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MELAG

User Manual

for the

Autoclave

Vacuklav®31 -B

with device software version 3.20 et sqq.

Dear Doctor:

Thank you very much for the trust which you have shown by purchasing this autoclave.

For 50 years now, MELAG — a medium-sized family-owned and -operated business — has specialised in the production of sterilization equipment for medical practice. During this period, MELAG has succeeded in becoming a leading manufacturer of sterilization equipment. More than 335,000 MELAG units sold throughout the world testify to the exceptional quality of our products — which are manufactured exclusively in Germany.

As all other MELAG products, this autoclave was manufactured and tested according to strict quality criteria. Before placing this unit into operation, please carefully read this User Manual. The long-term functional effectiveness and the preservation of the value of your autoclave will primarily depend on careful preparation of instruments before sterilization, and on proper care of the unit.

The staff and management of MELAG

CE 0124

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The functional effectiveness and the preservation of value of this unit depend on:

1. Proper preparation of the instruments to be sterilized
2. Proper care of the autoclave
3. The use of sufficiently pure demineralized / distilled water

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1 Description of the unit

1.1 Views of the unit

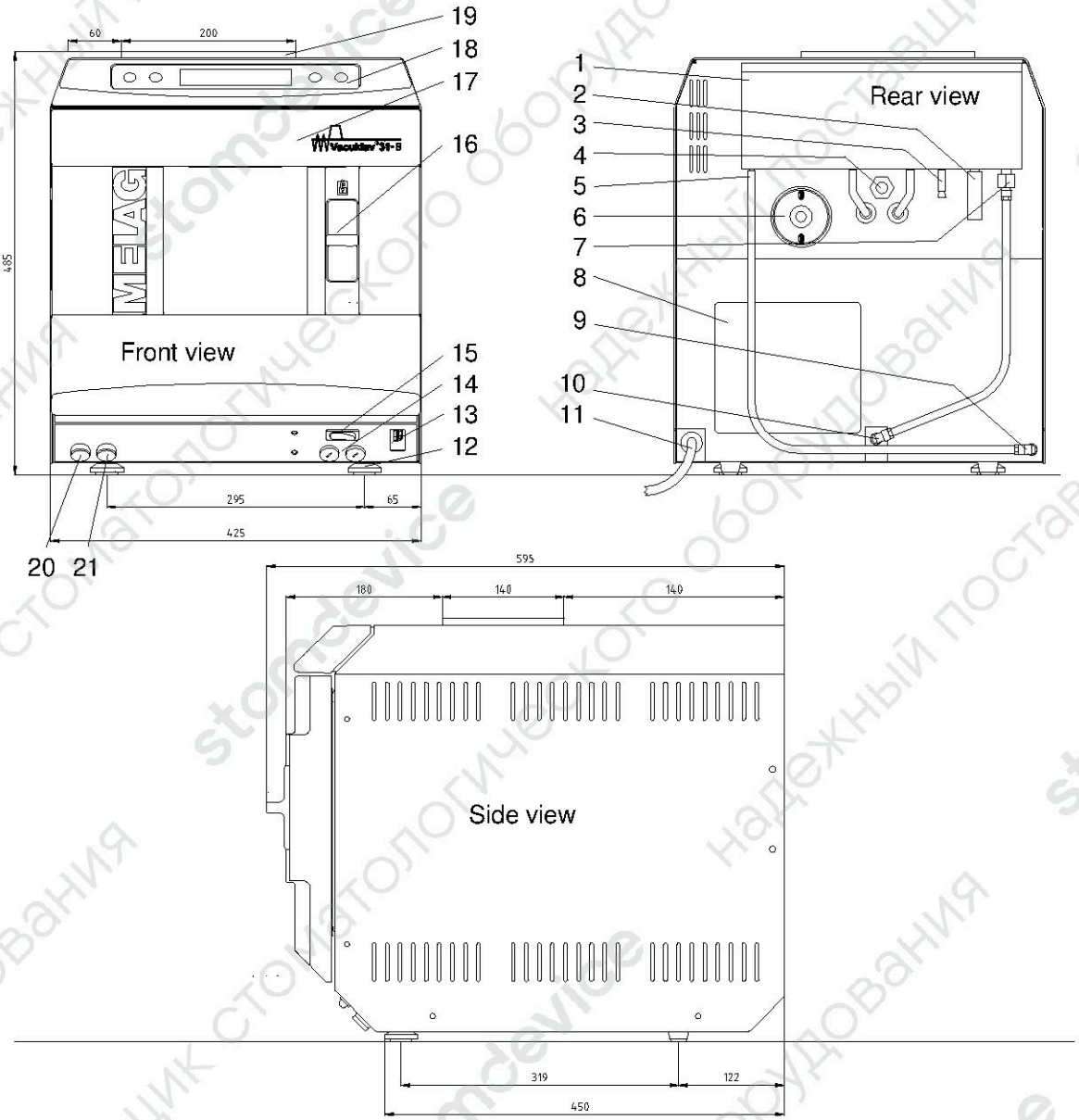


Fig. 1 Views of the Vacuklav®31-B

1 Water storage tank
2 Emergency overflow **(OUT)**
3 One-way drain **(OUT)**
4 Spring-operated safety valve
5 Connection for demineralized / distilled water **(OUT)**
6 Sterile filter
7 Connection for pressure release for water storage tank **(IN)**
8 Cooler
9 Connection for demineralized / distilled water **(IN)** (quick-fitted threaded connection for 6 × 1 hose)
10 Connection for pressure release **(OUT)**
11 Power cable
12 Front adjustable feet of the unit
13 Serial data and printer interface (RS 232)
14 Fuses for the unit: 2 × 16 A / FF
15 Power switch
16 Sliding-lock handle
17 Hinged door (opens to the left)
18 Operator's control and monitoring panel
19 Cover to water tank
20 Drain hose for water tank, drain side **(OUT)**
21 Drain hose for water tank, demineralized-water side **(OUT)**

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1.2 Technical data

1.2.1 Primary technical data

Sterilization chamber (× depth)	25 cm × 36 cm
Power ratings	2400 W / 230V AC / 10.4 A / 50 ... 60 Hz
Sterilization pressure / temp.	2 bar / 134°C; 1 bar / 121°C
Disinfection pressure / temp.	0.3 bar / 105°C
Maximum load	5 kg of instruments or 1.8 kg of textiles
Outside dimensions	48.5 cm high × 42.5 cm wide × 59.5 cm deep

1.2.2 Capacity / weights

Weight of unit (without load)	43 kg
Volume of chamber	17.6 litre
Maximum loading	5 kg of instruments or 1.8 kg of textiles
Water storage tank (demineralized / distilled water)	Fresh-water side: 5 litres (approx. 7 cycles); drain side: 3 litres
Loading variations	Mount “B” for max. 4 norm tray cassettes or 4 MELAG trays Mount “C” for max. 3 norm tray cassettes or 6 MELAG trays MELAG sterilization containers: 28M,G, 23R, 15K, 17K,R; MELAG Package Holders

1.2.3 Operating media

Power ratings:	
Electricity ratings	230 V AC / 10.4 A / 50 ... 60 Hz
Power ratings	2400 W; fuse = 16 A; RCCB (residual current circuit breaker); 30 mA
aqua dem / aqua dest	Demineralized / steam-distilled water in accordance with VDE 0510

1.2.4 Operational parameter

1.2.4.1 Programs / operating times

Program	Operating time (not including drying period) *)		Drying
	Hot start; load = 0.5 kg	**Hot start; load = 5 kg**	
"Quick program" (134°C, 2 bar)	12 min	20 min	10 min
"Universal program" (134°C, 2 bar)	23 min	38 min	15 min
"Gentle program" (121°C, 1 bar)	41 min	50 min (1,8 kg textiles)	20 min
" Prion Program" (134°C, 2bar)	40 min	55 min	15 min
"Bowie & Dick" (134°C, 2 bar)	33 min	40 min	5 min
"Vacuum Test"	—	18 min (empty)	--

1.2.4.2 Consumption of energy / water *)

Power consumption	
"Pre-heating"	
One-time heating up to pre-heating temperature (134°C)	approx. 0.12 kWh (=x €[1])
"Stand by" operation per hour	approx. 0.2 kWh (= x €[1])
"Program cycle" (including drying)	0.3 kWh (=x €[1]) for “Quick program” / hot start / light load, up to ... 1.1 kWh (=x €[1]) for “Gentle program” / cold start / full load
Consumption of demineralized / distilled water	300 ml (= 3 Cent[2]) for “Quick program” 500 ml (= 5 Cent[2]) for “Universal program” 600 ml (= 6 Cent[2]) for “Gentle program”

*) These values are valid for a constant power supply of 230 V
[1] x = energy consumption kWh x price for one kWh in €/kWh
[2] Based on following price for one litre of distilled water from the MELA*dest*®65: = 0,10 €

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1.3 Installation examples

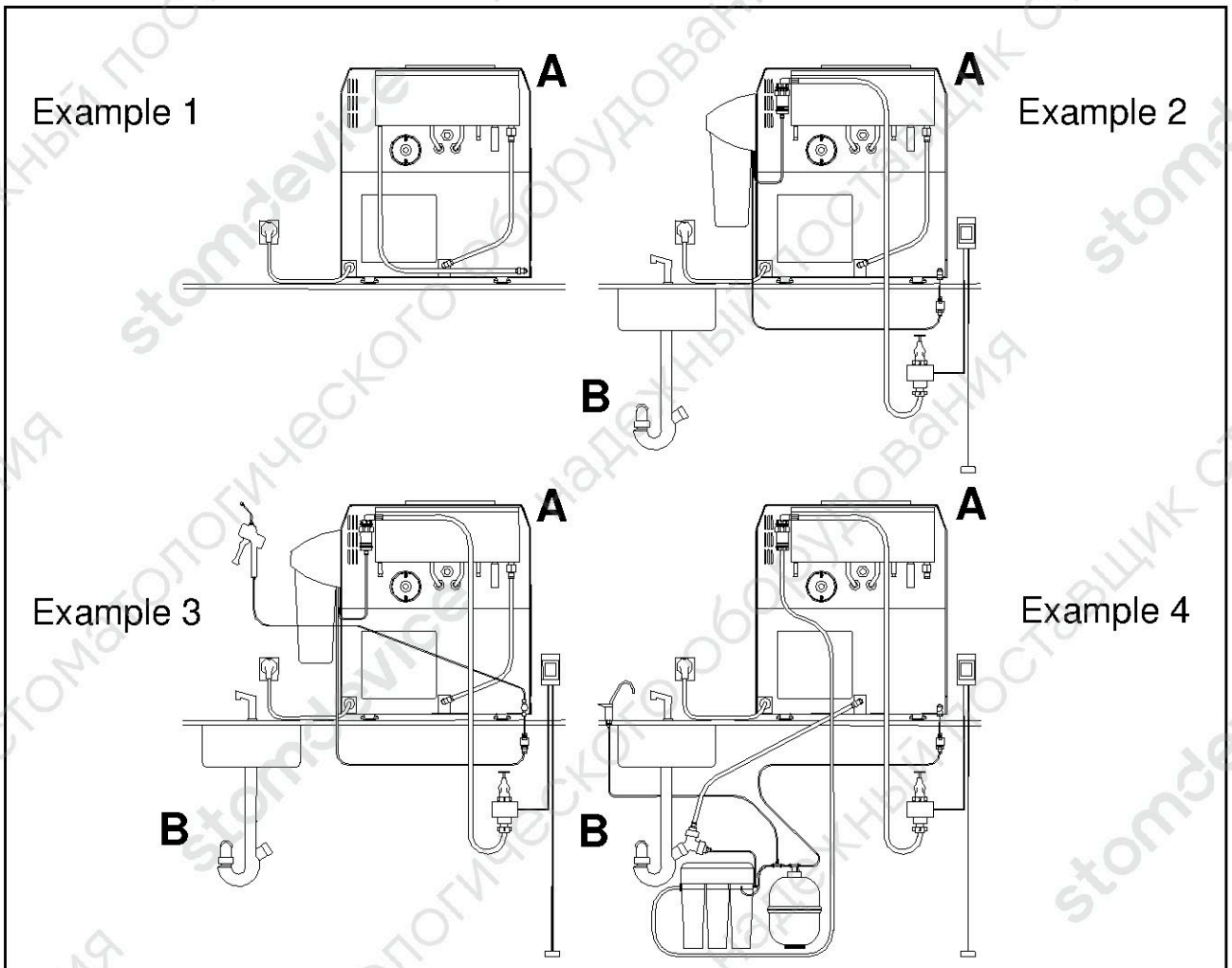


Fig. 2. Installation examples for Vacuklav® (**A**) with double-chamber trap (**B**)*1

*1 Alternative: a separate drain with stench trap, instead of the double-chamber trap.

Example 1
Vacuklav®31-B rear view
Standard version = version as supplied
(with internal supply of water)

Example 2 EN1717
Vacuklav®31-B rear view
MELA*dem*®40 (optional), external water supply,
with manual draining of the waste-water tank
Leak detector with shutoffvalve and sensor
(optional)

Example 3 EN1717
Vacuklav®31-B rear view
MELA*dem*®40 (optional), external water supply,
with manual draining of the waste-water tank
MELA*jet*® (optional)
Leak detector with shutoff valve and sensor
(optional)

Example 4 EN1717
Vacuklav®31-B rear view
MELA*dem*®47 (optional), with drain of waste water
automatically into a double-chamber trap
Leak detector with shutoff valve and sensor
(optional)

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1.4 Control panel

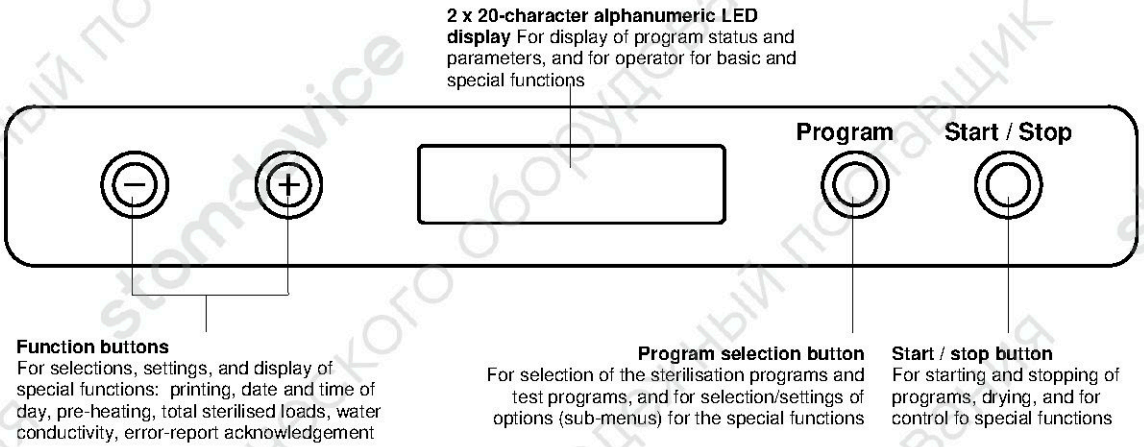


Fig. 3: Vacuklav®31-B control panel

1.5 Performance features of this autoclave

1.5.1 Preliminary air removal by sub-atmospheric pulsing

Preliminary air removal by sub-atmospheric pulsing repeatedly evacuates the air from the autoclave and alternately introduces steam between evacuations: providing the required penetration of the sterilized objects with saturated steam. This ensures fast and effective execution of difficult sterilization tasks: e.g., instruments with narrow bores and large amounts of textiles. This autoclave also features a special program for the Bowie & Dick Test (a recognised procedure used in large-scale sterilization to confirm steam penetration.

1.5.2 Sterilization categories

The Vacuklav®31-B features three sterilization programs for temperatures at 134°C: the “Universal Program” (for wrapped objects), the “Prion Program” (a special Universal Program), the “Fast 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. The additional program "MELA*steam*®" is available as an option, and functions at a temperature of 136°C.

1.5.3 Separate steam generation

The powerful steam generator outside the actual sterilization chamber makes it possible to sterilize large loads of instruments or textiles in a short time. No waiting periods are necessary between the sterilization cycles, and excess temperatures within the sterilization chamber cannot occur.

1.5.4 One-way system / conductivity measurement / automatic re-supply of water

The Vacuklav®31-B operates with the tried-and-proven one-way system: this means that all evaporated water and all impurities contained in this water are removed from the autoclave upon pressure release. For the following program cycle, new demineralized / distilled water is therefore used. An integrated conductivity measurement system monitors the quality of the demineralized / distilled water used in steam generation. For heavy use of the autoclave, we recommend supply of the demineralized / distilled water by connection of a water-treatment system such as the MELA*dem*® 47 or MELA*dem*® 37. If the instruments are carefully prepared, this arrangement prevents spots on the items sterilized, and avoids fouling of the autoclave.

1.5.5 Electronic parameter control

The microprocessor installed in the Vacuklav®31-B implements electronic parameter control, which continuously monitors pressure, temperature, and time in the programs. The process evaluation and monitoring system contained in the program control system compares momentary process parameters with standard process data and monitors the process with respect to limit temperatures, limit times, and limit pressures. This function detects malfunctions in the program cycle and guarantees the security of the sterilization / disinfection results.

1.5.6 Vacuum drying

The vacuum drying feature ensures good drying results, even for wrapped items.

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1.5.7 Pre-heating

Activating the pre-heating function warms up the cold autoclave chamber before sterilization, or maintains the temperature between sterilization cycles. This shortens the duration of cycles and considerably reduces the formation of condensation, thus optimising drying results.

1.5.8 Documentation of results

The memory of the electronic control system stores records 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 record immediately after completion of a program, or to print out records from the memory. By connection of a PC, the program MELA*win*® can also transfer the records to the PC, for permanent archiving of all results, and for printing out these results as needed.

2 Installation

For the steps required to prepare for and carry out the setting up and installation of this autoclave, see the separate instructions contained in "Setting up the Vacuklav®31-B".

2.1 Requirements for installation

The autoclave should be set up in a dry place which is protected against dust. The base should be stable and capable of supporting the weight of the appliance (unloaded weight = 43 kg). The space required by the autoclave can be seen from the external dimensions (see Section 1.2.1 here). A minimum additional space of 10 cm should be allowed on both sides and above the autoclave in order to ensure that heat can escape.
The electrical power supply should be a separate 230V AC circuit with a 16 A fuse.
This autoclave operates with a blower for the cooling system, on the rear side of the unit. If there is a restriction of the escape of heat above the unit, this can impair the functioning and shorten the service life of the autoclave. **IMPORTANT: We therefore urgently advise our users not to install the autoclave in an area where there is not sufficient circulation of air.**
If the user decides to install an automatic one-way water system, it is necessary to have a connection to the wastewater plumbing near the autoclave, preferably a wall outlet (NW 40) or a sink drain (standard length of outflow pipe = 2 m, with 16 mm diameter). The work surface on which the autoclave stands must be higher than the outlet, and the outlet pipe must be without bends and twists which could prevent water flowing out freely. At the same time, the work surface must provide convenient access to the autoclave, and the display must be clearly visible.
The autoclave can be supplied with demineralized / distilled water from the integrated dual-chamber storage tank, with freshwater and wastewater chambers. Alternatively, the Vacuklav®31-B can also be connected to an external water purifier – the MELA*dem*®47 or MELAdem®40 (or an equivalent water purification system). However, please note that this will require additional space.

