Miele
PROFESSIONAL

Operating instructions
Steam-Sterilizer
PS 1201 B
PS 1202 B

To avoid the risk of accidents or damage to the machine, it is **essential** to read these instructions before it is installed and used for the first time.

en-CA

M.-Nr. 09893480

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Contents

This sterilizer complies with all relevant legal safety requirements. Inappropriate use can, however, lead to personal injury and damage to property. Read these instructions carefully before using it for the first time to avoid the risk of accidents and damage to the machine. Keep these instructions in a safe place and make sure they are available at all times to any user of the machine.

⚠ The machine must not be used to sterilize liquids.

Warning. Danger to life!
Sterilizing liquids can result in superheating and a sudden release of pressure at the end of the cycle when the sterilizer chamber door is opened. The consequences are similar to those of an explosion. The manufacturer cannot be held liable for misuse of the sterilizer.

Correct application

▶ This steam-sterilizer is only approved for the range of applications specifically mentioned in these operating instructions. Alterations or conversions to the machine or using it for purposes other than those for which it was designed are not permitted and could be dangerous.

▶ Sterilization processes are suitable for porous items, solid items, instruments or medical devices which have been declared as suitable for sterilization by the relevant manufacturer. Manufacturer's instructions for items to be sterilized (instruments, porous items etc.) must be observed. Miele cannot be held liable for consequential damage caused by inappropriate use or incorrect machine operation.

▶ This sterilizer is intended for indoor use only.

▶ The use of the sterilizer in non-stationary locations (e.g. on a ship) is prohibited.

Please pay attention to the following notes to avoid injury

▶ The sterilizer should be commissioned, maintained and repaired by a trained Miele service technician only. To ensure quality assurance and compliance with CSA.Z 314.3-09 "Effective sterilization in health care facilities by the steam process", a Miele service contract is recommended. Unauthorised repairs can pose considerable risks to the user.

▶ Do not install the sterilizer in an area where there is any risk of explosion or of freezing conditions.

▶ The electrical safety of this machine can only be guaranteed when correctly earthed. It is essential that this standard safety requirement is met and regularly tested. If in any doubt please have the electrical installation inspected by a qualified electrician.

▶ Always switch the machine off by the mains switch when it is not in use.

▶ The manufacturer cannot be held liable for damage or injury caused by the lack of or inadequacy of an effective earthing system (e.g. electric shock).

▶ A damaged machine is a safety risk. In the event of damage, disconnect the machine from the mains electricity supply immediately and contact the Miele Service Department.

▶ Personnel operating the machine must be instructed on its use and trained regularly. They must also possess the necessary technical knowledge regarding the reprocessing of instruments. Personnel who have not received instruction and training must not be allowed access to the steam-sterilizer or its controls.

▶ Be aware of possible high temperatures when the steam-sterilizer is in operation. If the door lock is opened manually, there is a risk of scalding as steam may be emitted and the chamber may be under pressure. There is also the risk of injury caused by the door flying open.

▶ There is a risk of trapping and crushing your hand and fingers when the pressure chamber door is closed if you were to place your hand between the machine cabinet and the door (near the door hinge) during the closing process. Use one hand to close the door until the door motor starts running. The locking spindle will not turn until the door contacts it (there is a sensor located in the front panel). Ensure that no-one else places their hand between the machine cabinet and the door during the manual closing process.

▶ After a cycle has finished, unloading should only be carried out wearing temperature resistant gloves or using the tray handle. The items can be extremely hot (more than 80 °C).

▶ Do not clean the sterilizer or near vicinity with a hose or a pressure washer.

▶ The sterilizer must be disconnected from the mains electricity supply before any maintenance or repair work is carried out.

▶ Do not use an extension lead or multi-socket adapter with cable cross-section of less than 3 x 2.5 mm^2. Fire hazard.

▶ Do not use a hose extension and make sure that the hose does not become twisted or kinked.

Quality assurance

The following points should be observed to assist in maintaining quality standards for reprocessing medical devices.

This also reduces any risk to patients and damage to equipment.

▶ The user must routinely check and document that sterilization is being carried out successfully. Processes must be subjected to thermoelectric tests and performance tests (steam penetration test: Bowie-Dick test, Helix test) on a regular basis and the results documented. All valid legislation and relevant standards must be observed. For safe and effective sterilization of medical devices comply with CSA Z314.3-09 "Effective sterilization in health care facilities by using the steam process".

▶ Performance qualification must be carried out in accordance with statutory and normative specifications.

▶ Trays must be used in accordance with the manufacturer's instructions. Lumened instruments must be thoroughly accessible by steam internally. Where necessary, instruments must be taken apart. Follow the instrument manufacturer's instructions (in accordance with CAN/CSA-Z 17664, ISO 17664) on how to do this.

