instruments unwrapped**	**Textiles**
Universal-Program	1 kg ... 15 kg	1 kg ... 15 kg	1 kg ... 7 kg
Quick-Program B	max. single wrapped 5.5 kg	1 kg … 15 kg	max. wrapped 4 kg
Quick-Program S	- - - -	1 kg ... 15 kg	- - - -
Gentle-Program	1 kg ... 15 kg	1 kg ... 15 kg	1 kg ... 7 kg
Prion-Program	1 kg ... 15 kg	1 kg ... 15 kg	1 kg ... 7 kg

Average power consumption:		
Program	**Energy consumption**	**Conditions**
Universal-Program	approx. 3.4 ... 3.6 kWh	1 kg ... 15 kg load
Quick-Program B	approx. 2.2 … 3.2 kWh	1 kg … 5,5 kg load
Quick-Program S	approx. 1.57 ... 2.1 kWh	1 kg ... 15 kg load **unwrapped**
Gentle-Program	approx. 2.8 ... 3.6 kWh	1 kg ... 7 kg load
Prion-Program	approx. 2.8 ... 4.0 kWh	1 kg ... 15 kg load
Bowie & Dick Test	approx. 3.0 kWh	reduced standard test package 4 kg
Vacuum test	approx. 0.02 kWh	Chamber without any load
Quick-Program S for pre-heating the chamber	approx. 1.73 kWh	Chamber without any load

Average power consumption (porous partial load):		
Program	**Energy consumption**	**Conditions**
Universal-Program	approx. 4.08 kWh	4 kg porous partial load
Quick-Program B	approx. 3.7 kWh	4 kg partial load
Quick-Program S	---	---
Gentle -Program	approx. 3.5 kWh	4 kg partial load
Prion-Program	approx. 4.3 kWh	4 kg partial load
Bowie & Dick Test	approx. 3.0 kWh	reduced standard test package 4 kg

Average cooling-water consumption (with drying):		
Program	**Cooling water consumption**	**Conditions**
Universal-Program	approx.. 65 … 66 l	1 kg ... 15 kg load
Quick-Program B	approx. 43 … 57 l	1 kg ... **5,5 kg load (single wrapped)**
Quick-Program S	approx. 35 ... 37 l	1 kg ... 15 kg load **unwrapped**
Gentle-Program	approx. 65 ... 69 l	1 kg ... 15 kg load
Prion-Program	approx. 60 ... 71 l	1 kg ... 15 kg load

Average feed-water consumption (normal setting with steam generator cleaning):		
Program	**Feed water consumption**	**Conditions**
Universal program	approx. 4.4 ... 5.8 l	1 kg ... 15 kg load
Quick-Program B	approx. 4.0 … 5.5 l	1 kg … **5,5 kg load (single wrapped)**
Quick-Program S	approx. 2.3 ... 3.5 l	1 kg ... 15 kg load
Gentle program	approx. 4.8 ... 6.7 l	1 kg ... 15 kg load
Prion program	approx. 4.3 ... 6.5 l	1 kg ... 15 kg load
Bowie & Dick Test	approx. 4.5 l	reduced standard test package 4 kg
Vacuum test	- - - -	chamber without any load

Times, Pressures, Temperatures – Program constants:				
Program	**Pressure**	**Temperature**	**Sterilizing time**	**Drying time**
Universal-Program	2.1 … 22bar	134 … 136 °C	3:30 min	20 min.
Quick-Program B	2.1 ... 2.2 bar	134 ... 136 °C	3:30 min	12 min
Quick-Program S	2.1 ... 2.2 bar	134 ... 136 °C	5:30 min	10 min
Prion-Program	1.1 ... 1.2 bar	121 ... 122 °C	20:30 min	20 min

Variable cycle times with max. load of 15 kg instruments (with complete drying):		
Program	**Duration of the program**	**Conditions (at ambient temperature of 20°C)**
Universal-Program	approx.60 … 61 min	1 kg … 15 kg load
Quick-Program B	approx. 41 … 52 min	1 kg ... **5.5 kg load (single wrapped)**
Quick-Program S	approx. 31 ... 34 min	1 kg ... 15 kg load **unwrapped**
Gentle-Program	approx. 71 ... 78 min	1 kg ... 15 kg load
Prion-Program	approx. 67 ... 80 min	1 kg ... 15 kg load