2.2 Transport ribbons

Lift the autoclave out of the packaging by using the transport straps. The straps themselves are each removed by unscrewing the two retaining screws, which must then be screwed firmly back in place without washers.

2.3 Levelling

In order to operate properly, and to allow unimpeded return flow of condensate into the steam generator, the autoclave must be installed so that it **definitely** slopes toward the rear. First install the autoclave in a horizontal (level) position, and check that this position is in fact horizontal with a spirit level at the chamber flange. Then extend the front feet to lift up the front side of the autoclave, by screwing the feet out by at least three (3) turns.

2.4 Mains power supply

The electric cable of the appliance must be plugged into a mains socket rated at 230 V / 50 Hz. The power rating of the autoclave is 2400 W. In order to avoid overloading the building electricity supply, we recommend using a separate electrical circuit fitted with a 16 A fuse and optionally protected with a type RCCB (residual current circuit breaker) with a tripping current of 30 mA.

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2.5 Outlet connection for one-way water

The connection for the one-way water outlet at the back of the unit (3) must be hooked up to the drainage system of the building by means of the outlet pipe supplied (transparent pipe). It is important that the pipe should **have a steady downward gradient, without twists and kinks**. The outlet must be connected to an existing sink drain, or to a separate NW40 drain pipe with use of the wall-mounted drain (MELAG article no. 37410).

2.6 Internal water supply with demineralized / distilled water

If the user decides for internal supply of the autoclave with demineralized / distilled water, this water is taken from the right chamber of the built-in water storage tank. To install the internal system for supply of demineralized / distilled water, connect the hose at the demineralized / distilled water connection of the supply tank to the swivell threaded connection at the supply point for demineralized / distilled water on the rear side of the autoclave. For this variation of water supply, the autoclave is delivered ready for installation. To fill the feed water tank, remove the cover of the tank and fill the right chamber with demineralized / distilled water up to the maximum mark.

2.7 Connection of a water treatment system

The autoclave can be directly connected to a water treatment system for direct supply with demineralized / distilled water. Instead of being connected to the water storage tank (as in Section 2.6), the demineralized / distilled water connection is hooked up directly to the water treatment system. The reverse-osmosis system MELA*dem*®47 and the ion-exchanger MELAdem®40 are designed to optimally satisfy the requirements of the Vacuklav®31-B. Please consult the operating manuals of these reverse-osmosis systems for detailed instructions on installation and placing into operation. If you decide to use water treatment systems made by other manufacturers, be sure that they deliver water with sufficient quality and quantity. Please get in touch with the company MELAG before connecting such systems made by other manufacturers. In addition, a water stop valve (MELAG article no. 01056) should be installed upstream of such water treatment systems, in order to satisfy insurance requirements.

2.8 Emptying the water storage tank

It is easy to completely empty the water storage tank of this autoclave. This is required, for example, to clean or repair the autoclave, or to place it out of operation. To drain the tank, pull the drain hoses out of the front panel at the plug (see Fig. 1: drain side [21], and tank side, with demineralized water [22]). Pull out the plugs, and allow the water to drain into a separate container.

3 Placing the autoclave into operation

3.1 Printer connection and initialisation (optional)

3.1.1 Connection of the MELA*print*®42

The accessory printer MELA*print*®42 is designed for connection to the autoclave Vacuklav®31-B. This is an optional item which is not supplied with the normal scope of delivery for the autoclave. Follow the instructions in Section 6.3.1.1.1 of this manual to connect the printer to the autoclave.

3.1.2 Initialisation of the printer / setting for immediate printout

Follow the instructions in Section 6.3.1.1.2 of this manual to initialise the external printer after it has been connected. This initialisation will log the printer on to the computer control system in the autoclave. Follow the instructions in Section 6.3.2 of this manual to set the immediate-printout option to "Yes". This means that the system will automatically print out a report when the system program has come to an end.

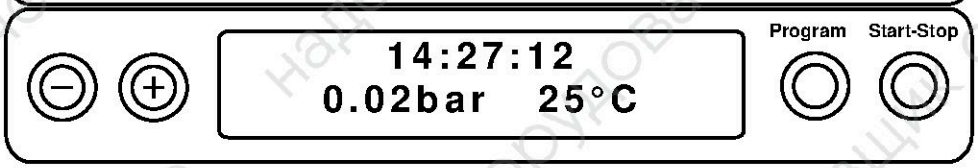
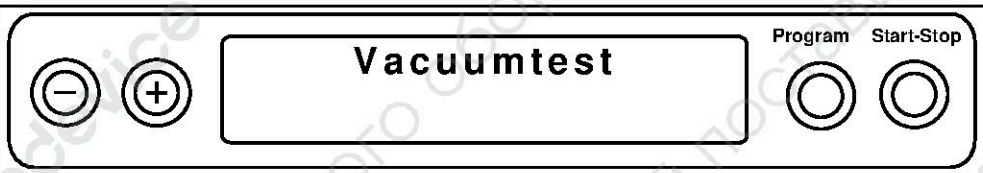
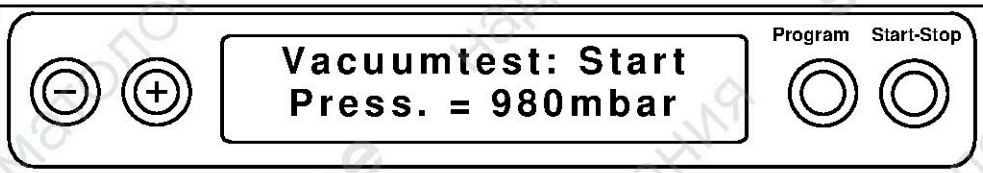
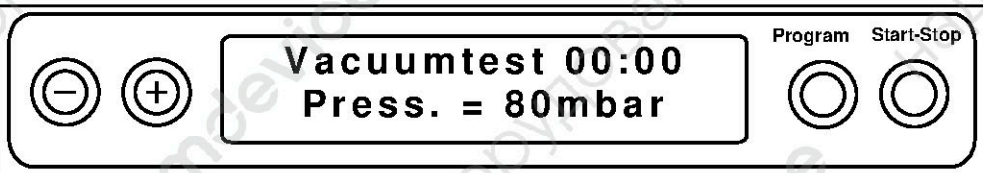
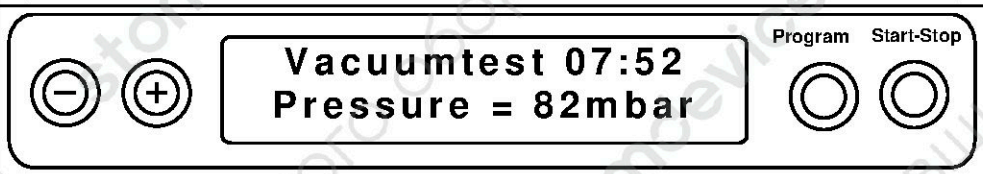
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3.2 Vacuum test

A vacuum test (leak test) should be conducted under the following conditions to assure proper functioning of the autoclave:

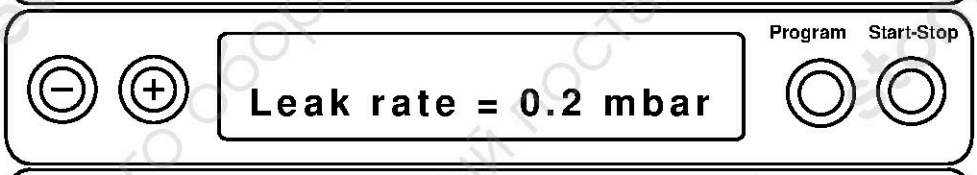
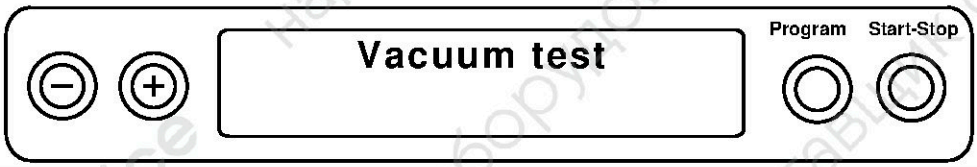
- Once when a new autoclave is set up for the first time
- When the autoclave is being put back into service after a long period of inactivity
- When the autoclave is moved to a new location
- Periodically as part of routine operations.

The vacuum test should be performed on the cold autoclave as follows:

Operator action:		Shown on the display:
1.	Switch on the autoclave at the power switch: After the following message ...	
	... the display will show the initial state:	
2.	Press the “Program” button several times until the program “Vacuum test” appears.	
3.	Close the door	
4.	Press the “Start – Stop” button	
5.	The vacuum pressure has been reached. The equilibration time begins to run (waiting time until beginning of measurement).	
6.	After the waiting time has run out (5 min), the measuring time will begin (here: 7 min 52 s).	

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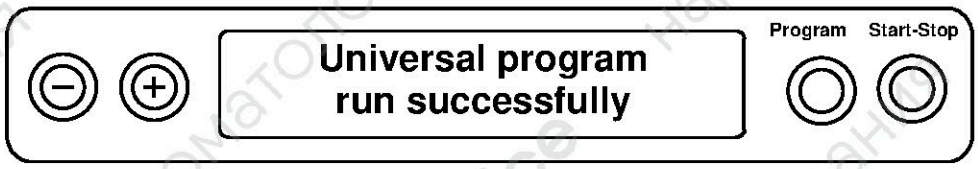
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Operator action:		Shown on the display:
7.	After the measuring time has run out (10 min), the chamber is vented, and ...	
	... then the leak rate is given (with connected printer and setting for immediate printout = "Yes", a record will now be printed out. After the message "Please wait – door unlocking", the following request will appear:	 
8.	Open the door.	

If the leak rate determined is greater than the maximum permissible value, the following will appear in the display and on the printed log: "Test not successful". In such a case, follow the instructions given in this manual under Section 7.3.

3.3 Trial run

To continue the functional check of the autoclave, carry out the trial run by loading the autoclave with a typical load for your daily work, and then run the program "Universal program, 134°C, wrapped". Load the autoclave and use the "Program" button to select this program. Then press the button "Start – Stop". If the program runs correctly (also see Section 4.7 here), the following message will appear at the end of the program:



This display will also show the maximum values achieved for pressure and temperature. If a printer is connected, and with setting for immediate printout = "Yes", a record will now be printed out.

3.4 Installation log – sent to MELAG

As documentation that the autoclave has been set up properly, an installation record 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.

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3.5 Safety instructions

- **Danger:** Be careful when **opening the door** of the autoclave, especially if you are interrupting a drying cycle. Small amounts of **residual steam** can escape through the door and can burn operating personnel.
- **Warning:** After opening the autoclave door, do not touch **exposed hot metal parts**. **Warning:** These parts can burn operating personnel. Be sure to use a MELAG or standard tray handle to remove still-hot trays from the autoclave. Be sure to use suitable hand protection (for example, potholders or gloves) when removing other sterilizing containers.
- We recommend the installation of a leak monitor in the water supply line (see Section 2, Installation, for instructions).
- If you wish to connect to this autoclave water-treatment systems which are made by **other** equipment manufacturers, get in touch with the MELAG company **before** you install this equipment.
- This device is **not** suitable for the sterilization of **liquids**.
- According to presently valid regulations published by the Society of German Electrical Engineers (VDE), this device is **not** suitable for operation in hazardous areas which are endangered by the **possibility of explosion** (for example, in hazardous atmospheres).
- **Important**: Empty the water supply tank before moving the autoclave. If the autoclave has water inside, do not tip it.
- This device may be repaired only by the company MELAG or by persons authorised by MELAG (specialist personnel or customer-care staff). These persons must use original spare parts and must observe the instructions for service published by MELAG.
- **Danger:** Do not open the enclosure to this device before disconnecting the electrical power plug from its outlet.
- This autoclave will properly sterilize only if the operating personnel observe the instructions in this User Manual – especially the instructions for loading the autoclave in accordance with the program required.
- This appliance is only intended for use outside the patient environment (radius of 1.5 metres around the treatment location).

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4 For each sterilization cycle

4.1 Water and power

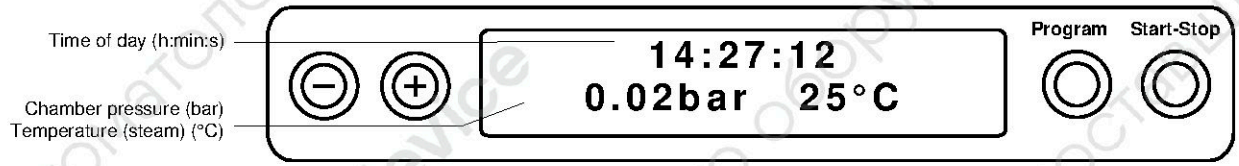
4.1.1 Demineralized / distilled water

This autoclave automatically checks to make sure that there is enough demineralized / distilled water, and it checks that the quality of the demineralized / distilled water is sufficient for starting a program. In order to start a program without delay, to avoid error messages, and to prevent a program from stopping before it is finished (see Sections 7.3 and 7.4), please make sure to carry out the following:

1. Before starting the first sterilization cycle of a day, check to make sure that there is enough water in the right side of the dual-chamber water supply tank (this applies if you are using the system's own internal supply: i.e., if you are not using a connected water-treatment system). If there is not enough water in the tank, fill with water of sufficient quality (see Section 8.3.2 of this manual).
2. If you use a direct water supply from the MELA*dem*®47 water-treatment system, make sure that the water feed to the autoclave is open in time. If the pressure tank is empty, this feed must be opened at least one hour before starting a program. This step is not necessary if the water supply remains open continuously .

4.1.2 Power supply

Switch on the power switch at the bottom right of the front of the autoclave. The message "Please wait – Door unlocking" will appear in the display. After approx. 15 s, the device will then be in its initial state.



4.2 Preparation of instruments

MELAG — use of non-rusting materials for parts which come into contact with steam

All parts of the Vacuklav®31-B which come into contact with steam are made of non-rusting materials. The sterilization chamber and the chamber door are of stainless steel, steam lines are Teflon®, and threaded connections and solenoid valves are brass.

Drag-in rust

The non-rusting parts used in the Vacuklav®31-B ensure that the autoclave itself cannot cause rust to form. In any cases in which rust has developed on the autoclave or on the sterilized items inside, investigations have consistently shown that this rust has been dragged into the autoclave from the outside by rusty instruments. **We must point out that rust can form on stainless-steel instruments made by even the best manufacturers.** One main cause of instrument rusting is improper treatment with chemical cleaning and disinfecting agents during preparation for sterilization.

Preparation of instruments for sterilization

The problem of drag-in rust shows how important it is to properly prepare items for sterilization. **It is urgently necessary to observe the following procedures:**

1. Clean and prepare (for example, by oiling) handpieces and contra angles as described in the instructions provided by the manufacturers of these items.
2. Immediately after their medical use, all other instruments must be placed in a disinfection and/or cleaning solution in accordance with UVV/VBG 103 and properly cleaned and disinfected there.
3. Always be sure to use the correct dosage of disinfection and/or cleaning agents in these solutions.
4. **Important:** Be sure to carefully follow the instructions for the length of time that the instruments must soak in the solutions.
5. We also recommend the use of ultrasonic equipment, recommended cleaning and care equipment for handpieces and contra angles, as well as thermal disinfecting techniques.
6. The proper cleaning of instruments is also essentially important in preventing particles of soiled matter from separating from the instruments during sterilization and from clogging the filters, nozzles, and valves of the autoclave. It is extremely important to use a brush to very carefully clean the locks, joints, and hinges of the instruments before sterilization.
7. **Important:** Use a brush under running water to completely rinse all cleaning and disinfecting agents from instruments before placing them in the autoclave. **Residue of chemical cleaning and disinfecting agents must by no means be allowed to enter the autoclave, since they will cause corrosion there.**
8. As a final step before placing the instruments into the autoclave, rinse them with demineralized water, and dry them well.
9. Be sure to use oil (as indicated in the manufacturers' instructions) to prepare turbines and handpieces for sterilization, in order to ensure their long service life.

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Instruments new from the factory:
Be sure also to follow the above-described pre-cleaning procedure even for instruments new from the factory. Often there are small amounts of oil, grease, and impurities still on new instruments, from their production. **Important: It is absolutely necessary to carefully follow the instructions for preparation and re-sterilization procedures which are provided by manufacturers of instruments.**

4.3 Loading the autoclave

The correct loading of the autoclave is essentially important in guaranteeing the sterilization effectiveness and the proper drying of the items being sterilized. Be sure to observe the following basic instructions in loading the autoclave:

Tray mounts:
There are 2 different tray mounts for the Vacuklav®31-B:

1. Tray mount "B" (MELAG art.-no. 40234) for loading of either a maximum of 4 trays, or 4 standard tray cassettes
2. Tray mount "C" (MELAG art.-no. 40232) for loading of either a maximum of 6 trays, or 3 standard tray cassettes.
   Both of these tray mounts are also designed to support the following MELAG sterilization containers:
   Types 15K, Type 17K,R; Type 23R, Type 28M,G.

In normal cases the autoclave should always be operated with a tray mount, since this ensures optimal steam penetration and drying. In exceptional cases, it may be possible to remove the tray mount and place the suitable containers directly into the sterilization chamber (for example, with use of sterilization containers of other manufacturers). But please check with your specialist dealer or with MELAG before attempting this solution.
For sterilization of instruments sealed in see-through sterilization packaging, we recommend the use of the MELAG Package Stand (MELAG article no. 22410). The Package Support considerably improves the results of the drying process for instruments wrapped in this way.

Trays:
Trays used for the loading of sterilized items must be perforated, in order to allow the condensate to run out. MELAG trays fulfil this requirement. We cannot advise the use of non-perforated trays or bowls (e.g., unperforated standard-tray supports), since they do not allow proper trying.

Closed sterilization containers:
Closed sterilization containers must be perforated on at least one side (preferably the bottom), or they must have valves, in order to allow the steam to properly penetrate and the condensate to flow out. All MELAG sterilization containers satisfy this requirement, with perforations on two sides and with a sterile filter cloth insert. We cannot recommend sterilization with sterilization containers with holes only on the top, since they do not allow proper drying.