▶ Vessels containing liquid residues must be emptied before being loaded into the sterilizer.

▶ The machine casing must only be opened by a Miele service technician.

▶ In order to guarantee successful sterilization, items to be sterilized must be clean (see "Application technology"). The medical devices and products to be sterilized must be visually clean and residual contamination must comply with the requirements of CAN/CSA-Z 15883 (ISO 15883).

▶ Only use conditioning agents which are declared by the agent manufacturer as being suitable for purpose.

▶ Please note that the external casing should only be cleaned with a soft cotton cloth and clean water. A neutral liquid cleaning agent can be used to remove heavier soiling.

▶ Do not allow any acid or solvent residue, in particular hydrochloric acid or chloride solutions, to enter the sterilizer chamber with load items. Never sterilize items which contain iron as it corrodes.

▶ Ensure that solutions or steam containing hydrochloric acid do not come into contact with the outer casing of the sterilizer in order to avoid any damage through corrosion.

▶ Follow the notes in these instructions regarding the correct installation of the sterilizer.

▶ Note that the sterilizer may not be connected to a switchable outlet (e.g. Smart Home).

Using accessories

▶ Only additional equipment recommended by Miele for particular purposes may be connected to the machine. The model designations of suitable equipment can be obtained from Miele.

▶ Only Miele accessories may be used with this machine. Using the wrong or incorrectly modified accessories will invalidate the warranty.

Symbols on the sterilizer


Warning:
Danger of electric shock


Warning:
Observe the operating instructions


Warning:
Hot surfaces

▶ Please contact Miele Service to arrange for the technical decommissioning of the sterilizer and for it to be disposed of in accordance with regulations.

The manufacturer cannot be held liable for damage caused by non-compliance with these Warning and Safety Instructions.

Guidelines

Medical Device Regulations
The steam-sterilizer is defined as medical device in accordance with Medial Device Regulations issued by Health Canada. The machine is registered as Class II medical device and has a Health Canada Medical Device License.

Pressure Equipment Directive
Pressure Equipment Directive 97/23/EC. Current amendment.
Every pressure chamber is designed and manufactured to comply with Appendix I and in accordance with the procedures described in Module A.

Standards

EN 13060
European standard for small steam sterilizers. Current amendment.

EN 1717
European Standard - Protection against contamination of potable water in water installations and general requirements of devices to prevent contamination by backflow. Current amendment.

EN 61010-1
Safety requirements for electrical measurement, control and laboratory appliances. Current amendment.

EN 61010-2-040
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005). The steam sterilizer is CSA approved for electrical safety.

EN 61326-1
+ A1: 1998
+ A2: 2001
Electrical equipment for measurement, control and laboratory use; EMC requirements. Current amendment.

Intended use

The Miele steam-sterilizer is designed to sterilize medical products and devices suitable for steam sterilization. The sterilization cycles comply with EN 13060 Class B (134°C Universal, 121°C Universal, 134°C Prions) or Type S (134°C Unwrapped). Programs which are designated as Type B are suitable for sterilizing wrapped and unwrapped solid medical instruments and devices and hollow and porous items. Programs are fully automatic. The machine is intended for medical purposes for use in clinics and surgeries, such as doctors' and dental surgeries and beauty clinics where medical instruments and equipment require sterilization before being used again.

Follow the instructions of the manufacturer of the medical instruments and devices (in accordance with CAN/CSA-Z17664, ISO 17664) on how to machine reprocess the items which require sterilizing.

Example applications

– surgical instruments,

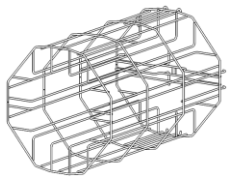
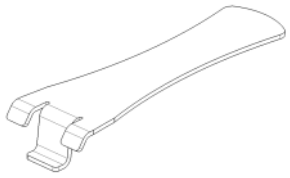
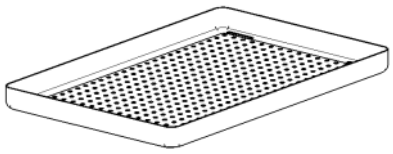
– ophthalmic surgical instruments,

– dental instruments,

– porous items

Items supplied

The machine is supplied with the following standard equipment which is packed in the pressure chamber or included with the transport pack.

Description	Illustration
Rack for trays	
Tray handle	
Trays (ZS131)	
Drain hose	
Hose clip for drain hose	
Water inlet hose with water protection device (fixed in position)	
Power cable	

Installation

Packaging

The steam-sterilizer is supplied in transport packaging. The machine is mounted on a pallet.

- Remove the transport straps from the packaging.
- Lift the lid off the box.
- Remove the wooden frame.
- Remove the outer cardboard sleeve from the machine.
- Remove the cardboard corners.
- Remove the polystyrene corners.
- Remove the protective cover.