Variable cycle times (without drying):		
Program	**Duration of the program**	**Conditions (at ambient temperature of 20°C)**
Universal program	approx. 38 ... 40 min	1 kg … 15 kg load
Quick-Program B	approx. 28 … 40 min	1 kg ... **5.5 kg load (single wrapped)**
Quick-Program S	approx. 20 ... 22 min	1 kg ... 15 kg load **unwrapped**
Gentle-Program	approx. 49 ... 56 min	1 kg ... 15 kg load
Prion-Program	approx. 45 ... 58 min	1 kg ... 15 kg load

11.3 Nominal value tolerances

	Universal-Pr.		Quick B		Prion-Pr.		Gentle-Pr.		Quick S		◄ same meaning as in Universal-Pr.	
Step	Press. P	Tolerance	P	Tol.		Tol.	P	Tol.	P	Tol.	*All values in mbar*	
1. F.	80	+ 50/- 20	◄	◄	◄	◄	◄	◄	110	◄	evacuate	Fractionation
	1400	+ 50/- 30	◄	◄	◄	◄	◄	◄	◄	◄	steam entry	
2. F.	160	+ 50/- 20	◄	◄	◄	◄	◄	◄	230	◄	evacuate	
	1400	+ 50/- 30	◄	◄	◄	◄	◄	◄	◄	◄	steam entry	
3. F.	160	+ 50/- 20	◄	◄	◄	◄	◄	◄	---	---	evacuate	
	1400	+ 50/- 30	◄	◄	◄	◄	◄	◄	---	---	steam entry	
4. F.	160	+ 50/- 20	◄	◄	◄	◄	◄	◄	---	---	evacuate	
	1400	+ 50/- 30	◄	◄	◄	◄	◄	◄	---	---	steam entry	
	3050	+ 70/- 30	◄	◄	◄	◄	2060	◄	◄	◄	heat up	
	3050	+ 70/- 30	◄	◄	◄	◄	2060	◄	◄	◄	sterilization start	
	3160	+ 90/- 90	◄	◄	◄	◄	2115	◄	◄	◄	sterilization	
	1200	+ 30/- 90	◄	◄	◄	◄	◄	◄	◄	◄	pressure release	

11.4 Instructions for drying

The Cliniklav®25 provides very good drying standards for sterilized items. Particularly difficult drying tasks (e.g. double wrapping) can also be dried to very good standards with the help of the supplementary drying function and the automatic pre-heating. Please read the following sections, which may help you to optimise your drying results.

11.4.1 Drying in sterilization containers

In the autoclave steam is produced by heating water. The steam transfers heat to the instruments and sterilization container and warms these. This leads to steam condensing on the instruments and containers.

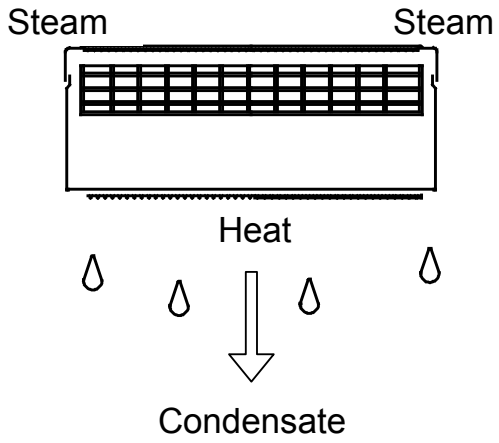


Fig. 8: Formation of condensation on the sterilization container

The steam also heats the objects contained in the sterilization containers. Condensate forms on the objects being sterilized, and some of the condensate drops to the bottom of the sterilization container.