See-through sterilization packaging:
If you use see-through sterilization packaging (for example, MELA*fol*®), these should be placed vertically on the tray for sterilization. We recommend the use of MELAG Foil Holders (MELAG article no. 22410).
Important: Do not stack the see-through sterilization packages horizontally on top of each other. If the sealing seam of the package breaks during sterilization, please use a longer sealing pulse on the MELAG MELASEAL Package Sealing Device, or seal with a double seam.
If standard tray cassettes are sealed in MELA*fol*® (250 mm wide), clamps or tape must be used to reinforce the side seam and to prevent it from breaking open. In addition, be sure to press excess air out of the package before sealing it.

Multiple packaging:
Air removal by sub-atmospheric pulsing allows multiple-wrapping.

Loading limits:
Be careful not to exceed the prescribed maximum loading amounts: 5kg of instruments or 1.8kg of textiles.

Mixed loads of textiles and instruments:
If you are sterilizing textiles and instruments at the same time, place the textiles above the instruments and do not allow the textiles to come into direct contact with the instruments. Do not sterilize textiles and instruments in the same sterilization container. **Important:** Do not by any means allow the textiles to come into direct contact with the wall of the sterilization chamber. Please observe the following instructions for different types of packaging in one sterilization cycle:
Place the see-through sterilization packaging and paper packing on the top (but if you are using a combination with textiles: then arrange these packages on the bottom)

Sterilization of liquids:
Danger: The Vacuklav®31-B is not suitable for the sterilization of liquids.

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4.4 Closing the door

Close the door by slightly pressing it shut in the direction of the sterilization chamber flange, and at the same time press down the sliding handle until it will go no farther. The following message will appear on the display:

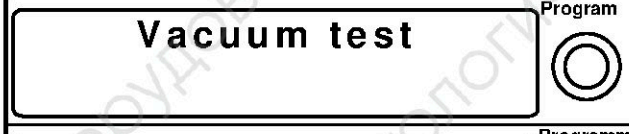
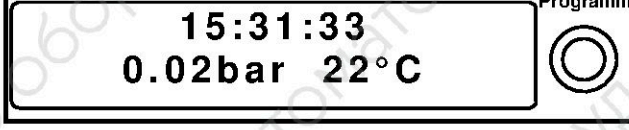


4.5 Selection of the program

Select the required program on the basis of the following criteria:

- The physical properties of the items to be sterilized (especially their ability to resist high temperatures)
- The type of packaging (you must use the “Universal program”, or the “Gentle program” if part or all of the load is wrapped).

Press the button “Program selection” repeatedly to run through the following programs (and the initial position), and to make your selection:

Program name / Display message	Parameters / applications
	**Universal program** at 134°C, 2 bar, and a sterilization time of 3.5 min, for: Sterilization of all kinds of wrapped items, especially instruments, or mixed loads (wrapped and unwrapped)
	**Quick program** at 134°C, 2 bar, and a sterilization time of 3.5 min, for: Sterilization of **only unwrapped instruments** (and no textiles), for fast re-use of the sterilized items (you must interrupt the drying cycle manually)
	**Gentle program** at 121°C, 1 bar, and a sterilization time of 15 min, for: Sterilization of all kinds of wrapped items, especially larger amounts of textiles, and of items sensitive to heat (plastic and rubber articles), and for mixed loads (wrapped and unwrapped)
	**Prion Program** (a special Universal Program) at 134°C, 2 bar, and with sterilization time extended to 20 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).
	**MELAsteam Cleaning** at 136°C, 2.3 bar, and a maximum cleaning time of 60 min., for the steam cleaning of instruments that have **already been disinfected**. **CAUTION: Use only together with a permanently installed MELA*steam*® Pistol (otherwise the system is disabled.** See the Operator’s Manual for MELA*steam*®.
	**Bowie & Dick Test Program** at 134°C, 2 bar, and a sterilization time of 3.5 min, for: Functional testing of the autoclave (verification of steam penetration by using special indicators)
	**Vacuum test** program for: Functional testing of the autoclave (verification of the vacuum seal of the autoclave by determining the leak rate). Start this program when the autoclave is cold.
	**Initial position** of the autoclave (no program selected)

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4.6 Start of program

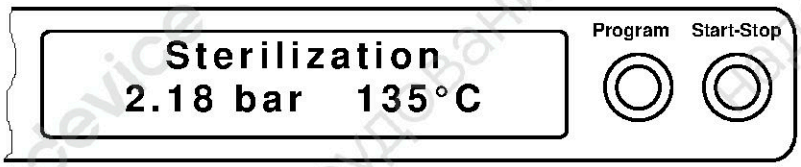
Start the selected program by pressing the button “Start – Stop”. When you press this button, the autoclave will automatically begin to check the quality and quantity of the available demineralized / distilled water, and will run a conductivity test.



When you start the “Quick program”, the display will also show the warning message: “Warning: only unwrapped instruments”. When you start the disinfection program, the display will show the warning: “Warning: Not sterilization”. When you see these messages, you must acknowledge them by pressing the button “Start” again.

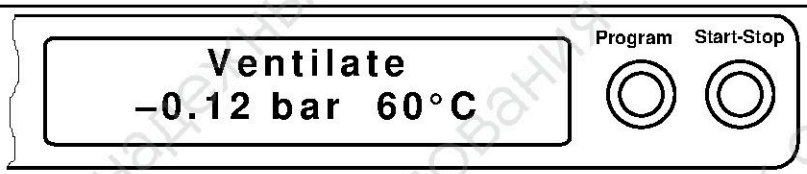
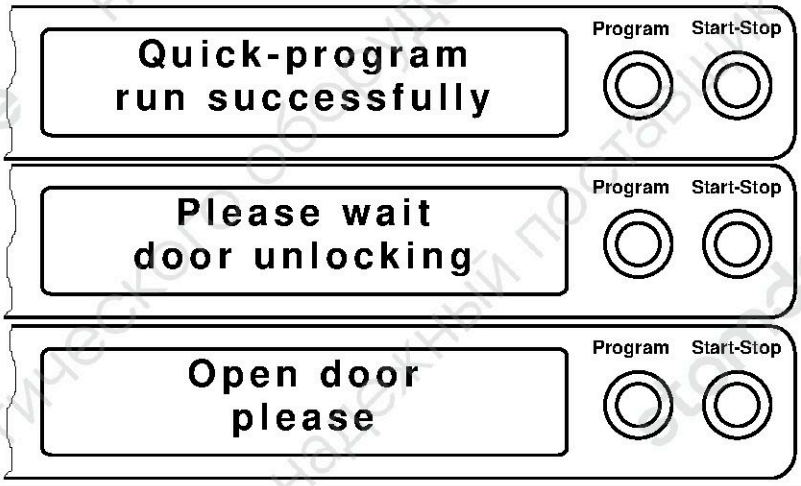
4.7 Program sequence

After you start the program, its sequence will begin to run fully automatically. The display will continuously show the status of the running program as follows:

Program status:		Shown on the display:
1.	**1. Pulsing**, consisting of evacuation (air removal), until a programmed evacuation pressure, and with steam injection until a slight overpressure are reached. The display shows the chamber pressure and the steam temperature.	
2.	**2. ... and additional pulsing steps** Additional pulsing (as described above) will take place, depending on the program selected. This continues until the required vacuum is achieved and the required penetration of the items with saturated steam have taken place.	
3.	**Heating-up phase** The heating-up phase follows pulsing. Continued injection of steam into the chamber increases the pressure and temperature, in accordance with the saturated-steam curve, until the programmed parameters are achieved.	
4.	**Sterilization phase** When pressure and temperature are in accordance with the saturated-steam curve, and when the programmed required values are reached, the actual sterilization time begins to run. The display flashes between showing the pressure / temperature, and showing the time remaining in the sterilization phase.	 
5.	**Pressure release** After the sterilization phase has come to an end, pressure release will follow, with simultaneous emptying of the steam generator. Pressure and temperature fall.	

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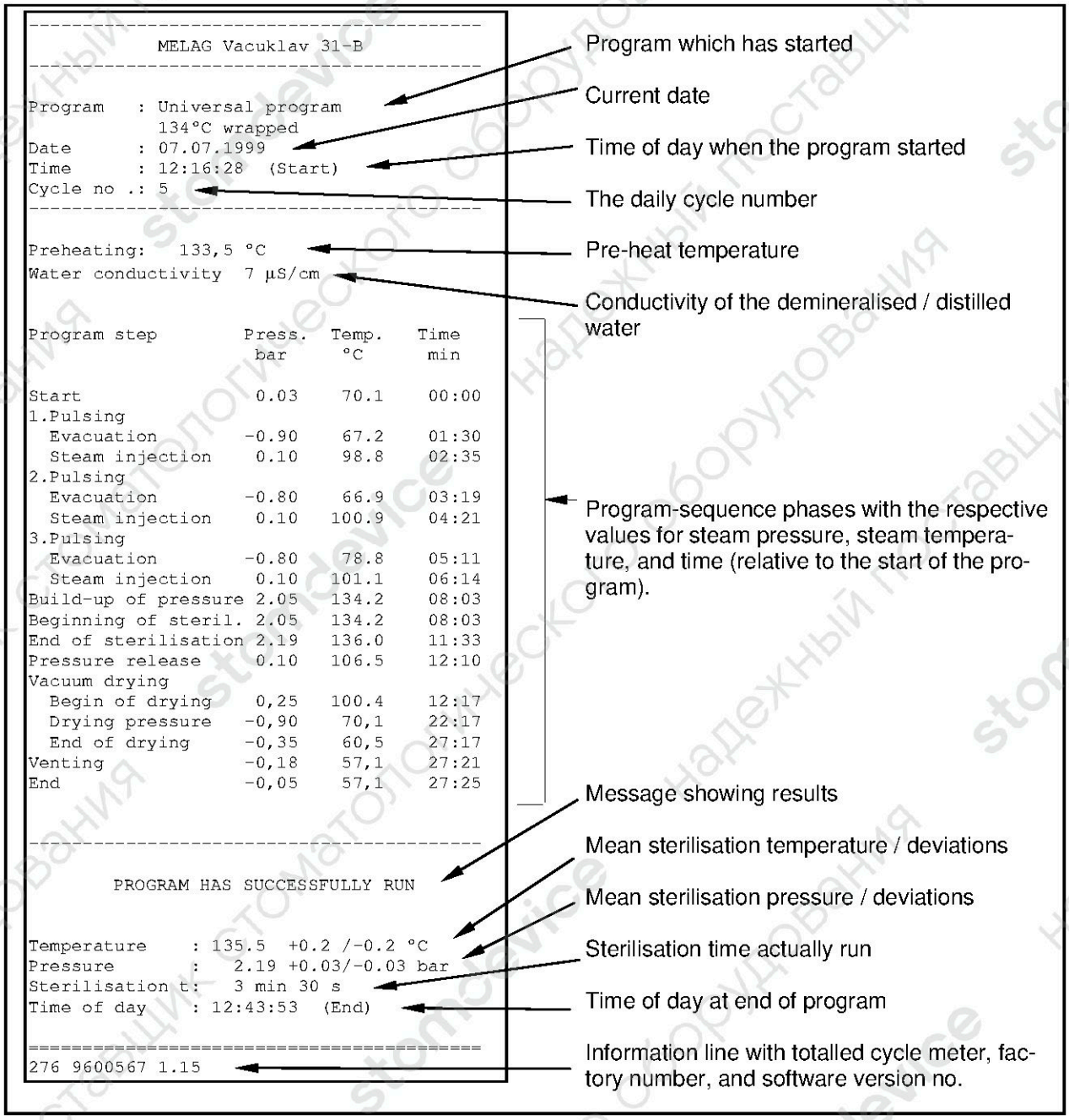
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Program status:		Shown on the display:
6.	**Drying phase** After the pressure has been released, the drying phase begins. After the drying phase begins, it is possible to interrupt the program without causing an error message. This is because the actual sterilization phase is complete. You should wait until the drying has come to an end, however (unless you are using the "Fast program").	
7.	**Ventilation** At the end of the drying period, the sterilization chamber is vented in a pressure-compensation process, until the pressure returns to normal atmospheric level.	
8.	**End of program** When the venting of the sterilization chamber is complete, the program cycle is finished. If a printer is connected to the autoclave, and if the immediate-printout option is set to "Yes", a record of the sterilization cycle will be printed out. When the autoclave has automatically unlocked the door, you can open the door to remove the sterilized items.	

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Printout of cycle log

The printout of the cycle log contains the following information:



4.8 Removing the sterilized items

You can remove the sterilized items after opening the door. **Danger of burning!** Do not touch the hot sterilization chamber or the door of the autoclave unless you are wearing sufficient protection for your hands (gloves, etc.). Be sure to use the proper tools (MELAG Tray Lifter or standard tray lifter) or hand protection (pot holders or gloves) to remove the hot sterilized items from the autoclave.

4.9 Sterile storage

After removing sterilized items which are wrapped, check the package to determine whether it is damaged. If it is damaged (broken package seals, for example), you must sterilize the contents once again. **Important:** If you must sterilize the contents again, they must be wrapped in a new package.
The sterilized items must be sufficiently dry before proper sterile storage is possible. The Vacuklav®31-B provides excellent drying if the complete program is allowed to run (i.e., without interrupting the drying process), and if the loading instructions given in this manual are properly observed (see Section 4.3 above). Immediately after

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sterilization it can occur that condensation residue remains on the sterilized items or on their package. The heat from the still-hot sterilized items will evaporate this condensate after completion of sterilization. DIN 58953, Part 7, Section 7, contains the following on moisture residue on paper wraps or see-through sterilization paper after sterilization: "Small amounts of water on the outside of the packages are harmless if they have dried away within 30 minutes after taking them out of a steam sterilizer."
After they have cooled down, provide sterile storage for wrapped sterilized items where they are **not subjected to dust** (for example, in an instrument cabinet). Under conditions of dust-protected storage, DIN 58953, Part 7, provides a rule of thumb for the maximum shelf life of sterilized items: six (6) weeks for sterilized items in single wrapping (e.g., see-through sterilization packages), and six (6) months for sterilized items in double sterilization packages.

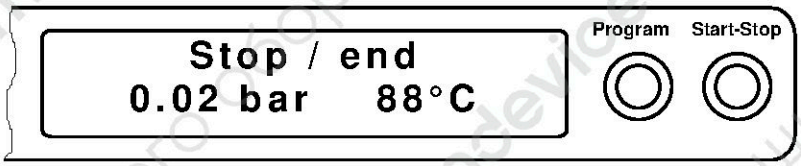
4.10 Sterilization frequency / interval periods

After the drying phase has run out, or after it is interrupted by the user, the autoclave can be immediately loaded with new items and started again at once. It is not necessary to wait before starting the next cycle.

4.11 Manual abort of the program

4.11.1 Aborting during the sterilization phases

It is possible to terminate any started program prematurely by pressing the "Start-Stop" button. **Caution:** If you abort a program before it reaches the "Drying" step, then the items inside the autoclave must be considered **not sterile**.
Warning! When you open the autoclave door, it is possible that dangerous steam can escape from the sterilization chamber (depending on the operating status just before the door is opened). If you abort a program before it reaches the "Sterilization" program phase, we recommend that you run the next program without any items in the sterilization chamber.

Operator action		Shown on the display:
1.	Press the "Start-Stop" button. A safety question will then appear for 5 seconds on the display so that you can confirm that you really want to abort the program. If you take no further action, the program will continue as usual after this 5 s has run out.	
2.	If you press the "Start-"Stop" button again before the above-stated confirmation question disappears from the screen (within 5 seconds), then the program will prematurely stop. If the autoclave is operating in a state in overpressure (greater than normal atmospheric pressure) when you abort a program, a pressure-release step will follow. If the autoclave is in a vacuum status, a venting step will take place	 
3.	After pressure compensation has been achieved, the following two messages will alternate on the display: "Termination end" and "Confirmation with '–' key". If you press the "–", this will confirm that you wish to terminate the program.	 
4.	Press the "–" button to confirm that you really want to abort the program. You will then see the message "Please wait – Door unlocking." The display will then show the program which you have selected.	

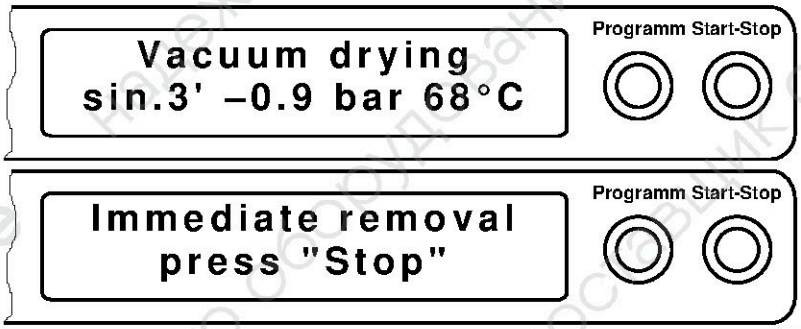
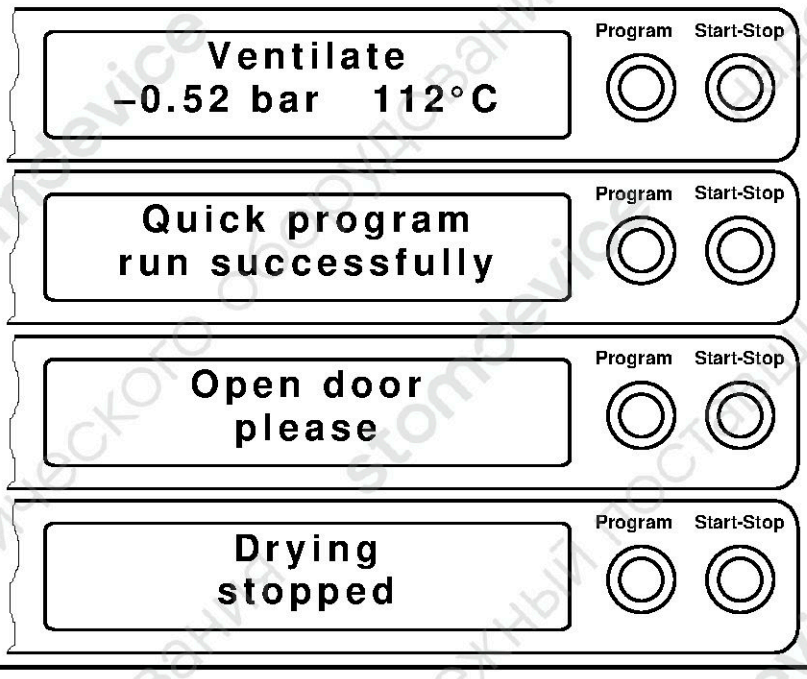
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4.11.2 Interruption of a drying phase

A program can be terminated after starting of the program step “Drying”, e.g. in case of needing an instrument urgently for use. Since the sterilization has been completed, the items are sterilized at this point. Drying is crucial for sterile storage. Depending on when the drying phase was terminated, in particular in the case of wrapped sterile items, insufficient drying must be expected.