Useful tip: With the help of at least one other person, lift the sterilizer out of the remaining packaging. The machine weighs approx. 63 kg. This is the weight when empty, as the machine has not yet been filled with water and / or a load.

Please retain the original packing material after you have unpacked the machine. This could be useful should you need to move the machine to another location at a later date.

Refer to "Decommissioning" and "Transporting the machine or a longer period of inactivity".

The pressure chamber door is not completely closed during transportation.

- After you have unpacked the machine, remove the tape securing the door.
- Remove the foam from the door.
- Open the door and take the accessories out of the pressure chamber.

The chamber must be empty for the commissioning process.

Connections and installation notes

Please connect the machine in accordance with the connection data in the following chart:

Installation data	
Total connected load	3,200 W
Current draw	15 A
Fuse rating	20 A (surge-proof)
Voltage	208 VAC (+/- 6 %)
Frequency	60 Hz
Water inlet hose	
Threaded union	3/4"
Hose length	1.50 m
Flow pressure	150 - 1000 kPa (22 - 145 psi)
Drain hose	
Connection / Pipe coupling	Ø 22.5 mm
Hose length	1.50 m

⚠ The machine is supplied with a NEMA L6-20P plug ready for connection to the electricity supply via a suitable switched socket with earthing connector. The socket must be easily accessible after installation in order to disconnect the steam-sterilizer from the electricity supply.

The drain hose must not exceed 5 metres in length and must be laid at a constant gradient without kinks. The on-site drainage point must be at least 20 cm below the drain hose connection point on the machine. To avoid any water damage, please close the faucet at the end of the working day.

Ambient conditions

Permissible ambient temperature / Air humidity	+5 °C to +40 °C / 0 % - 80 %
Permissible storage temperature / Air humidity	-10 °C to +60 °C / 0 % - 80 %
Maximum height above sea level	2000 m
Minimum air pressure (ambient pressure)	80 kPa (12 psi)

The machine should not be installed or operated in any area where there is a risk of explosion or of freezing conditions existing.

Installation

Setting up the machine

– Install the sterilizer in a well-ventilated room.

– Do not position it beside a sink as splashes of water could cause the machine to short circuit.

– Keep the machine away from heat sources.

– The steam-sterilizer must not be installed in areas which are accessible to patients.

– The steam-sterilizer must be installed in the clean area of the preparation room.

– The ventilation grilles in the rear panel must not be covered.

– The service panel must not be blocked.

– The mains switch must be accessible at all times.

– There must be a gap of at least 2 cm between the steam-sterilizer and surrounding surfaces both above and to the sides.

– Do not place any objects directly next to the cabinet in order to ensure that air can circulate around it freely. Ensure that there is a gap of 7 cm between the back of the machine and the wall behind it.

⚠ It is recommended that the machine is connected to a separate spur socket with its own separate RCD (residual current device). This RCD should be checked regularly by the operator.

Place the steam-sterilizer on a smooth, even surface such as a table or worktop. The installation surface must be water repellent and heat resistant (to 80 °C).

Place the machine on a stable surface (table, worktop). Please note that the steam-sterilizer when filled and loaded can weigh approx. 80 kg.

⚠ The machine casing should never be used as a surface on which to place utensils or other objects.

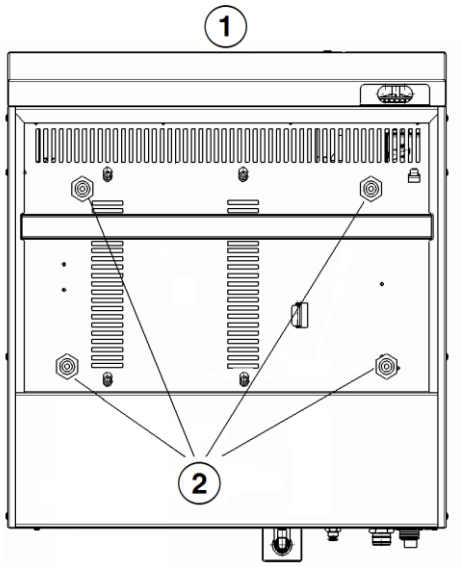
There are four height adjustable feet on the underside of the machine.

At the final check, the machine is aligned on an even surface and the height adjustable feet are secured using counternuts.

Use a spirit-level to check that the machine sits level in its final location. Place the spirit-level on the sealed casing. The steam-sterilizer must be level in both axes. If necessary, adjust the feet until the machine is in the correct position.

⚠ If the machine needs to be moved in order to adjust the feet, it is essential to ensure (e.g. with the help of another person) that it cannot fall off the installation surface.