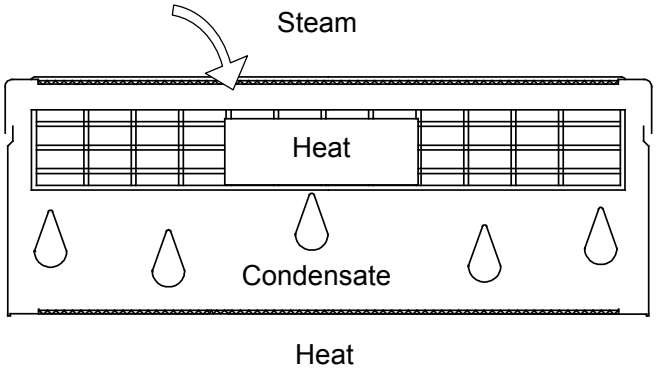


Fig. 9: Formation of condensation on sterilized objects

After sterilization, during the drying phase, all the condensation must evaporate from the sterilization container and from the sterilized items themselves. This is achieved by the transfer to the condensate of heat stored in the walls of the sterilization container and in the sterilized items themselves. It is preferable that the sterilization container be made of aluminium, as this metal stores and conducts heat well, ensuring faster drying than other materials.

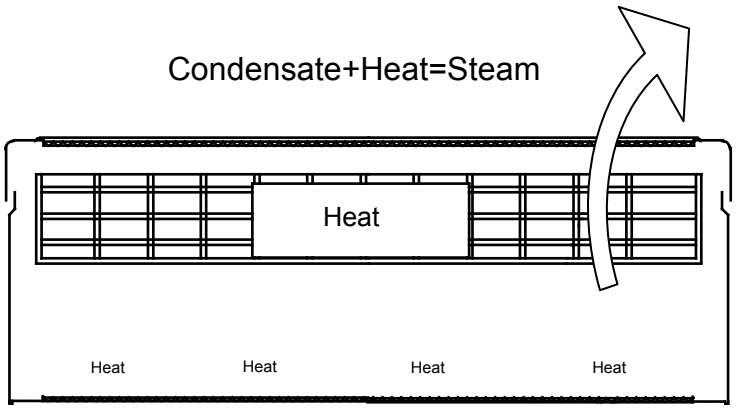


Fig. 10: Drying

For good drying it is essential that surplus heat be transfered to the objects which have been sterilized. In addition, the condensate must be led out of the sterilization containers. The floor of the containers have channels and the lid has an arched filter area.

11.4.2 Textiles

When preparing textiles for treatment in the autoclave, care must be taken that the folds in the textiles are arranged in parallel, and that the items are packed side-by-side. This vertical configuration ensures that channels can form between the textile folds for the air to flow out and steam to flow in. Do not stack textiles on top of each other as this hinders the penetration of steam into the packages of textiles.

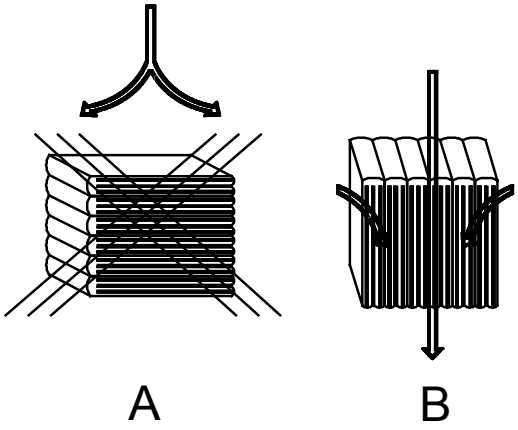


Fig. 11: Loading textiles properly

When loading sterilization containers with textile items, care should be taken to ensure that they retain their vertical orientation, but that the items are not squashed together. This would prevent the formation of flow channels for air and steam. If the packages of textiles cannot be kept upright, then it might be advisable to wrap them in sterilization paper.
The textiles must not touch the sides or the base of the sterilization container, since they might become saturated with condensate.
For good drying results, the textiles should also be as dry as possible when they are placed in the autoclave. The heat stored in the chamber and sterilization container may not otherwise be sufficient to evaporate both the moisture and condensate.

11.4.3 Instruments

Where appropriate, instruments should be disassembled before placing them in the autoclave, as this will improve the drying results.
The use of lubricants (such as instrument oil) should be avoided unless absolutely necessary. Prior confirmation should be obtained from the manufacturer of such agents that they are in fact suitable for steam sterilization. Substances which are hydrophobic or impenetrable for steam can not only lead to poor drying results, but may also mean that the steam sterilization is unsuccessful, since not only the instruments are protected but also micro-organisms.