Warning! The EU standard EN 13060 stipulates very good drying results for “class B” – autoclaves, which are not ensured by terminating the drying cycle. So in this case the sterilization was not executed according to “Class B”.

With the “Quick-program”, it is possible to interrupt the drying phase in order that the items can be immediately used. Once the interrupted program comes to a stop, take the unpacked instruments out of the autoclave. The intrinsic heat of the instruments will dry the moisture on them as they cool down. **Warning!** When you open the autoclave door, it is possible that dangerous steam can escape from the sterilization chamber (depending on the operating status just before the door is opened).

Operator action		Shown on the display:
1.	The autoclave is in the drying phase. The display alternates between the two following messages: “Vacuum drying”, followed by the length of drying time which has already run. ... and ... The message showing how you can interrupt the drying phase.	
2.	Press the "Start-Stop" button. A safety question will then appear for 5 seconds on the display so that you can confirm that you really want to abort the program. If you take no further action, the program will continue as usual after this 5 s has run out.	
3.	If you press the "Start-"Stop" button again before the above-stated confirmation question disappears from the screen (within 5 seconds), then the program will prematurely stop.	
4.	The system will then vent the sterilization chamber. When the sterilization chamber has been vented, the program sequence is finished. The following status message will appear on the display: It will alternate with the following message: And with the following message: If a printer is connected to the autoclave, and if you have selected “Yes” for the option for immediate logging, the printer will immediately log the message that the drying phase has been interrupted.	

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4.12 Response in case of warnings and error messages

The Vacuklav®31-B has safety features as well as an extensive checking and monitoring system which is integrated into the computer control. These functions guarantee a maximum of possible reliability for the sterilization process, and eliminate risks arising from the autoclave for the patient and the autoclave operator.
For example, the system continuously tests a number of autoclave functions (for example, the sensor systems for pressure and temperature) after the power switch is turned on. The autoclave system also checks to make sure that further conditions are met for successful program start: For example, that power and water are present in sufficient quantity and quality. Start of the program is not possible if these conditions are not fulfilled.
After the initial test, and after the program starts, the system will monitor all parameters relevant for sterilization, as well as additional limit values for the individual program phases. If these limit values are exceeded, the system will display the respective error messages and will automatically interrupt the program.
In addition to instructions, warnings, and error messages on the display, the printer (if connected) will log out the type of errors and faults, and the time of their occurrence.
If any of the above-stated messages appear, please read Section 7 of this manual for appropriate reactions. This section also contains instructions concerning possible operator faults.

4.13 Operational shutdowns

If the autoclave is not being used for a certain period of time (for example, overnight), leave its door slightly open rather than closing it. This will spare the door gasket and will lengthen its service life (e.g., by preventing it from sticking shut).
In case of longer inactive periods – such as vacations – shut off the supply of water from the water treatment system.

5 Placing the autoclave out of operation / transport / putting the autoclave back into service

If you wish to take the autoclave out of operation, or if you wish to transport it, please proceed as follows:

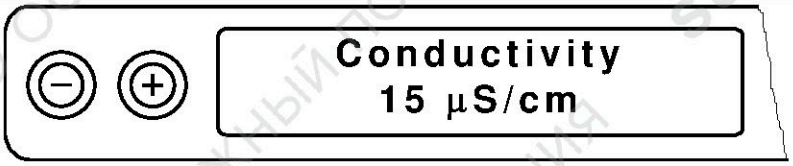
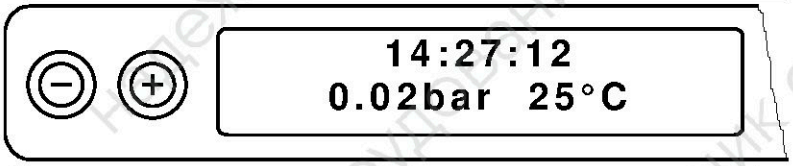
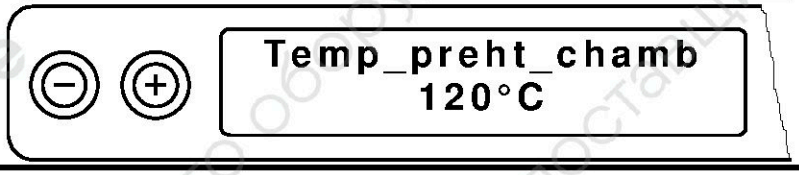
- Pull out the power plug. Allow the autoclave to cool down.
- Drain both chambers of the water supply tank (see Section 2.8). Or, if you have a direct connection to a water-treatment system, shut off the supply of demineralized / distilled water from this system.
- Disconnect the hoses on the rear of the autoclave if you are using a water-treatment system (external water supply).
- If you are transporting the autoclave with its tray racks and trays still inside, protect the surface of the door window by inserting a layer of foam rubber or other suitable material (e.g., bubble wrap) between the door and the sterilization chamber.
- **Important: To prevent transport damage, be sure to use the original packing of the autoclave. If there is a danger of frost damage during transport, be sure to follow the steps provided in the special service instructions.**
- To place the autoclave back into service after transport or repair, follow the instructions given in Sections 2 and 3 of this manual.

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6 Special functions

6.1 Display of water quality (conductivity) / pre-heat temperature of the sterilization chamber

Be repeatedly pressing the "–" button, you can at any time display the pre-heat temperature of the sterilization chamber, and the conductivity of the demineralized / distilled water being used. These two displays will flash alternatively on the screen, as follows:

Operator action	Shown on the display:
1. Press the "-" button and hold it down: This will display the conductivity of the demineralized / distilled water in µS/cm.	
Release the button "-": This will return you to the normal display (the initial position, the selected program, or the program status). Shown here: the initial position.	
Press the "-" button repeatedly and hold it down: This will show the pre-heat temperature of the sterilization chamber in °C.	

6.2 Selection for additional drying

The standard drying times for each specific program guarantee sufficient drying of the sterilized items if all instructions for loading are followed (see Section 4.3). If, however, residual moisture remains on the sterilized items after you have used special loading variations, you can select the function “Additional drying” to lengthen the drying time by 50%, as follows:

Operator action	Shown on the display:
When you start the program, press the button "+" at the same time. The display will confirm the selection for additional drying. Then the program will run as described in Section 4.7. The drying times will be extended by 50%.	

6.3 Logging / documentation of sterilization cycles

The non-volatile memory of the autoclave computer control system archives the records of the last 40 sterilization / disinfection cycles. The user can print out these logs immediately, or at any other time, by using the serial interface (RS232). If the computer memory is full, with 40 records, the system will overwrite the oldest record automatically when the next program starts. If an external printer is connected for logging, if it has been initialised, and if the printout option setting is for “No” under “Immediate printout”, then the system will ask the user if he or she really wants to overwrite the oldest record (see Section 7.3). The following section describes the various possibilities for output media, and for the manner of outputting the logs.

6.3.1 Output of logs

6.3.1.1 External printer

6.3.1.1.1 Connection of the external printer Mela*print*®42

To connect the Mela*print*®42 external printer to the autoclave, plug in the data-transfer cable at the 9-pole jack on the front of the autoclave, and plug in the other end to the 25-pole jack at the rear of the printer. Securely insert the cable plugs and tighten the screws to fasten them down. Hook up the printer to the mains power supply by plugging in the delivered power supply unit with its power cable to a power outlet. Then plug in the coaxial plug (the low-voltage output of the power supply unit) to the power-supply jack at the rear side of the printer. The printer will confirm that it is ready for operation when the operating-voltage display shows “P”, and when the status display (the ON / OFF line) shows “SEL”. For more instructions on placing the printer into operation (e.g., installation of the

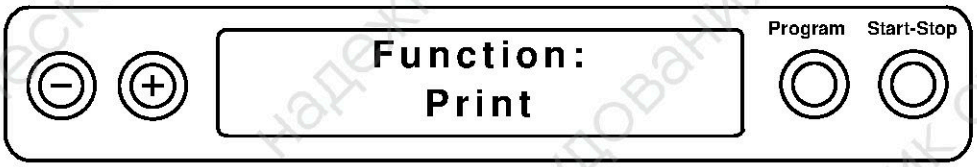
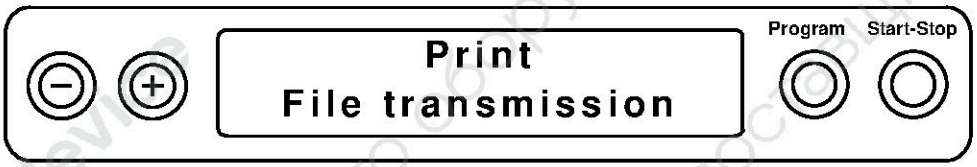
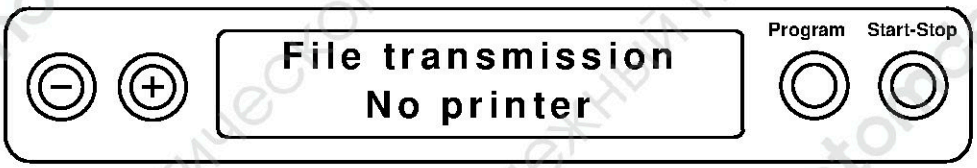
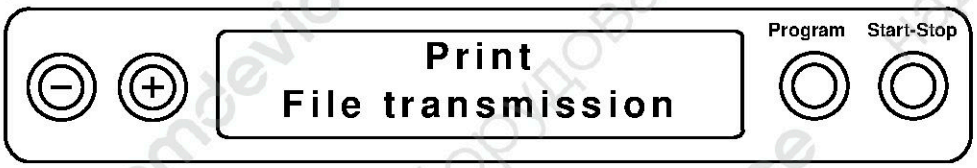
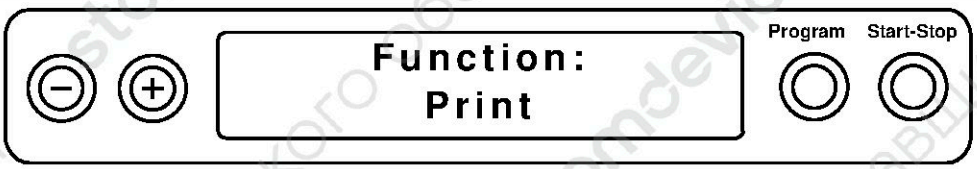
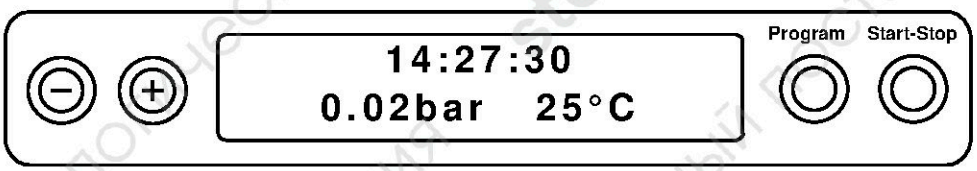
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external paper-roll mount, insertion of the paper roll, etc.), and on how to operate the printer, please consult the manual for the printer.

6.3.1.1.2 Initialization of the printer

After you have connected the printer to the autoclave, you must initialise the printer. This means logging it in to the autoclave computer control system. Please proceed as follows:

Operator action		Shown on the display:
1.	Switch on the autoclave. It must be in its initial position: 1st line: time of day 2nd line: chamber pressure and temp.	
2.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item “Function” with sub-menu “Print” will appear.	
3.	Press the button “Program”. The menu item “Print” with sub-menu “File transmission” will appear.	
4.	Press the button “Program”. The menu “File transmission” will appear. The current setting will appear (e.g., “No printer,” as shown to the right).	
5.	Press the button "+" (or "-") until the message “External printer” appears in the display.	
6.	Press the button “Program”. The display will confirm the setting and will return to the menu “Print”.	
7.	Press the button "Start-Stop". The system will return to the menu "Function".	
8.	Press the "Start-Stop" button. The system will leave the menu "Function" and will return to the initial position.	

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6.3.1.2 Connection to an external PC

6.3.1.2.1 Installation

You can also use an external PC to output the autoclave log, and to archive data. To install this mode, use a null modem cable to connect the serial interface of the PC to the printer interface of the autoclave. You must install the program MELA*win* on your PC to allow data transfer and to enable processing of this data. The software manual for MELA*win* provides detailed instructions on all the possibilities you can use.

6.3.1.2.2 Initializing the output on your PC

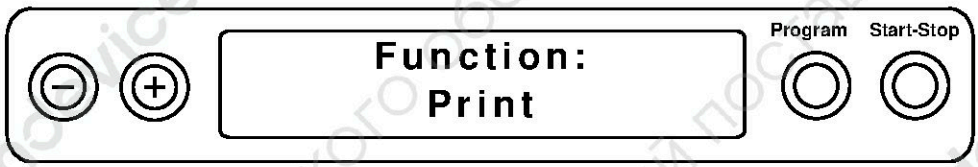
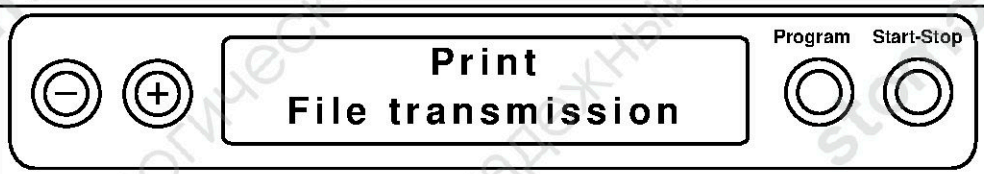
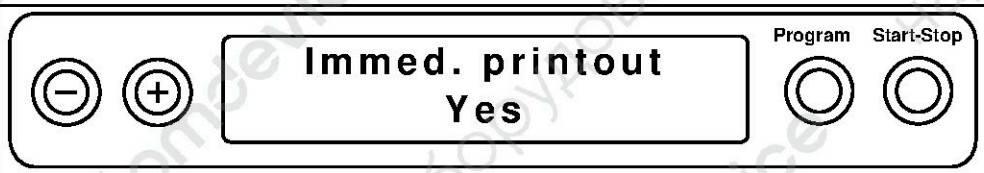
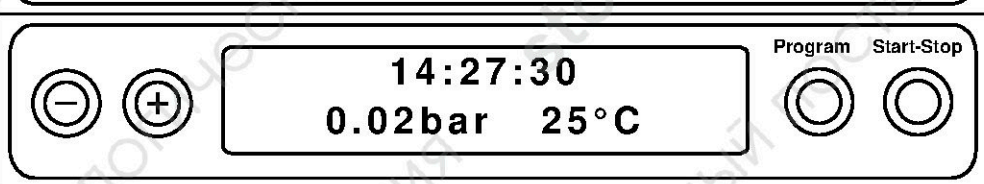
After you have connected the autoclave to your PC, you must set the log output function to "External PC". Follow the same procedure here as for initialisation of an external printer (see Section 6.3.1.1.2 of this manual). There is one difference, however: under step no. 5, use the "+" or the "–" button to set the option to "External PC".

6.3.1.3 No printer

In order to set the option "No printer", follow the same procedure as described under Section 6.3.1.1.2. There is one difference, however: under step no. 5, use the "+" or the "–" button to set the option to "No printer".

6.3.2 Immediate printout option: YES or NO

If you have connected an external printer to the autoclave, and if you have initialised this printer, you can have the autoclave automatically log out a printout at the end of each program cycle. To make this setting, first switch on the main power to the autoclave, and then carry out the following steps:

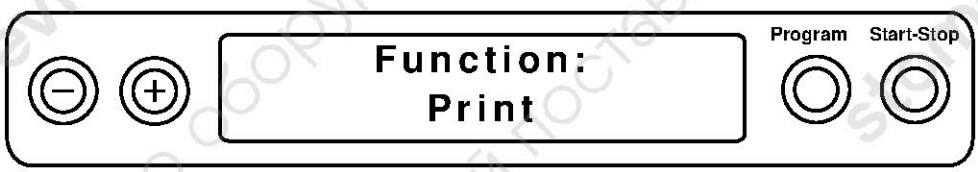
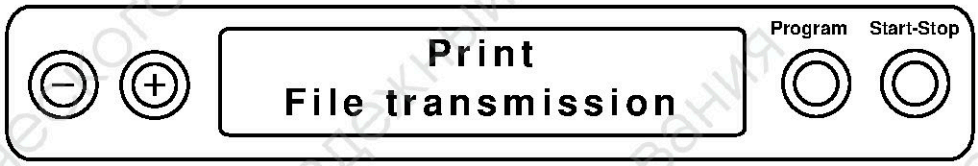
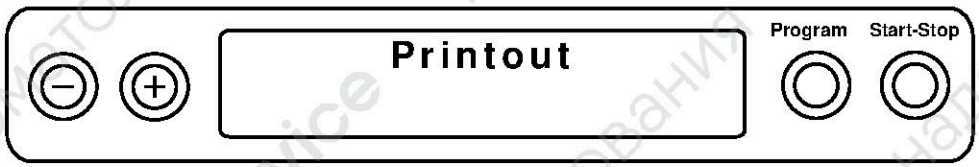
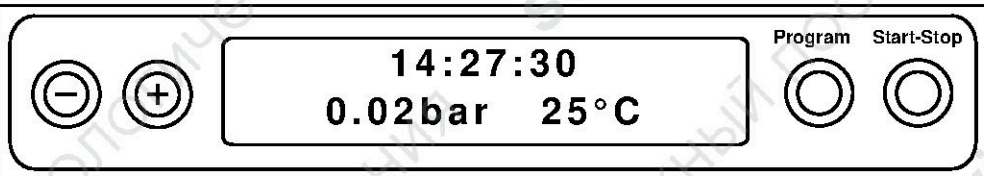
Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+". The selection in the sub-menu "Immediate printout" will appear. The display will show the option set until now (in this example: "No").	
4.	You can use the "Program" button to toggle back and forth between "Yes" and "No". Press "Program" until the option "Yes" appears.	
5.	Press the "Start-Stop" button. This will confirm the new setting and return you to the menu "Function" with sub-menu "Print".	
6.	Press the button "Start-Stop". You will now leave the menu "Function" and return to the initial position.	