Loosen the counternuts of the front feet from below, adjust the feet and retighten the nuts.

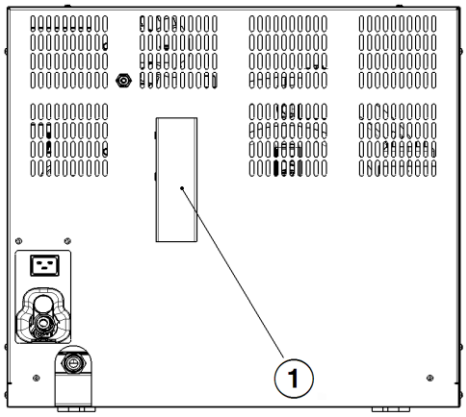


① Front

② Height adjustable feet

If the steam-sterilizer is correctly aligned water cannot remain in the pressure chamber after processing a batch. This guarantees that the machine functions efficiently.

⚠ The machine must be installed in such a way that no-one can access the immediate vicinity of the rear panel in case the overpressure valve ever reacts.



① Safety valve

Commissioning

Commissioning of the steam-sterilizer is carried out by the Miele Service Department (see "After sales service"). Before the machine is used for the first time, the steam generator must be filled for the first ime. This procedure must be carried out by the Miele Service Department.

⚠ Allow the sterilizer to acclimatise to room temperature before commissioning is carried out. Otherwise individual components may fail or malfunction.

Successful commissioning should be documented using the commissioning report. A copy of he report should be retained by the operator.

Transporting the machine or a longer period of inactivity

Transporting the machine

All liquid must be removed from the sterilizer if it is to be transported any distance.

If the machine is to be stored in the interim at a temperature which is expected to be below 0 °C, the steam generator and all water pipework must also be emptied. Otherwise there is the risk of frost damage to components.

The procedure must only be carried out by a qualified and competent technician. Please contact the Miele Service Department to arrange for this to be carried out.

In accordance with current national and local safety regulations, technical safety measurements and tests must be carried out with the cabinet of the machine opened and closed.

The steam-sterilizer must not be used for at least a day before transportation. Ensure that the steam-sterilizer is cool and that the jacket (steam generator) is no longer under pressure. Check the manometer behind the service panel. The display should show +/- 0 kPa.

Please arrange for commissioning of the machine at its new location to be carried out by the Miele Service Department.

Longer period of inactivity (> 10 weeks)

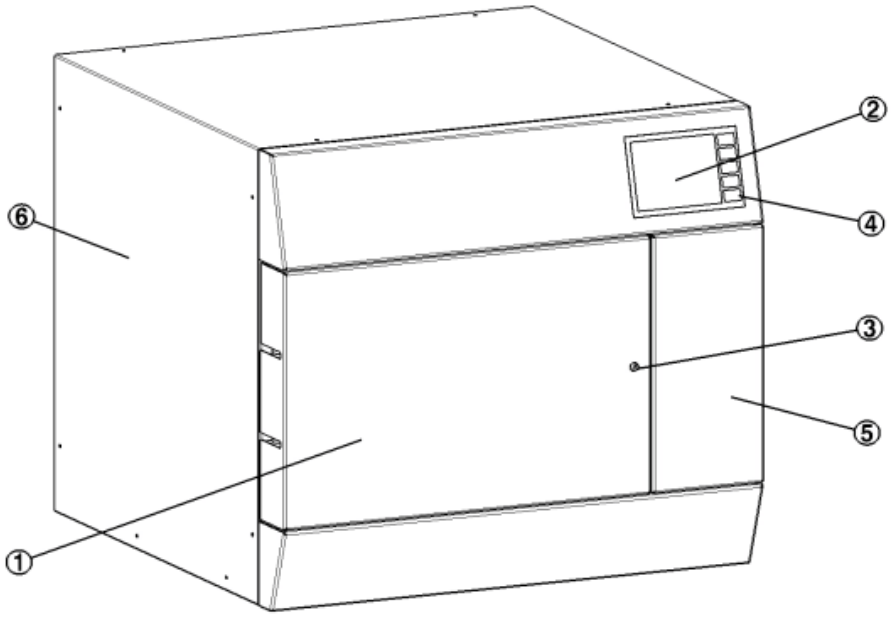
The steam-sterilizer must be decommissioned if it is not used for longer than 10 weeks. All liquid must be removed from the system to avoid corrosion and damage to components, by frost, for example. The manufacturer cannot be held liable if this is not done.

The procedure must only be carried out by a qualified and competent technician. Please contact the Miele Service Department to arrange for this to be carried out.

Performance qualification

The sterilization process must be verified in accordance with national regulations, guidelines and standards (CSA Z314.3-09: Effective sterilization in healthcare facilities by using the steam process). Performance qualification is in the responsibility of the operator. Performance qualification ensures that sterilization, when carried out under the on-site conditions, meets the requirements of the norm. The Miele Service Department can advise you regarding performance qualification.