11.4.4 Loading the autoclave

Textiles and instruments should not be sterilized together in one sterilization container. Textiles and instruments in separate sterilization containers should as far as possible not be sterilized in the same load. However, where this is unavoidable for economic or other reasons, the following rules should be observed:

- Instruments and sterilization containers should be placed at the bottom
- Textiles should always be placed at the top
- Transparent sterilization packages and paper sterilization packages should be placed at the top (except when in combination with textiles, in which case they must be at the bottom).

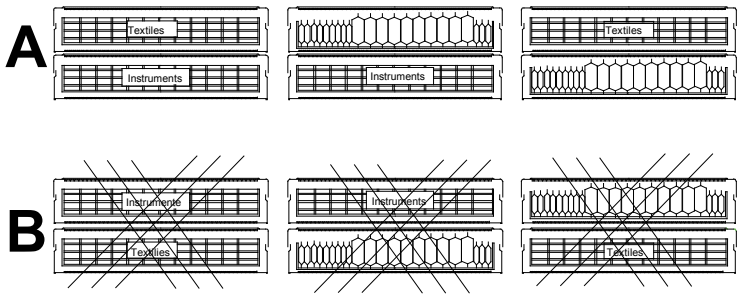


Fig. 12: Loading the autoclave

11.4.5 Loading containers with soft sterilization packing material

"Soft“ sterilization packages such as paper bags or transparent sterilization packages can be sterilized either in sterilization containers or sterilization baskets. To enable better drying, arrange such soft sterilization packages side-by-side and close to each other. This allows condensation to run off the packages, while at the same time preventing them from expanded excessively, and possibly bursting at the seams.

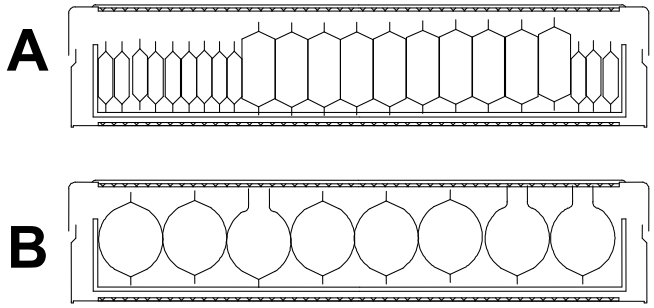


Fig. 13: Packing "soft“ sterilization packages in sterilization containers

11.4.6 Stacking sterilization containers

When arranging sterilization containers, care should be taken that drops of condensate do not wet items being sterilized beneath, but can flow away to the base of the chamber. The best arrangement is a stack of sterilization containers of the same size, so that condensate can flow down the sides.

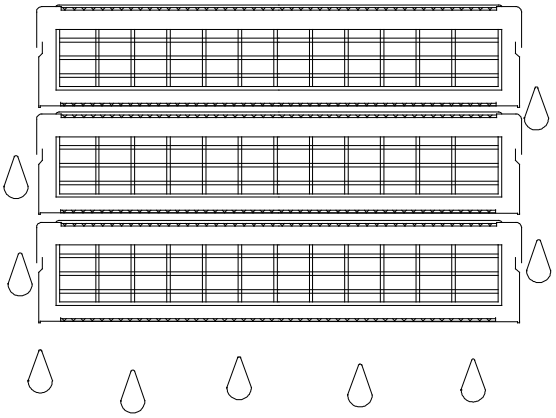


Fig. 14: Stacked sterilization containers

11.4.7 Removing the sterilized items

Immediately after the sterilization process, some condensate may remain on the sterilized items. However, heat transfer from the sterilized objects can evaporate this after the sterilization process has been completed.
The German standard DIN 58953 Part 7 Section 7 comments on residual moisture on paper bags or transparent sterilization paper after sterilization: "...Small amounts of water on the surface of packages do not represent a cause for concern if they dry completely within thirty minutes after removal from a steam sterilization system....“

11.4.8 Improving the drying

The drying can be improved by the following measures:

- Pre-heating the autoclave (empty sterilization)
- Arranging transparent sterilization and paper packing vertically
- Selecting the program option "Additional drying"
  Extending the drying times (please consult your MELAG customer service).