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6.3.3 Printing out stored cycles at a later time

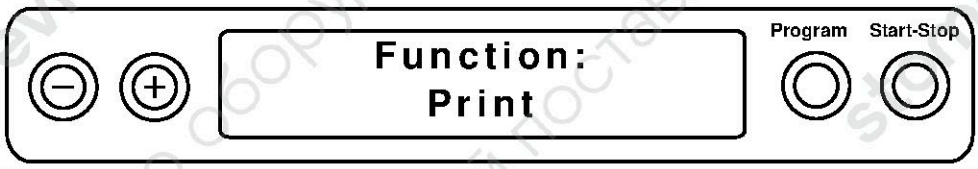
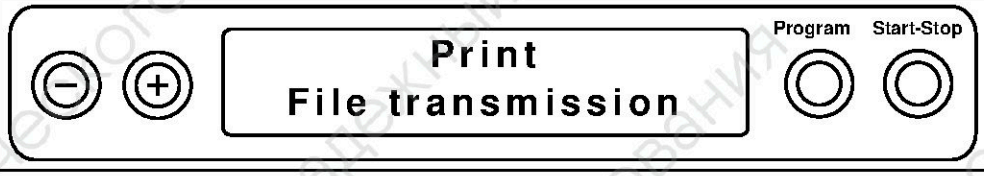
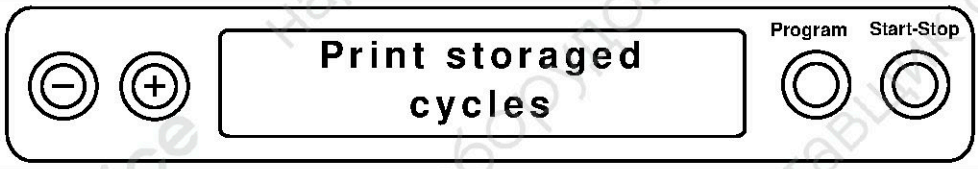
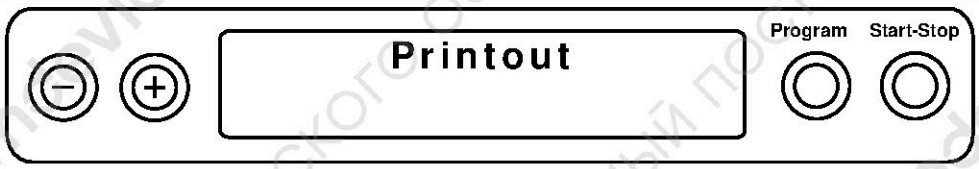
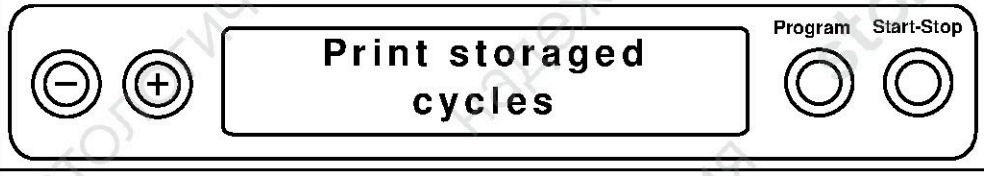
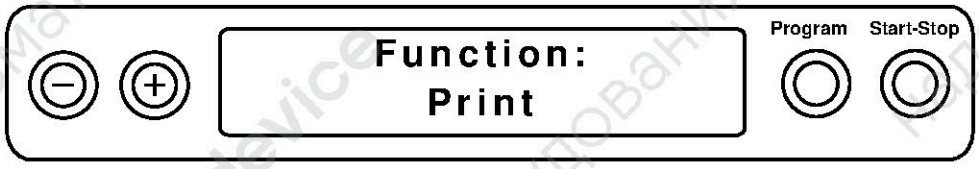
If you have connected an external printer to the autoclave, and if you have initialised this printer, you can print out earlier cycles which you have later selected. To do this, switch on the autoclave at its mains power switch, and make the following settings:

Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+" (or "-") repeatedly until the following display appears: "Last cycle: print no. 40".	
4.	Press the button "Program". The log number will flash in the display.	
5.	To select the log which you wish to print out, press the button "+" (or "-") until the number of the log appears on the display which you wish to print out: e.g., 25.	
6.	Press the button "Program" to start printing out the selected log. To interrupt the printing, press "Start-Stop". This will return you to the menu "Function".	
7.	After the printout is finished, the first display will appear again. To print out other stored cycles, start at step no. 4 again, or ...	
8.	... press "Start-Stop" to return to the menu "Function".	
9.	Then press "Start-Stop" when you wish to return to the initial position.	

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6.3.4 Printing out all stored cycles

If you have connected an external printer to the autoclave, and if you have initialised this printer, you can print out all stored logs at any point in time. To do this, switch on the autoclave at its mains power switch, and make the following settings:

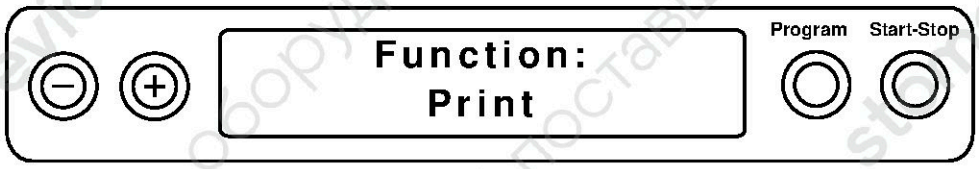
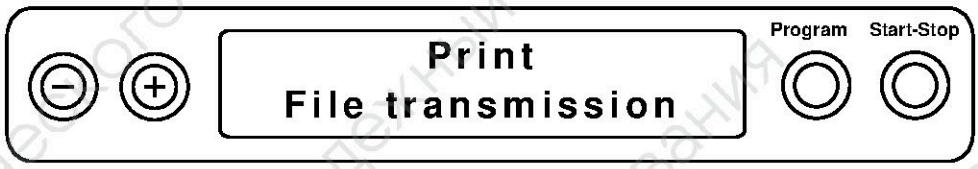
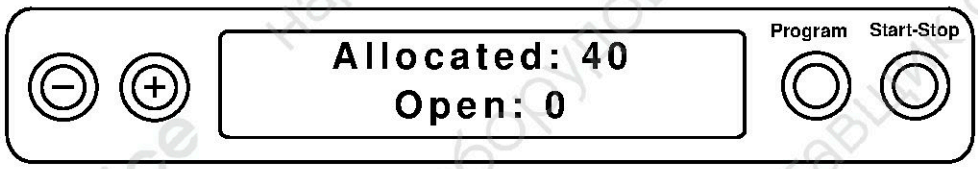
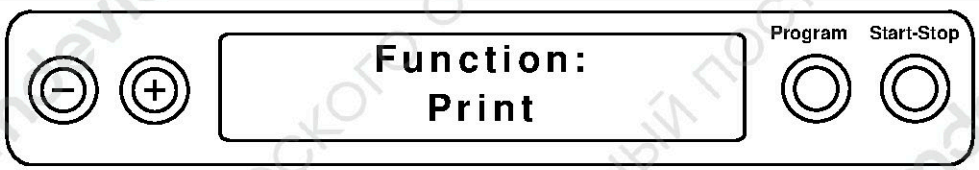
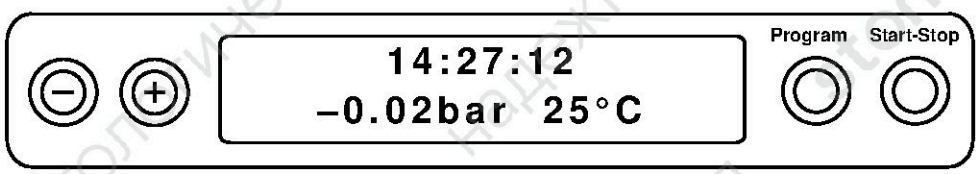
Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+" (or "-") repeatedly until the following sub-menu appears in the display: "Print storaged cycles".	
4.	Press the button "Program" to print out all stored cycles (up to 40). You can press "Start-Stop" to cancel printing, but once the printout has started, you can interrupt it only by switching off the main power switch.	
5.	After the printout is finished, the initial message appears again:	
6.	Press "Start-Stop" to return to the menu "Function".	
7.	Then press "Start-Stop" again to return to the initial menu position.	

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6.3.5 Displaying the contents of the printer memory

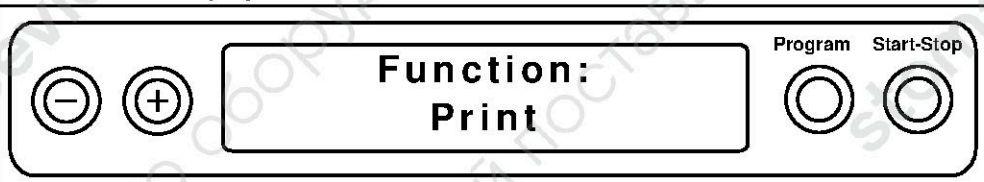
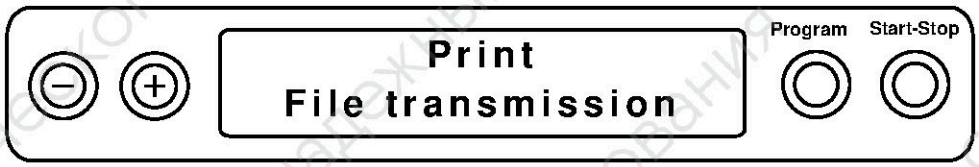
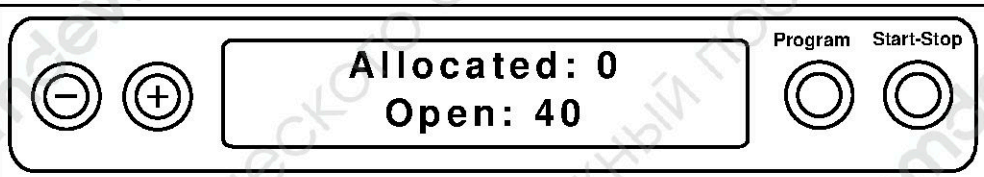
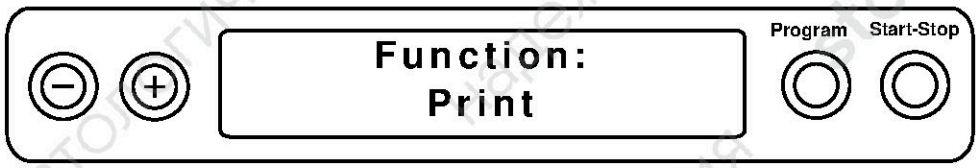
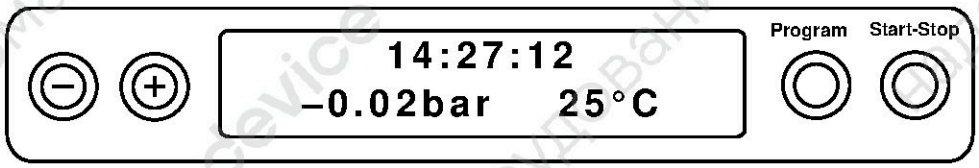
If you have connected an external printer to the autoclave, and if you have initialised this printer, you can look at the content of the printer memory by carrying out the following steps:

Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+" (or "-") repeatedly until the display shows the content of the print memory. This example shows 40 cycles stored and no free memory.	
4.	Press "Start-Stop" to return to the menu "Function" ...	
5.	Then press "Start-Stop" again to return to the initial menu position.	

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6.3.6 Deleting stored cycles from the memory

You may wish to erase all stored cycles from the memory: for example, to avoid the warning “Printer memory full”. This is possible only if you have set the immediate-printout option to “No” (see Section 7.3 of this manual). First, switch on the power to the autoclave, and proceed as follows:

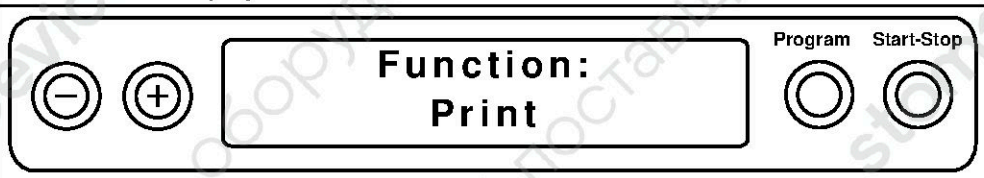
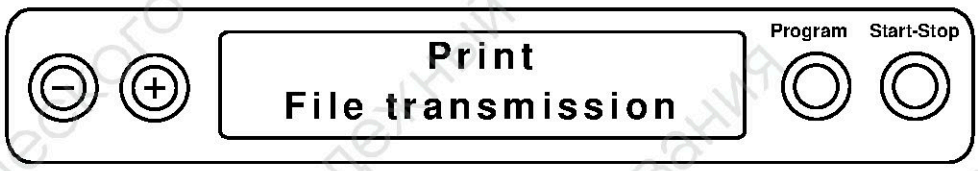
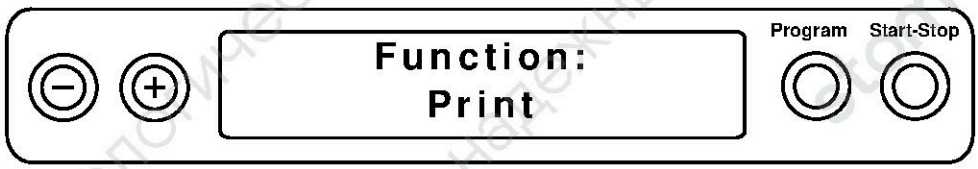
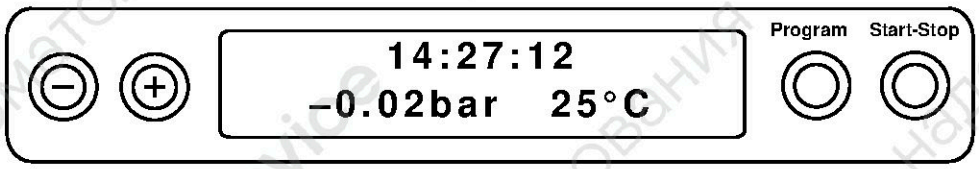
Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item “Function" with sub-menu “Print" will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+" (or "-") repeatedly until you see the following in the display: "All cycles delete".	
4.	Erase all cycles from memory by pressing the button "Program". You can cancel this action by pressing "Start-Stop".	
5.	Press "Start-Stop" to return to the menu "Function".	
6.	Then press "Start-Stop" again to return to the initial menu position.	

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6.3.7 Test printout

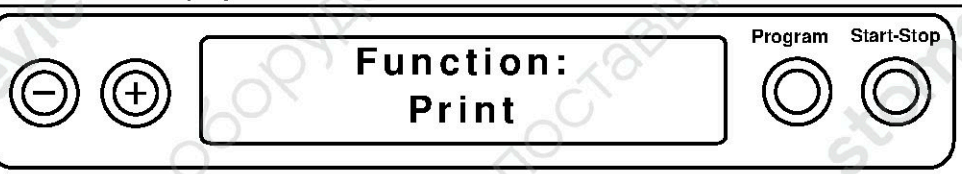
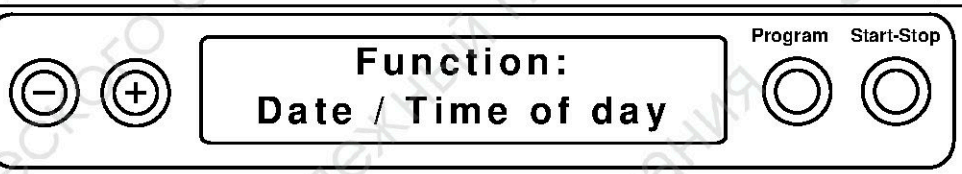
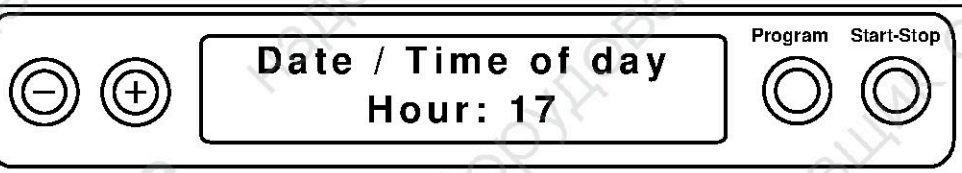
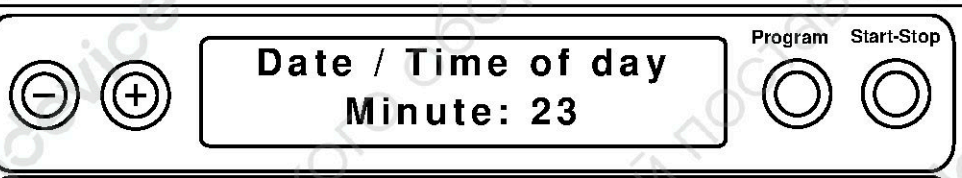
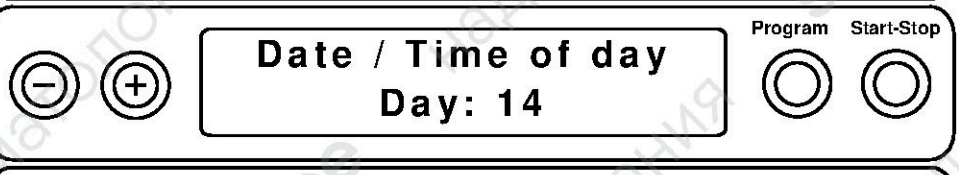
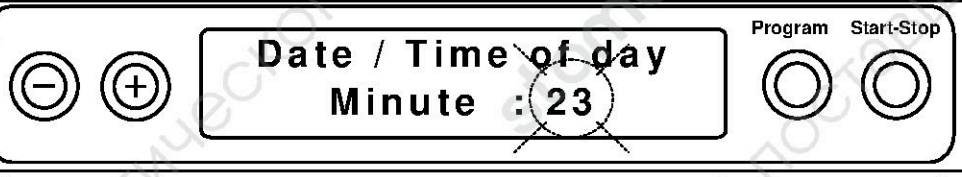
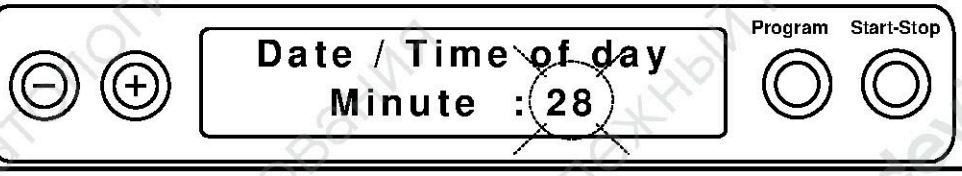
To check the printer functions and the communication between the printer and the autoclave, print out a test log as follows:

Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item “Function” with sub-menu “Print” will appear.	
2.	Press the button "Program". The menu item "Print" with sub-menu "File transmission" will appear.	
3.	Press the button "+" (or "-") repeatedly until the following appears in the display: "Test printout".	
4.	Press the button “Program” to start the test printout. Or, you can press "Start-Stop" to cancel this printout.	
5.	Press "Start-Stop" to return to the menu “Function”.	
6.	Then press "Start-Stop" again to return to the initial menu position.	