Front, controls, displays and cabinet



① Pressure chamber door

② Display for programs and messages

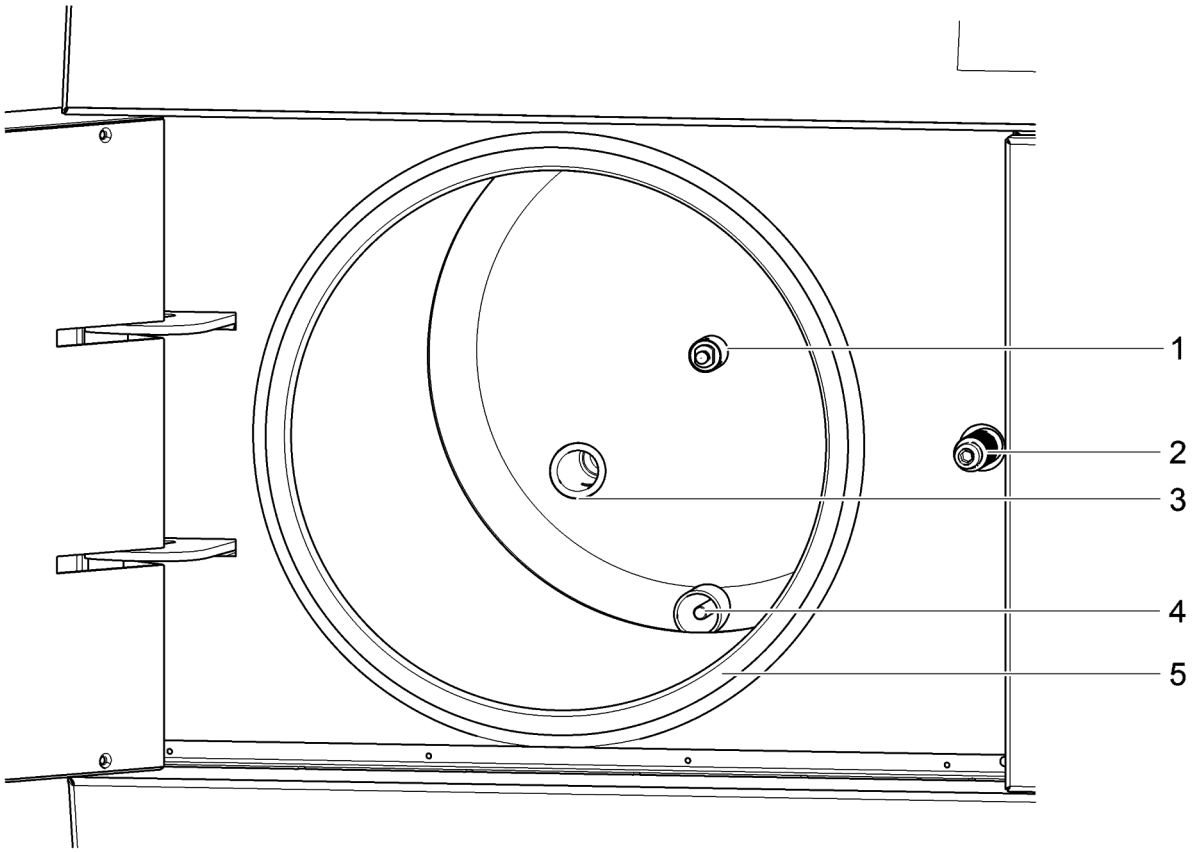
③ Opening for the emergency release of the pressure chamber door

④ Operating and function buttons

⑤ Service panel

⑥ Cabinet

Chamber interior



① Steam intake

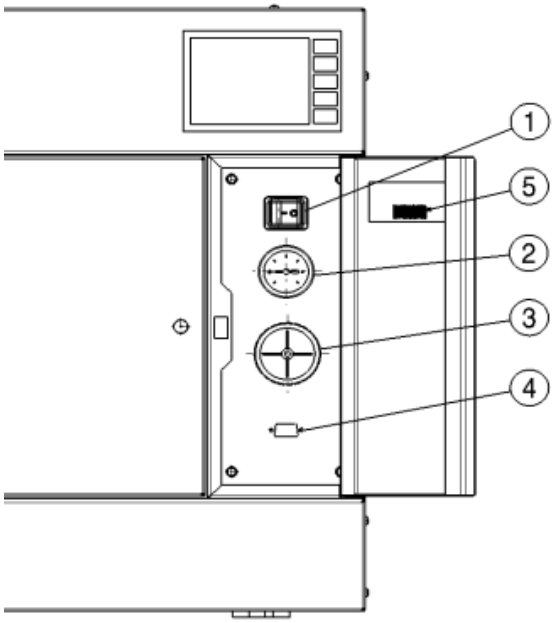
② Door spindle

③ Connection for measurement devices

④ Chamber drain

⑤ Door seal

Service panel



① Mains switch (with power surge trip switch)

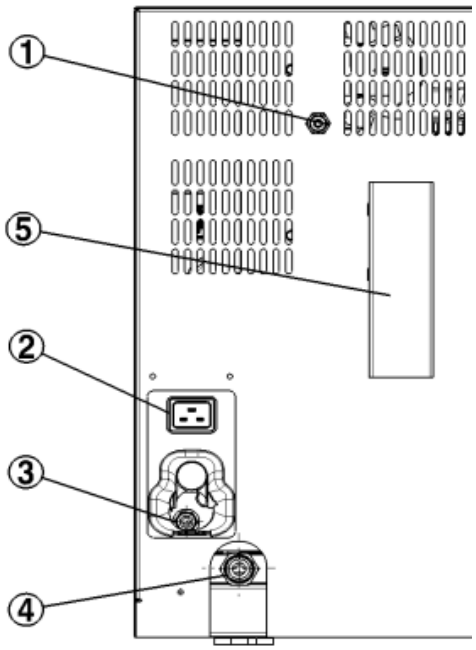
② Manometer for steam generator (pressure gauge)
The manometer shows the pressure in the steam generator (jacket) relative to ambient pressure. The atmospheric pressure is approx. 0 kPa. At 0 kPa the pressure chamber is unpressurised.

③ Sterile air intake filter

④ RS 232 serial interface

⑤ Data plate

Rear panel, Connections



① Priming connection

② Mains connection (machine plug connector)

③ Water inlet (with WPS system) *

④ Drainage (socket)

⑤ Safety valve cover

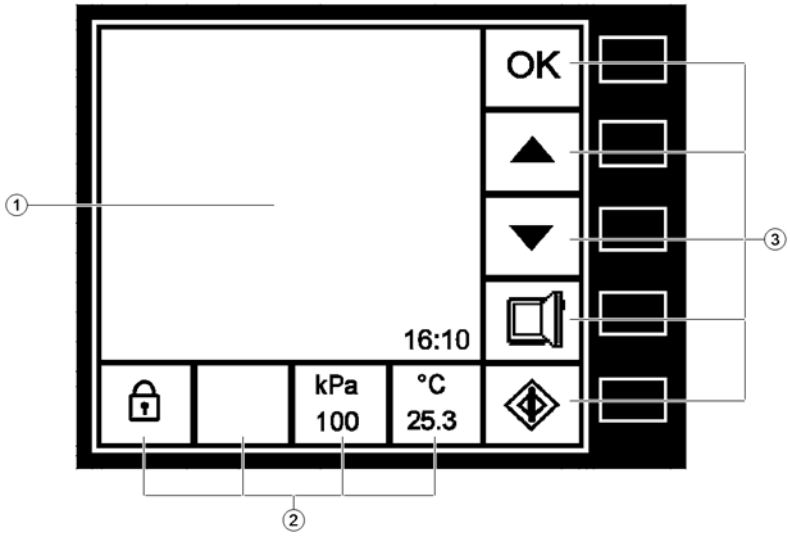
⚠ The ventilation grilles in the rear panel must not be covered.

⚠ Do not remove the safety valve cover. Caution. Danger of burning.

*) The fixed water protection device (WPS - Waterproof System) is located at the other end of the hose.

Using the machine

The display functions, status information and function buttons are described in this section. Status information is shown in the lower section of the display.



①Display	
② Status information	
/	**Pressure chamber door** Open (open lock symbol) / Closed (closed lock symbol)
	Service This symbol will appear when the steam-sterilizer requires servicing. Please contact the Service Department immediately to arrange a service visit.
kPa 100	**Pressure in the pressure chamber** Ambient pressure (ready for operation) / operating pressure (while the program is running). The unit displayed is kPa (kilopascal). 100 kPa = 14.5 psi. The pressure value displayed is the absolute pressure.
°C 25.3	**Temperature in the pressure chamber** The temperature sensor is located in the lowest part of the pressure chamber. The unit display is °C (degrees Celsius).