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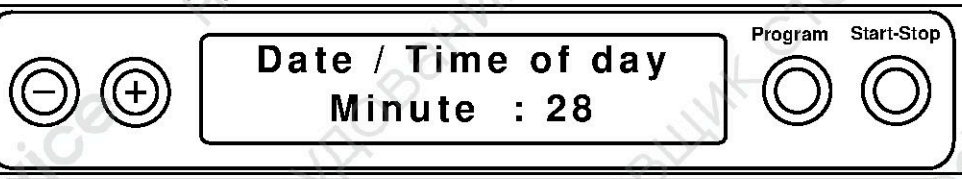
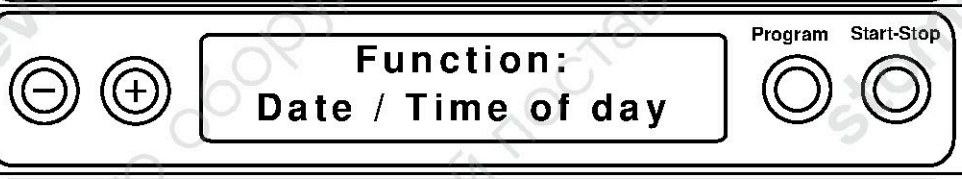
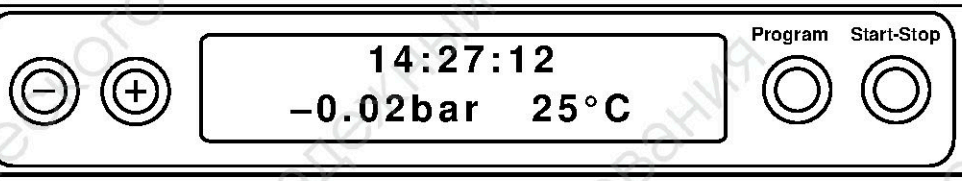
6.4 Setting the date and time of day

You can set the date and time of day as required (for example, for changes between winter and summer time). Proceed as follows:

Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item “Function” with sub-menu “Print” will appear.	
2.	Press the button "+" (or "-") repeatedly until the following sub-menu appears in the display: "Date / Time of day",	
3.	Press the button "Program". The display will show the time as currently set (here, for example, 17.00 hours = 5:00 p.m.).	
4.	Press the button "+" (or "-") repeatedly to move among the options shown in the examples at the right:	    
5.	When you reach the option which you want to set (for example, "Minute"), press the button "Program". The value as currently set will begin to flash.	
6.	Press the button "+" or "-" to increase or decrease the value which is flashing. In the example here, the "+" button was pushed to increase the value for minutes.	

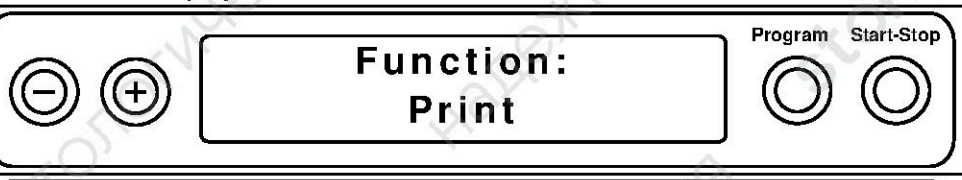
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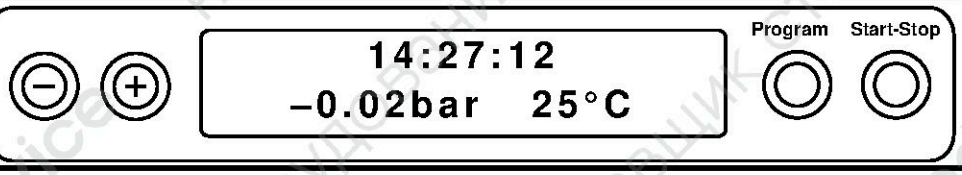
Operator action		Shown on the display:
7.	Press the button "Program" to confirm the newly set value. The new value will now stop flashing. To set other values, return to step 4 above and follow the same procedure.	
8.	To finish the settings, press the "Start-Stop" button to return to the "Function" menu, and ...	
9.	Then press "Start-Stop" again to return to the initial menu position.	

6.5 Automatic pre-heating

The Vacuklav®31-B has a function which, before the program starts, heats the sterilization chamber to the pre-heating temperature required by the specific program. This function can also keep the chamber at this temperature between consecutive cycles. This heating reduces the formation of condensate on the walls of the sterilization chamber: which shortens the cycle times and enables excellent drying results. If the automatic pre-heating function has been activated, it will go into operation when the autoclave is turned on at its power switch. The default setting for the autoclave (the setting when delivered from the factory) is for automatic pre-heating. You can change this default setting, however, and can switch this automatic pre-heating function off and on as required. To do so, proceed as follows:

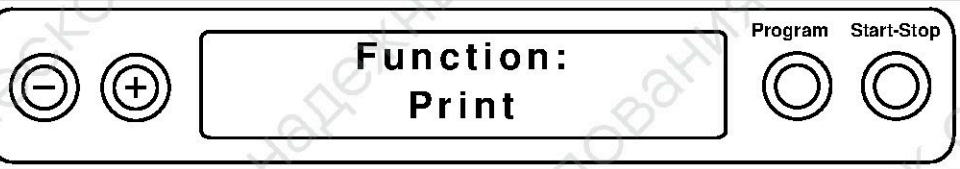
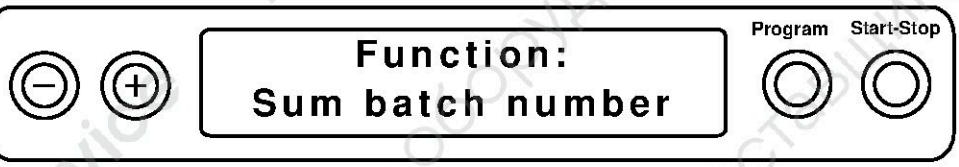
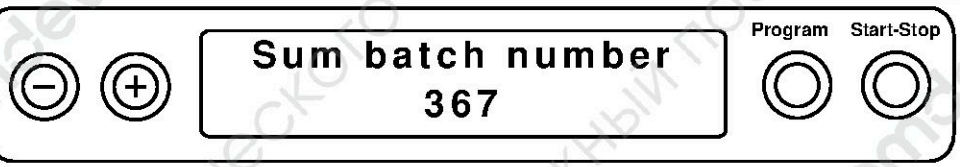
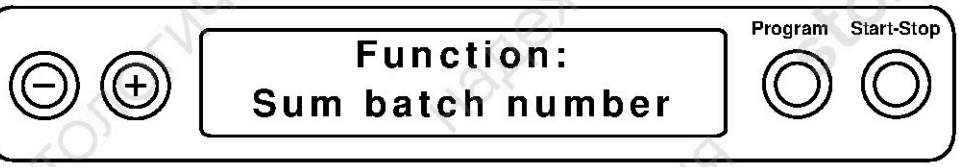
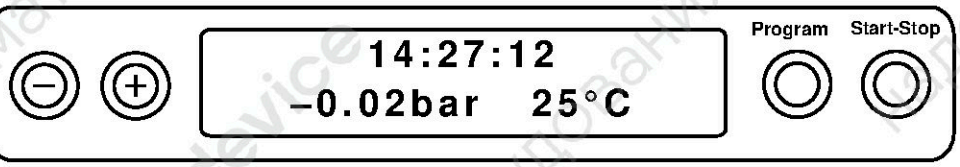
Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "+" (or "-") repeatedly until the sub-menu "autom. Preheating" appears in the display.	
3.	Press the button "Program". The display will show the current setting. In the example to the right, the current setting is "Yes".	
4.	You can press the button "Program" to toggle back and forth between "Yes" and "No". In the example to the right, the user has pressed the button once to change from "Yes" to "No".	
5.	To end the setting procedure, press "Start-Stop", and you will return to the menu "Function".	

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Operator action		Shown on the display:
6.	Then press "Start-Stop" again to return to the initial menu position.	

6.6 Total-cycle counter

The Vacuklav®31-B has a total-cycle counter. You can read the current number of total cycles by proceeding as follows:

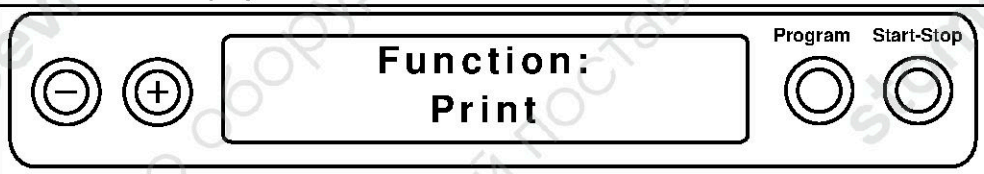
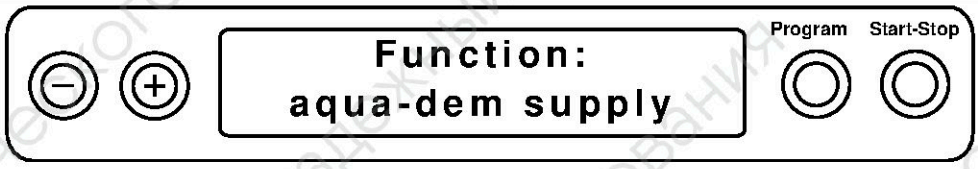
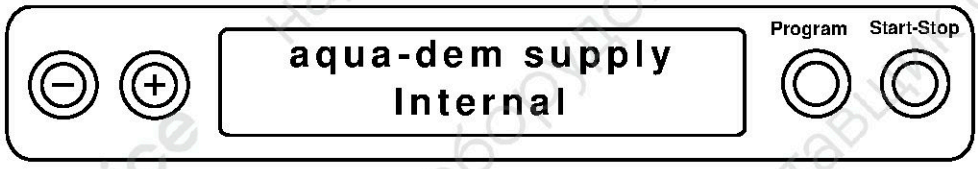
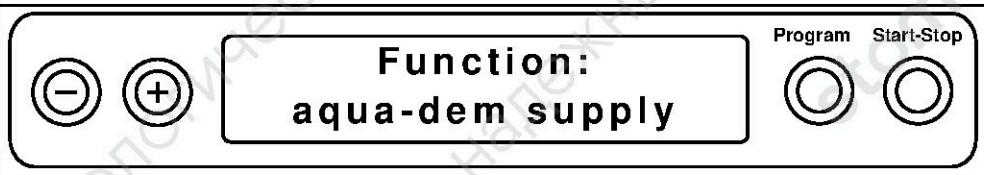
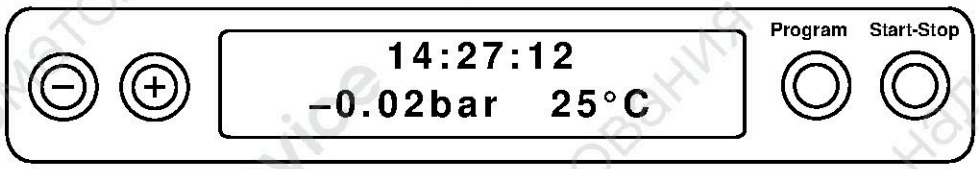
Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "+" (or "-") repeatedly until the sub-menu "Sum batch number" appears in the display.	
3.	Press the button "Program". The display will show the current meter reading. This is the total number of cycles executed until now.	
4.	To leave this display, press the button "+" (or "-"). This will return you to the menu "Function". Now ...	
5.	Then press "Start-Stop" again to return to the initial menu position.	

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6.7 Changing the setting for supply of demineralized / distilled water

The Vacuklav®31-B can be set to accept demineralized / distilled water from either outside sources (a separate water-treatment system) or from internal sources (purchased demineralized / distilled water which is poured into the water supply tank). Proceed as follows to make this setting:

Operator action		Shown on the display:
1.	Press the "+" button and hold it down; while holding it down, press the "–" button. The menu item "Function" with sub-menu "Print" will appear.	
2.	Press the button "+" (or "-") repeatedly until the sub-menu "ayua-dem supply" appears in the display.	
3.	Press the "Program" button. This will display the currently set option. In the example here, the internal option was set.	
4.	You can now press the "Program" button repeatedly to toggle back and forth between the "Internal" or "External" option.	
5.	To end the setting procedure, press "Start-Stop", and you will return to the menu "Function".	
6.	Then press "Start-Stop" again to return to the initial menu position.	

6.8 Program modifications

The program sequences (sub-atmospheric pulsing , heating up, sterilizing, pressure release, drying, and venting), as well as the program parameters (pressure, temperature, and time) satisfy the usual requirements encountered in everyday medical practice.
It is the responsibility of the user, however, that the items to be sterilized are correctly loaded. This includes the type of wrapping, the number of articles loaded, and the arrangement of items so as to ensure proper drying.
The two options "Automatic pre-heating" and "Additional drying" offer two of the standard possibilities to influence the program sequence which can be implemented by the user.
It is possible in individual cases to modify the program sequences on a customised basis (and within the context of the guarantee for sterilization effectiveness). These modifications, however, may be carried out only by personnel authorised by MELAG. If you require such modifications, get in touch with your specialist dealer or with the MELAG company.

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7 Faulty operation / malfunctions

7.1 What to do in case of malfunctions

In case of conditions which deviate from normal operating states (for example, poor drying results, notification reports, warnings, or error messages), please consult the following instructions to ensure that faulty operator actions are not the cause of such conditions.
Observe these instructions and correct and faulty operating action. Then continue your work with the autoclave. Only if the malfunction occurs again, get in touch with your specialist dealer, an authorised MELAG customer-care representative, or directly with the MELAG company.

7.2 Malfunctions without an error message

7.2.1 An empty display window

When you switch on the power to the autoclave, the display should show the initial position (see Section 4.1.2 of this manual).
If there is no text in the display window, please check the following:

1. Is the electrical plug of the autoclave inserted into a power socket?
2. Does this socket supply the proper mains voltage (one possibility: use another electrical device to test the power supply).
3. Check the fuses. First unplug the power cable of the autoclave from the power socket. Then exchange the two mains fuses located below the power switch (see page 4, Fig. 1, no. 9). Use a screwdriver or a coin to unscrew the threaded cap of the fuse mounts. Then use the 2 spare fuses on the inside of the door to replace the 2 fuses used until now. Now replace the threaded cap and plug in the power cable to the socket. If there is still no text in the display, or if the autoclave fails after a short period (for example, during the first program start), then please notify your specialist dealer. If you need to replace the original fuses, be sure to order two new fuses from your specialist dealer (MELAG article no. 57590).

7.2.2 The autoclave uses too much demineralized / distilled water

The amount of demineralized / distilled water used by the autoclave will depend on the program and on the loading of the autoclave. If the autoclave uses considerably more water than the amounts given in Technical Data (see Section 1.2.4.2), then check the following:

1. Check to make sure that the condensate is not obstructed in its return flow. The autoclave must be set up correctly to ensure the correct return flow. If necessary, increase the slope of the autoclave toward the rear by farther unscrewing the front autoclave feet to raise the front (see Section 2.3 of this manual).
2. Check to make sure that fallen instruments, filter paper, or the like have not clogged the condensate return flow on the bottom of the chamber.
3. If the above measures do not reduce the excessive consumption of water, please notify your specialist dealer.

7.2.3 Poor drying

In addition to proper functioning of the autoclave itself, satisfactory drying will essentially depend on properly setting up and operating the autoclave. Please check the following if drying is not satisfactory:

1. Check to make sure that the condensate is not obstructed in its return flow. The autoclave must be set up correctly to ensure the correct return flow. If necessary, increase the slope of the autoclave toward the rear by farther unscrewing the front autoclave feet to raise the front (see Section 2.3 of this manual).
2. Check to make sure that fallen instruments, filter paper, or the like have not clogged the condensate return flow on the bottom of the chamber.
3. Check to make sure that you have not loaded too many items into the autoclave (especially textiles). Make sure that loading is correct (for example, avoid direct contact of items with the sterilization chamber wall, which causes absorption of condensate). Use tray racks, and see instructions under Section 9.1 of this manual.
4. Activate the automatic pre-heating function (see Section 6.5 of this manual).
5. Start the program with the "Additional drying" function: see Section 6.2 of this manual.
6. If unsatisfactory drying still results despite the above measures, please notify your specialist dealer.

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7.3 Warning messages

If you see the following warning messages in the display, check the instructions given below at the right. Take the corrective action. Then start the program again. If the warning appears again, please notify your specialist dealer.

Warning message	Cause of trouble / Corrective action
WARNING! **Door open** **No start possible** **Acknowledge with button "–"**	• The door contact is not closed when the autoclave is started: – **Corrective action:** Slide the locking handle down to the bottom catch. The display will then be "Door closed" if this action is properly taken.
WARNING! **Water supply** **aqua dest./dem Check supply** **No start possible** **Acknowledge with button "–"**	• This message will appear when the supply of demineralized / distilled water is set to "Internal", and if there is not sufficient water in the internal tank. The "Internal" setting is used when the water supply to the autoclave comes from demineralized / distilled water which is purchased and filled into the built-in water supply tank of the device. • When the water level in the water supply tank (right chamber) has fallen below the prescribed minimum level, the built-in float switch initiates this warning. – **Corrective action:** Check the level of water in the right chamber of the water supply tank. If it is low, fill the tank up to the maximum-level mark with demineralized / distilled water in sufficient quality.
Water quality bad **No start possible** **Acknowledge with button "–"**	• The conductivity of the demineralized / distilled water is above the second limit value. The internal test system of the autoclave prevents the device from starting. – **Corrective action:** Empty and clean the water storage tank of the autoclave and refill it with demineralized / distilled water: Or: check the external water supply (i.e., the mixed bed resin of the MELA*dem*®).
WARNING! **sterile filter Replace** **Acknowledge with button "–"**	• The minimum or maximum pressure value for ventilation drying has been exceeded. This warning will appear at the end of the program. It will also appear in the printed log in the last line: – **Corrective action:** The sterile filter is defective. Exchange the sterile filter (MELAG article no.: 20160)

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Warning message	Cause of trouble / Corrective action

Printer is Not ready	• Communication with the printer via the serial interface is interrupted. This warning will appear when the operator attempts to print. This warning will appear for 20 s and then will disappear. If the communication is restored during this 20 s, the data will be printed out. **Corrective action:**
	  • It is possible that the autoclave is being operated without a printer, but that the printer is installed. In this case, follow Section 6.3.1.3 to set the option "No printer" in the menu "File transmission".
	  • Check to make sure that the data cable is correctly connected to the autoclave and to the printer.
	  • Check to make sure that there is power supply to the printer. If not, restore power. If power is provided, the MELA*print*® 42 LED display will show a red "P".
	  • If the printer is offline, set it to online. To set the MELA*print*® 42 online, press the button "SEL". The green LED "SEL" will then light up when it is online.

Printer memory full	• The internal printer memory is full (i.e., 40 cycles have been stored there: the maximum). An external printer is installed, the option "Immediate printout" is set for "No" in the menu "Print". This warning appears each time when a program is started. **Corrective action:**
	  • Press the button "Start-Stop" for a second time. The warning may disappear, and the program may start.
	  • Set the immediate-printout option for the printer to "Yes" (see Section 6.3.1.3).
	  • Erase all stored cycles (see Section 6.3.6). **Warning:** If you need this data, be sure to print it out before deleting the memory (see Section 6.3.4). Deinstall the printer in the menu "File transmission" by selecting "No printer" (see Section 6.3.1.3).