Guide to the machine

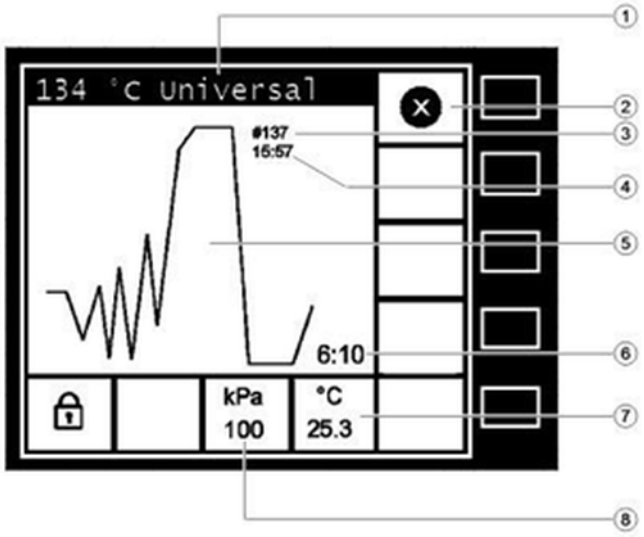
The buttons on the right of the display are allocated the following symbols in the display. Depending on function, the fields can be allocated different symbols or can be empty.

③Function buttons	
OK	Confirmation button, "OK" button This button activates a highlighted option. You can also use this button to move from a sub-menu to the menu immediately above.
⊗	Program cancellation button You can use this button to cancel a cycle which is running at any time. The program will automatically change to carrying out a cancellation routine and will be terminated. A message will then appear which you will need to confirm. You can then open the door and select a program.
▲	For scrolling up the menu Highlighted options are backlit in yellow. Use this button to move to the option above.
▼	For scrolling down the menu Highlighted options are backlit in yellow. Use this button to move to the option below.
	Door activation "Open" This button is used to open the pressure chamber door. This function is only possible after a program has finished or before a program has started.
▶	For scrolling to the right This button takes you to the next field.
	Quick start button This function allows you to select a sterilization program by simply pressing a button. The allocation is made in the "Settings" menu.

The door activation "Open" symbol for opening the door is not visible whilst a program is running as it is not possible to open the pressure chamber door during a program. For safety reasons, the door can only be opened after the program has finished completely.

During operation, any error messages which occur will be displayed together with a code. See "Error messages and instructions" for a description of the codes.

Once the 134 °C Universal program has started, the following graph will appear in the display.



① Program selected

② Program cancellation button

③ Batch number

④ Time remaining for the program to run (mins : secs)

⑤ Phases of the program selected (the relevant phase with flash)

⑥ Current time of day (24 h clock)

⑦ Current temperature in the pressure chamber

⑧ Current pressure in the pressure chamber (absolute pressure)

Main menu

The steam-sterilizer has the following menus:

– Sterilisation

  These programs are used to sterilize various items.

– Testing

  These programs are used for carrying out daily and weekly test routines.

– Settings

  This menu is used for setting functions such as time of day, date etc.

– Quick start

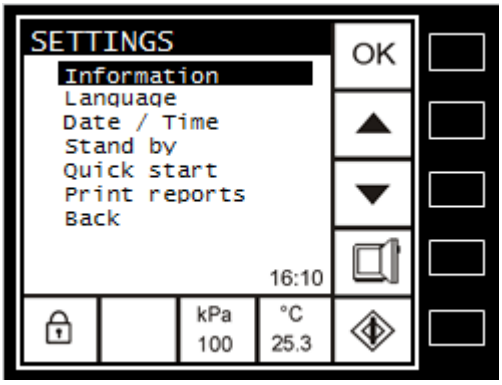
  Various sterilization programs can be allocated to this function button. You can then use this button to start a program which you have allocated to it previously by simply pressing a button (see "Quick start function").

To select and start a program, proceed as follows:

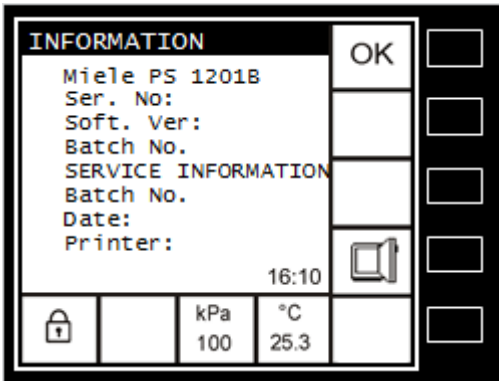
- Ensure that the machine is ready for operation. (Open the service panel and check the pressure manometer. The display should show approx. +230 kPa after the heat-up phase).
- Use the "Open" function button to open the door.
- Load the items to be sterilized. Close the pressure chamber door (see "Pressure chamber door").
- Select the "Sterilisation" or "Testing" option by scrolling to it with the ▲ or ▼ function button.
- Confirm with the OK button.
- Use the function buttons to select the program you want.
- Press the OK button again to start the program you have selected.

Information

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Information".
- Confirm with the OK button.