Execute service please	• The service message is activated because the device has reached the maximum number of cycles before the next service is due. This message will appear each time you start a program. **Corrective action:**
	  • Press the button "Start-Stop" again. The warning may disappear, and the program for this cycle may start. This solution may enable you to use the autoclave until the proper service has been performed.
	  • Have the required service performed by a MELAG service company, or by the authorized specialized dealer. The service personnel will reset the service counter after the service.

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Warning message	Cause of trouble / Corrective action

Test unsuccessful
Leak rate: 3.2
	• The leak rate determined in the vacuum test is greater than the maximum permitted value. **Corrective action:**
	  • Check the door gasket and the sterilization chamber flange for cleanliness. Clean them if they are dirty.
	  • Repeat the vacuum test while the autoclave is completely cold
	If no other error messages appear during the program sequence, you can continue to work with the autoclave. At the next regularly scheduled inspection by authorized service staff, however, the personnel must find the cause for the increased leak rate.

WARNING! **Battery dead**	• The monitoring of the internal device battery voltage has determined a too low voltage value. The battery has to be changed by the MELAG service-company/ service.

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7.4 Error messages

Error messages generally occur with the display message "Error", followed by the error number and a description of the error.
Error messages can appear before a program is started: i.e., as soon as the power switch is placed on, or some time after the power is switched on. Or, they can occur after program start, while the program is running. If errors occur while the program is running, the system will always issue an error message, and it will abort the program. Depending on the chamber pressure at the time that the error appears, the system may stop the program immediately and may automatically release the pressure in the chamber. Or, it may stop the program together with ventilation of the chamber. During abort of the program, the display will alternate between the error message and the program phase ("Pressure release" or "Ventilation"). After the program has been stopped, the display will alternate between the error message and the message "Acknowledge with button '–'" and "Stop / End". When you press button "–" this will delete the error message (unless the cause of the error remains, in which case the error message will also remain). The door of the autoclave will remain locked until you have acknowledged the error message.
If a program is aborted, the items loaded in the autoclave must be considered **non-sterile** or **not disinfected**. The sterilization or the disinfection program must be repeated. In such cases, we recommend that the user remove all items from the chamber after such an abort, and to run one sterilization cycle without a load. This is because the drying phase may not proceed properly after the first start.
If an external printer is connected, and if you have set the immediate-printout option for the printer to "Yes", the system will automatically print out a log at the end of the program abort. This will take place not only for non-cyclic errors (i.e., a program has not started), but also for cyclic errors (i.e., during a program). The printed log will show the complete error designation. If the program is aborted before the end of the sterilization phase, the printout will also show the message "Load not sterile".
The following tables show the error messages, their causes, and the corrective action:

Error message	Cause of trouble / Corrective action
Malfunction 1: Vacuum system	• The monitoring time was exceeded for achieving the sub-atmospheric pressures for the individual evacuation pulses, for the pressure release, and for the achieving of minimum pressure for drying. **Corrective action:** – Check the door gasket and the sealing surface of the chamber for defects and for soiling. If dirty, clean. – Check to make sure that the autoclave has been correctly set up (see Section 2.3). – Check to make sure that fallen instruments, filter paper, or the like have not clogged the condensate return flow on the bottom of the chamber. – Determine the leak rate by running the program "Vacuum test". If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 2: Steam generator	• The monitoring time was exceeded for the heat-up phases for the sub-atmospheric pulsing, and for reaching the sterilization pressure. **Corrective action:** – There may be too many items loaded into the autoclave for sterilization. Reduce the amount loaded. – If the mains voltage is too low, the heating output of the autoclave may be insufficient. Check the electrical building installation in the building. Try the autoclave on another, more powerful circuit. If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 4: Pressure release	• The monitoring time was exceeded for the pressure release. **Corrective action:** – Check the pressure-release fittings at the bottom rear of the sterilization chamber. Clean them out if they are clogged. If this error repeatedly occurs, please notify your specialist dealer.

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Error message	Cause of trouble / Corrective action
Malfunction 6: Ventilation	• The monitoring time was exceeded for venting the sterilization chamber. **Corrective action:** – The sterile filter may be dirty. If it is, there will be a warning to this effect before this error message (see Section 7.3 of this manual). – Change the filter.
Malfunction 8: Time base	• The maximum limit has been exceeded for the difference between the program run time and the internal computer clock. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 9: Door open	• The door contact has opened during a program. **Corrective action:** – Press down the sliding handle until it will go no farther. The following display will appear: "Door closed". If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 10: Steamgen. too hot	• The capillary-tube controller "Level control" is open when a program has started (this error message will appear immediately after the start of the program). Or, during a program run (until the end of the sterilization phase) the monitoring time is exceeded until the capillary-tube controller switches back (it will switch back upon additional feed of demineralized / distilled water). **Corrective action:** – This error message can appear if a program has been aborted and if the user tries to restart immediately. If so, wait for 2 minutes and start again. If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 12 Door locking	• The maximum permissible time for locking the door has been exceeded. **Corrective action:** – Check to make sure that the locking pin moves easily. If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 14: No feedwater	• The float switch for the supply of demineralized / distilled water does not shut during program run. **Corrective action:** – See the error message "**Warning: Water supply**"
Malfunction 18: Sensor defect 1,2	• The internal autoclave testing function for the temperature, pressure, and conductivity sensors has discovered an excessive deviation. This error message can occur when the autoclave is switched on, or during program run. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 21: Pre-heating	• The monitored time was exceeded from switching on the pre-heating, until reaching the particular required preheating temperature. **Corrective action:** – If this error repeatedly occurs, set the option "Automatic preheating No" (see Section 6.5). Please notify your specialist dealer.
Malfunction 22: Preheat too hot	• The maximum preheating temperature has been exceeded. **Corrective action:** – If this error repeatedly occurs, start the autoclave from a cold state. Please notify your specialist dealer.
Malfunction 26: A/D Converting	• The maximum permissible deviation has been exceeded for internal computer signal conditioning (A/D conversion). **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 27: Temp.sens.def. 1,2	• The maximum permissible deviation between the two temperature sensors for the steam temperature has been exceeded. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.

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Error message	Cause of trouble / Corrective action
Malfunction 31: System leak	• During the program “Vacuum test”, the maximum permissible pressure was exceeded after the evacuation pressure was reached (very large leak). **Corrective action:** – Repeat "Vacuum test". If this error message appears again, please notify your specialist dealer.
Malfunction 32: Power failure **Sterile filter sterilize**	• After a program has started, the operational voltage failed. This error message appears after the voltage has returned. **Corrective action:** – Please check the building electrical systems. If you cannot find the fault there, please notify service personnel. • The power fails while a started program is in an overpressure (hyperbaric) phase. The system additionally requests that you sterilize the sterile filter, since it has become moist and may have picked up micro-organisms. **Corrective action:** – Remove the sterile filter on the rear of the autoclave. – Then sterilize the filter in the "Fast program" (there will be no filter in the autoclave during this cycle). – After the program is finished, insert the sterilized filter in the autoclave again.
Malfunction 33: Pressure drop	• The maximum on-time of the steam generator has been exceeded for achieving the controlled pressure. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 34: Sterilization TU	• The temperature has fallen below the minimum permissible sterilization temperature. **Corrective action:** – The amount loaded in the sterilization chamber is too great. Operate the autoclave with a smaller load. – If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 35: Sterilization TO	• The sterilization temperature is greater than the maximum permissible limit. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 36: Sterilization PU	• The sterilization pressure has fallen below the minimum permissible limit. **Corrective action:** – The amount loaded in the sterilization chamber is too great. Operate the autoclave with a smaller load. If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 37: Sterilization PO	• The sterilization pressure has exceeded the maximum permissible limit. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.
Malfunction 38: Sterilization TD	• The difference between the measured and theoretical temperature has exceeded the maximum limit. **Corrective action:** If this error repeatedly occurs, please notify your specialist dealer.

8 Preserving the value of this device

8.1 Preparation of instruments

MELAG — use of non-rusting materials for parts which come into contact with steam

All parts of the Vacuklav®31-B which come into contact with steam are made of non-rusting materials. The sterilization chamber and the chamber door are made of stainless steel, steam lines are Teflon®, and threaded connections and solenoid valves are brass.

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Drag-in rust

The non-rusting parts used in the Vacuklav®31-B ensure that the autoclave itself cannot cause rust to form. In any cases in which rust has developed on the autoclave or on the sterilized items inside, investigations have consistently shown that this rust has been dragged into the autoclave from the outside by rusty instruments. **We must point out that rust can form on stainless-steel instruments made by even the best manufacturers.** One main cause of instrument rusting is improper treatment with chemical cleaning and disinfecting agents during preparation for sterilization.

Preparation of instruments for sterilization

The problem of drag-in rust shows how important it is to properly prepare items for sterilization. **It is urgently necessary to observe the following procedures:**

1. Clean and prepare (for example, by oiling) handpieces and contra angles as described in the instructions provided by the manufacturers of these items.
2. Immediately after their medical use, all other instruments must be placed in a disinfection and / or cleaning solution in accordance with UVV/VBG 103 and properly cleaned and disinfected there.
3. Always be sure to use the correct dosage of disinfection and / or cleaning agents in these solutions.
4. **Important:** Be sure to carefully follow the instructions for the length of time that the instruments must soak in the solutions.
5. We also recommend the use of ultrasonic equipment, recommended cleaning and care equipment for handpieces and contra angles, as well as thermal disinfecting techniques.
6. The proper cleaning of instruments is also essentially important in preventing particles of soiled matter from separating from the instruments during sterilization and from clogging the filters, nozzles, and valves of the autoclave. It is extremely important to use a brush to very carefully clean the locks, joints, and hinges of the instruments before sterilization.
7. **Important:** Use a brush under running water to completely rinse all cleaning and disinfecting agents from instruments before placing them in the autoclave. **Residue of chemical cleaning and disinfecting agents must by no means be allowed to enter the autoclave, since they will cause corrosion there.**
8. As a final step before placing the instruments into the autoclave, rinse them with demineralized water, and dry them well.
9. Be sure to use oil (as indicated in the manufacturers' instructions) to prepare turbines and handpieces for sterilization, in order to ensure their long service life.

Instruments new from the factory:

Be sure also to follow the above-described pre-cleaning procedure even for instruments new from the factory. Often there are small amounts of oil, grease, and impurities still on new instruments, from their production. **Important: It is absolutely necessary to carefully follow the instructions for preparation and re-sterilization procedures which are provided by manufacturers of instruments.**

8.2 Drag-in rust (rust brought into the autoclave)

Important: As explained above, the non-rusting materials used in the autoclave make it impossible for the autoclave itself to cause rust on the items being sterilized.

Any rust occurring on these items is drag-in rust which comes in on instruments or other metal objects placed into the autoclave. Rust can occur on normal steel objects whose electroplated finish has become defective, and even on stainless-steel objects. Often, only one single instrument with a rust spot is enough to drag in rust and cause it to spread to and develop on other instruments or on the autoclave itself. Drag-in rust spreads to other instruments in the form of film rust, which leads to rust corrosion on other instruments and on the autoclave. It is absolutely necessary to remove drag-in rust from instruments, from the sterilization chamber, and from tray racks, by using cleaning agents which are especially designed for use on stainless steel, which are not alkaline, **and which do not contain chlorine**. We recommend the German product Sidol®. **IMPORTANT: Do not use steel wool or wire brushes.** Clean off normal dirty spots with **a non-ravelling cloth** (i.e., which does not shed lint) which has been dampened in water, methylated alcohol, or other types of alcohol.

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8.3 Regular care of the Vacuklav®31-B

8.3.1 Cleaning

At least once a week perform a cleanliness inspection of the tray rack, the sterilization chamber, the sealing surface for the door gasket, and the round plate around the door of the sterilization chamber. Check for dirt and for deposits. Clean dirty spots from the sterilization chamber **with a non-ravelling cloth** (i.e., which does not shed lint) which is moistened with methylated alcohol. Before cleaning the sterilization chamber, remove the trays and the tray rack by lifting them out through the front of the chamber. If there are stubborn spots or stains on the sterilization chamber, use a non-ravelling cloth moistened **in small amounts** of a gentle cleaning agent which is especially designed for stainless steel and which has a pH of 5 ... 8. We recommend the German product Sidol®.
Warning: Be careful that none of this cleaning agent enters the piping which leads off from the sterilization chamber. **Important:** The cleaning agent used may not contain chlorine and may not be alkaline. **Do not use metal pot cleaners** (such as steel wool), and do not use wire brushes. Once a week inspect the door gasket for damage and soiling. Remove any dirty spots with normally commercially available, gentle cleaning agents which have a pH of 5 ... 8 and which do not contain vinegar. Or, use methylated alcohol. If required for cleaning, remove the door gasket from the plate around the door of the sterilization chamber.
The locking bolts of the door lock (right side of door), as well as the hinges of the door (left side) must be kept constantly lubricated. This is required to allow ease of shutting and locking the door, and to prevent premature wear. As required, use silicone grease as a lubricant. You can use normally commercially available, gentle liquid cleaning agents to clean the outer part of the autoclave enclosure. If water for your autoclave is supplied and disposed of directly through the built-in water storage tanks, check these tanks for cleanliness each time you fill the right tank with demineralized / distilled water. Before filling, clean the tanks out if necessary by flushing out with fresh demineralized / distilled water. Empty the water drain tank on the left side at least every two weeks and clean it out with clear tap water. In case the drain tank is soiled with stubborn or oily matter, use a suitable synthetic brush, washing-up liquid (kitchen detergent), and warm tap water to clean it. Then rinse out with demineralized / distilled water. If the right chamber of the water storage tank is soiled from long service in the circulatory-flow mode of water supply, then also use warm water and washing-up liquid and a suitable synthetic brush to clean it. After cleaning, likewise rinse out with demineralized / distilled water.

8.3.2 Use of demineralized / distilled water

Quality criteria for the demineralized / distilled water used
The following is required for steam sterilization: use of steam-distilled water, or fully demineralized water.
The autoclave operator must observe the values given in the following two tables as criteria for the water quality. These characteristics are in accordance with the European standard EN 13060.
Battery water is also suitable for operation of the Vacuklav®31-B, but only if it strictly conforms with the relevant VDE criteria. These criteria are:

Specifications for water quality n accordance with EN 13060:

Evaporation residue	≤ 10 mg/l
Silicon oxide, SiO_2	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Other heavy metals	≤ 0.1 mg/l
Chlorides (Cl)	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0.5 mg/l
Conductivity at 20°C	≤ 15 µS/cm *
pH (degree of acidity)	5 ... 7.5
Appearance	Colourless; clean; without sediment
Hardness (Σ of ions of alkaline earth)	≤ 0.02 mmol/l

* µS/cm = micro-Siemens per cm

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Where to get water for the Vacuklav®31-B
Battery water in accordance with VDE 510 is available in all major European drug stores, supermarkets, DIY centres and wholesale markets. The mark "VDE 510" must, however, be specifically contained on the labels of the water containers. If the VDE 510 standards are not met by the purchased water, calcium carbonate (lime) deposits in the steam piping and in the valves can seriously impair the functioning of the autoclave. Aggressive water (i.e., pH < 5 or > 7.5) can also damage the autoclave.

Spotting
The extent of formation of spots on the instruments will depend on the quality of the water used for steam generation.

8.4 Monitoring the functions of the autoclave

8.4.1 Continuous monitoring of sterilization progress

The electronic parameter control system of the Vacuklav®31-B continuously and automatically monitors the sterilization-relevant parameters and compares them with standard process data. In the event that the measured parameters do not satisfy these standard data, the control system will initiate an error message. When the program runs without error, an “End” message will additionally be shown. In addition, the log printout will output a verification message.
The user of the autoclave is able to continuously monitor the progress of the program by consulting the values shown on the display, or by reading the log printout (if a printer is connected to the autoclave).

8.4.2 Periodical bacteriological monitoring (every 6 months)

The standard DIN 58 946, Part 8, Section 3.2 recommends the following:
“Periodic testing takes place at the installation site at intervals of, for example, every six (6) months. The purpose of this testing is to confirm that the small sterilizer actually properly sterilizes when the operating instructions are followed.”
If the user so requests, German hygiene institutes and State Medical Testing Laboratories will mail test spores. After these spores have been treated in the autoclave, the spores are returned to such institutes for testing and evaluation, with results on a test form.

8.4.3 Periodic maintenance recommendation

In order to maintain the value of this device and to minimise the rise of its unexpected failure, the MELAG company recommends periodic maintenance of the Vacuklav®31-B. The maintenance may be conducted only by especially trained customer-care technicians, or by technicians from the specialised dealer, in accordance with the maintenance instructions for this particular autoclave. This periodic maintenance consists of visual and functional testing in which all functions and safety-relevant components and electrical systems are tested. The display of the Vacuklav®31-B will call attention to the need for this maintenance after 1000 sterilization cycles, whichever comes earlier.
Please get in touch with your specialist dealer, or with MELAG Customer Care staff.

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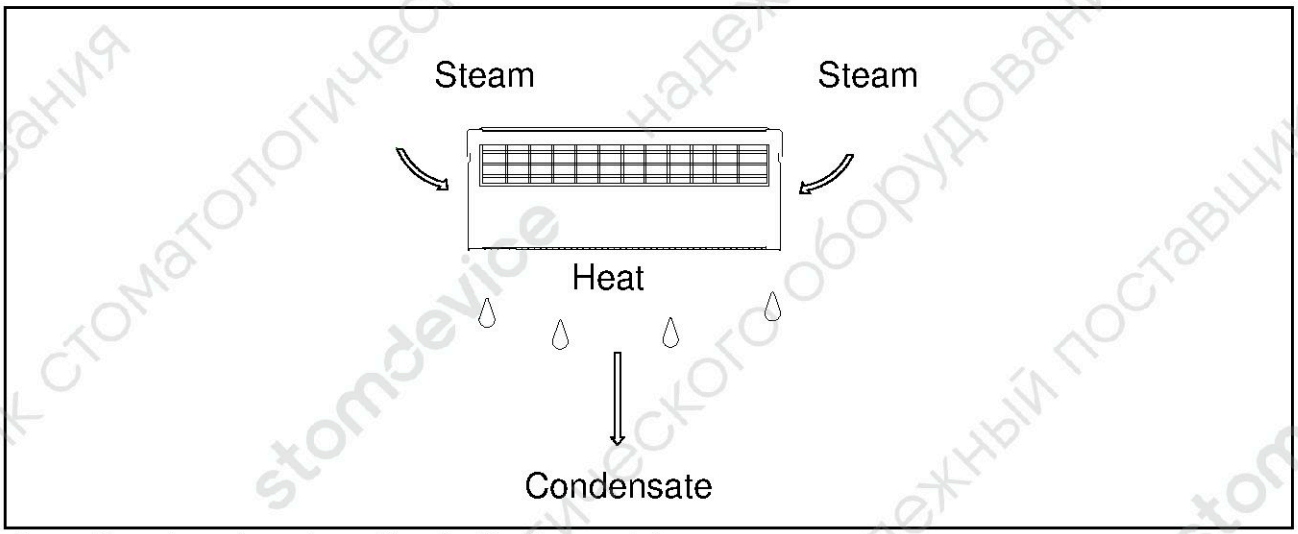
9 Annex

9.1 Instructions on drying

The standard programs of the Vacuklav®31-B alone provide very good drying of the sterilized items. The supplementary functions "Additional drying" and "Automatic pre-heating" effectively manage more difficult drying tasks: for example, with double wrapping (see Sections 6.2 and 6.5 of this manual). Please read the following sections for a better understanding of the drying processes and how they can be successfully managed. You will also see how to guarantee optimum drying results by proper loading.

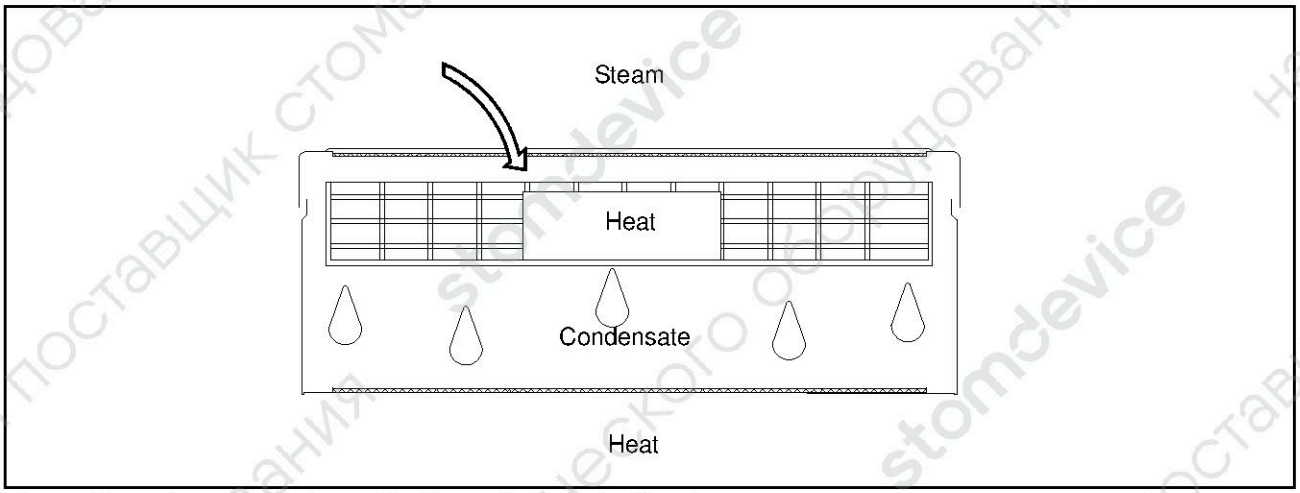
9.1.1 The drying process in sterilization containers

In autoclaves steam is produced by heating water. The steam heats the sterilization containers and the instruments inside by transferring its heat to the sterilized items and to their container. This heat-transfer process produces a change of state in the steam from vapour to liquid. The steam condenses into water, which collects to some extent as condensate drops on the instruments and their container.



Formation of condensate on the sterilization container

The steam likewise heats the items being sterilized in the sterilization container. Condensate precipitates out onto the sterilized items, and part of it drips onto the bottom of the sterilization container.

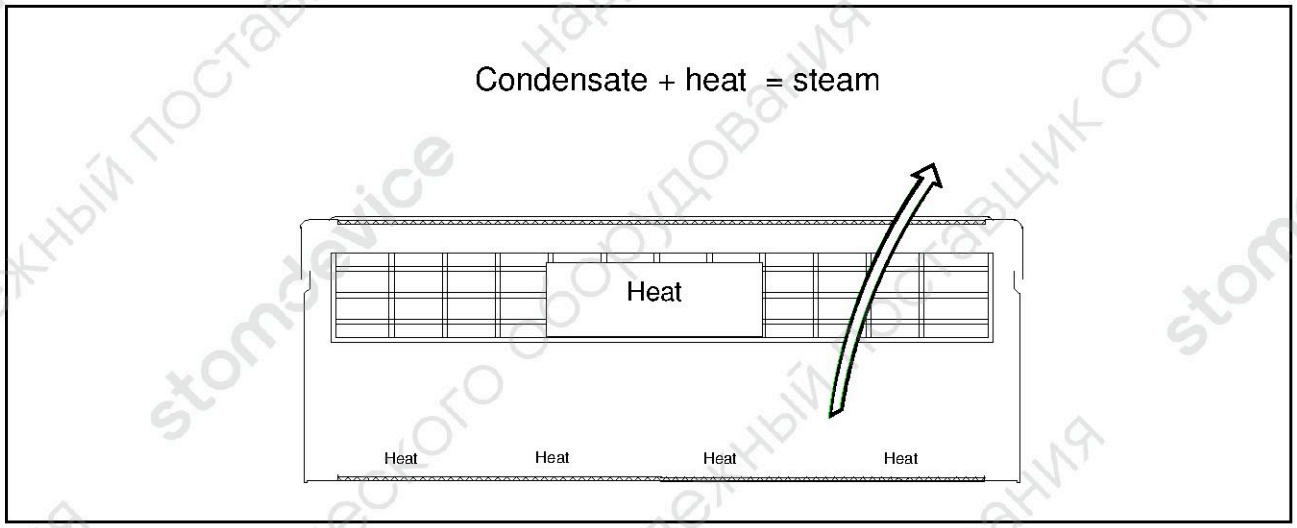


Formation of condensate on the items being sterilized

At the end of the sterilization process, during drying, the entire condensate must evaporate: both from the sterilization container, as well as from the sterile items themselves. This takes place by transfer of heat to the condensate from the heat stored in the walls of the sterilization container and in the sterilized items themselves. We recommend the use of sterilization containers made of aluminium, since the good heat-storage and heat-conductivity properties of this material accelerate the drying process in the autoclave.

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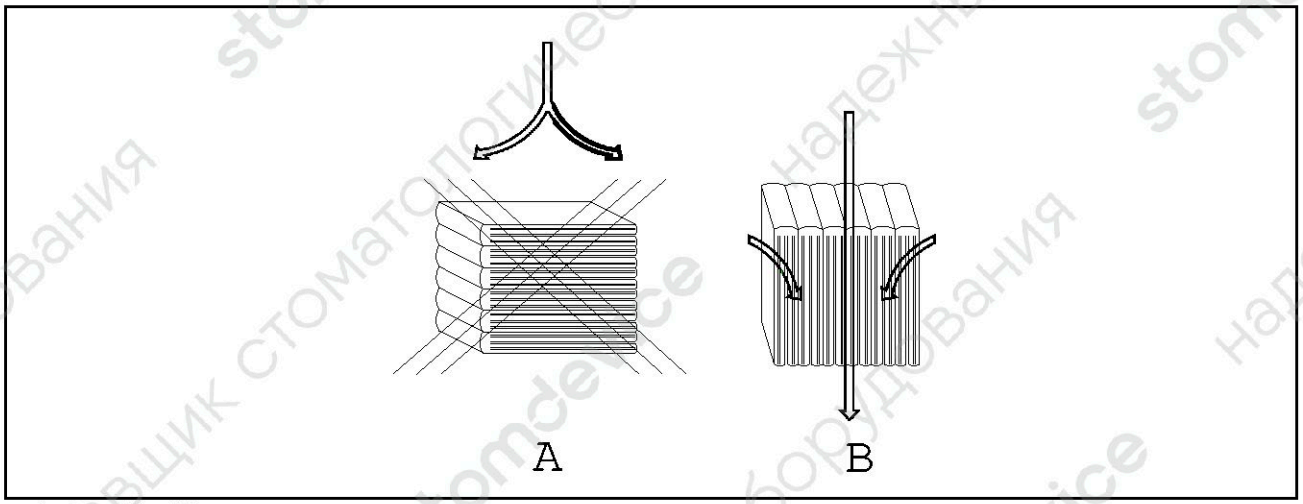


The drying process

For good drying, it is necessary to transfer the available excess heat to the sterilized items. This process requires removal of the condensate from the walls of the sterilization container. This is achieved by the special design of the sterilization containers: the recesses and beading in the bottom the bottom, and in the cover by the raised filter area so that the condensed water can run off.

9.1.2 Textiles

When preparing textiles for the autoclave, it is essential that the folds of the textiles lined up be in parallel, and that the textiles are lined up vertically: see illustration "B" below. This vertical orientation guarantees that channels form between the textile layers for the air to stream out and for the steam to stream in. Do not by any means stack the textiles horizontally ("A"), since this will prevent the steam from penetrating the textile package.



How to load textiles

When loading textiles into sterilization containers, make sure that the textiles will stay in their vertical position and not fall. Do not, however, **squeeze** the textiles into the container, since this would prevent air and steam flow channels from forming. If the textile packet will not remain in its vertical position, we recommend wrapping the textiles in sterilization paper. Make sure that the textiles have as little contact as possible to the walls and bottom of the sterilization container. If the textiles are in close contact with the walls and bottom, they will excessively absorb the condensate which has collected there.
For good drying, it is furthermore important that the textiles be dry before they are placed in the autoclave. The heat energy stored in the sterilization chamber and in the sterilization container is not sufficient to evaporate the condensate occurring during sterilization AND any moisture brought into the autoclave by damp textiles.

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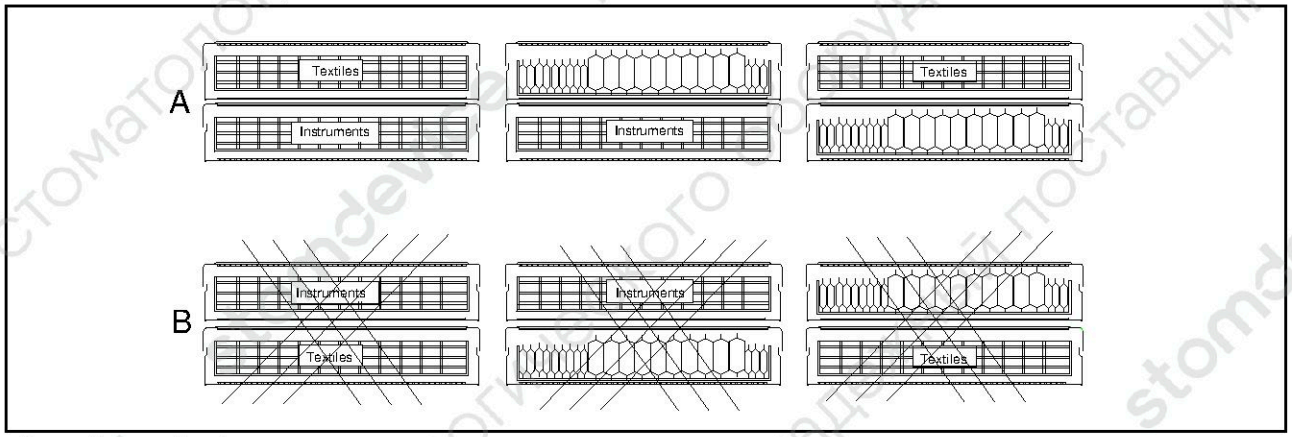
9.1.3 Instruments

If instruments are to be sterilized which can be taken apart, then they should be taken apart before being placed in the autoclave. This will improve drying results. Do not use lubricants (instrument oil or instrument milk) on instruments before placing them into the autoclave, unless this is absolutely necessary for the particular instruments. Before sterilizing instruments with these lubricating or instrument-care preparations, however, make sure to consult the manufacturer of these preparations and confirm that these substances are suitable for being subjected to sterilization. Unsuitable instrument-care preparations include types of oil which repel water or which do not allow the penetration of steam. With such preparations, not only the drying will be poor: even steam sterilization itself can fail, since these preparations protect not only the instruments but also the micro-organisms on the instruments.

9.1.4 Loading the autoclave

Do not sterilize textiles and instruments together in one sterilization container. If at all possible, you should not sterilize textiles and instruments in different sterilization containers in the same cycle batch. If this cannot be avoided for economic reasons, then please observe the following rules:

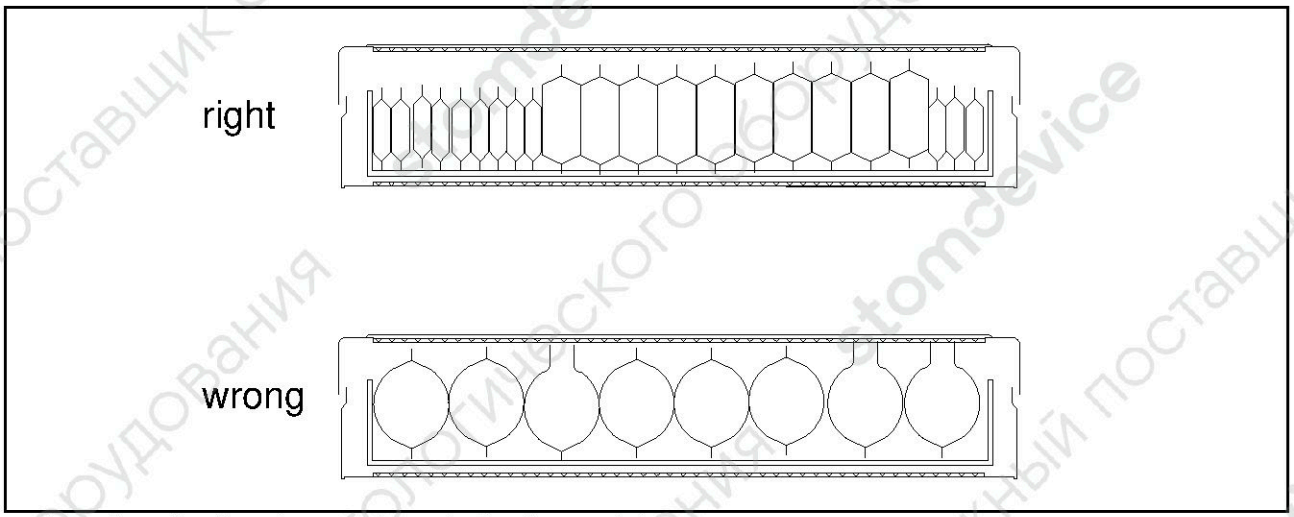
- Instruments and sterilization containers on the bottom
- Textiles always toward the top
- See-through sterilization packages and paper packages toward the top (exception: when together with textiles, then toward the bottom).



Loading of an autoclave

9.1.5 Loading of containers with soft sterilization packages

Soft sterilization packages such as paper pouches or see-through sterilization packages can be sterilized in sterilization containers or in sterilization baskets. To ensure better drying, such soft packages should be lined up vertically at close intervals. This allows the advantage that the condensate can flow off of the packages easily, and that the packages will not swell up excessively (which can burst the seams).



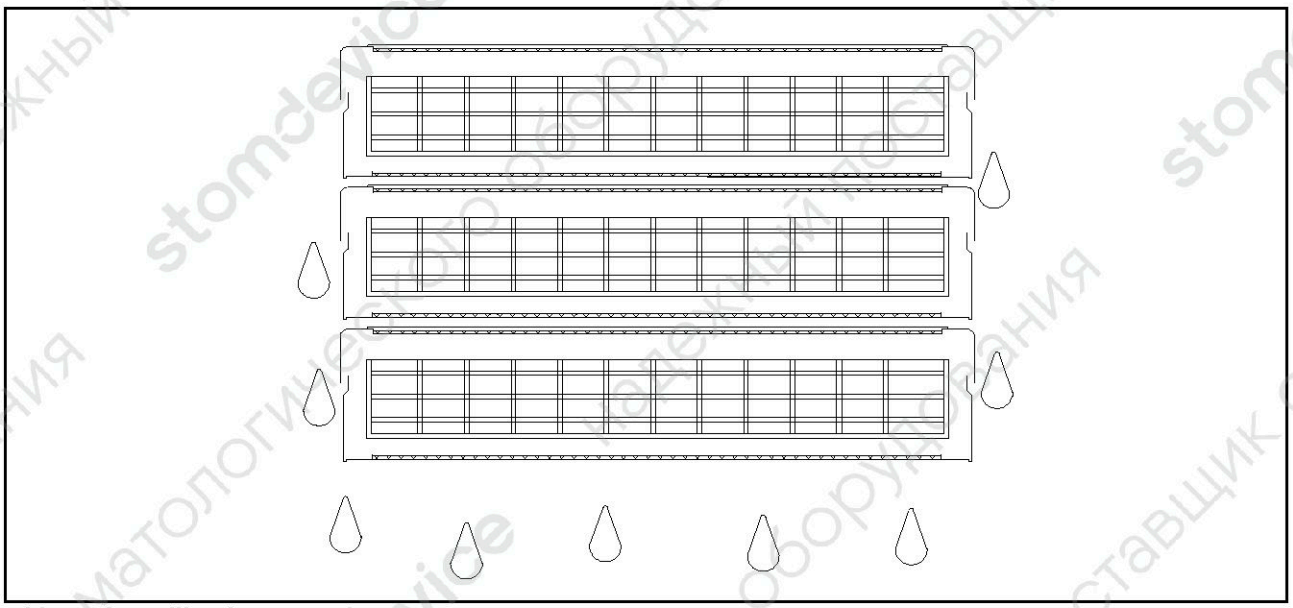
Correct loading of soft packages into a sterilization container

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9.1.6 Stacking of sterilization containers

When stacking sterilization containers, make sure that the condensate dripping from these containers cannot wet the sterile items loaded below. The optimum solution is to stack several sterilization containers of the same size on top of each other: then the condensate will run down the walls of all the containers.



Stacking of sterilization containers

9.1.7 Removing sterilized items

Immediately after sterilization, it can occur that small amounts of condensate are still remaining on the sterilized items. The ongoing transfer of heat from the sterilized instruments to the condensate can evaporate this moisture after sterilization is complete.
Information contained in DIN 58953, Part 7, Section 7 includes the following statement on condensate moisture which remains on paper pouches or see-through sterilization paper after sterilization:

> "Small amounts of water which remain on the outside of the packages are harmless if they have dried away within 30 minutes after removal from the steam sterilizer."

9.1.8 Further improvement of the drying process

Drying can be further improved by the following measures:

- Pre-heating OR running of an empty sterilization cycle (i.e., with no instruments in the autoclave)
- Lining up the see-through sterilization packages and paper pouches vertically, like 3 × 5 cards in a catalogue file
- Activation of the "Additional drying" function
- Lengthening of the programmed drying times (but only after first co-ordinating with MELAG customer care service).

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