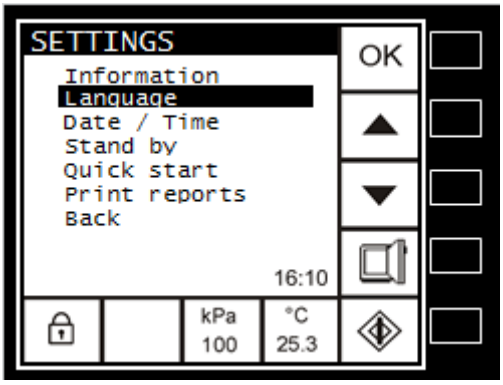


- Machine specific data and details of the next service are visible in this menu.

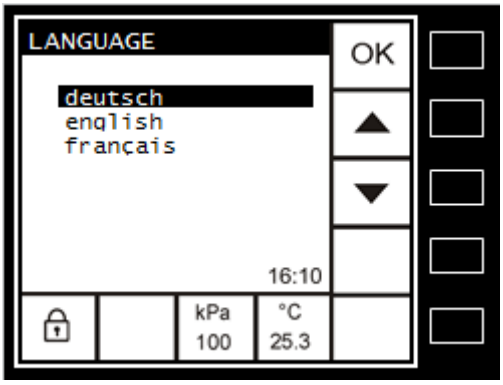


Language

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Language".
- Confirm with the OK button.

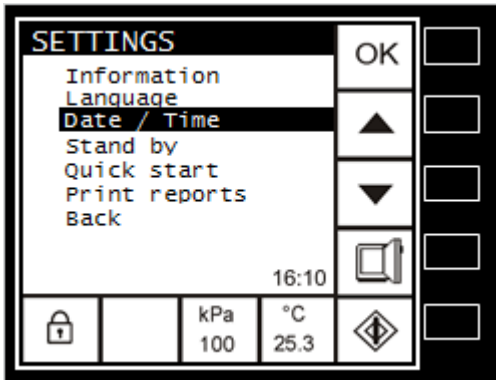


- Use the function buttons to select the language you want.
- Confirm with the OK button.

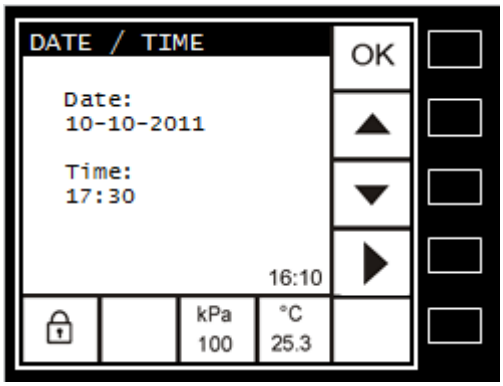


Date / Time

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Date/Time".
- Confirm with the OK button.



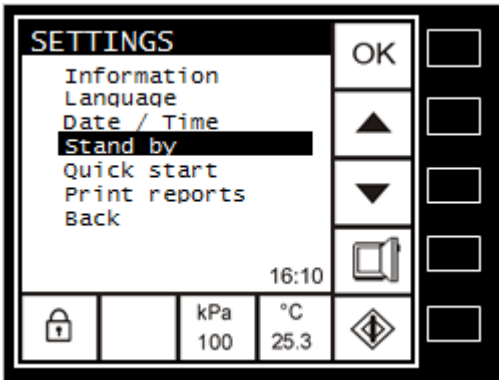
- Use the function buttons to set the current date and time of day.



- Use the ▶ function button to move the cursor to the number field you require. Use the ▲ or ▼ function button to increase or decrease the value in the field.
- Confirm your entries with the OK button.

Stand by

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Stand by".
- Confirm with the OK button.



There are two options available.

Energy save mode: in this mode the heating is regulated so that a pressure of only about 120 kPa prevails in the steam generator.

Idle mode: in this mode the heating is switched off completely and the machine only uses approx. 7 W of electricity.

Please note that these functions can only be activated or deactivated together.

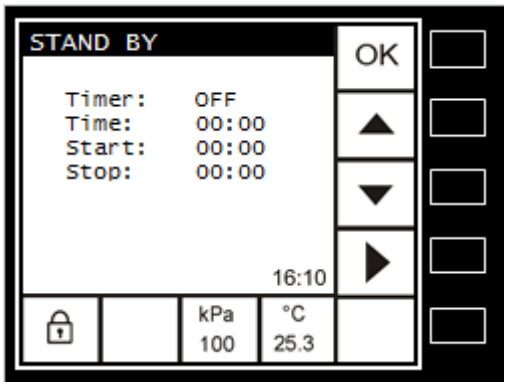
The display is dark when the steam-sterilizer is in either of these modes. However, "Please press any button" shows in the display.

- Press any button to get back to the main menu.

Timer / Time

- Use the ▲ or ▼ function button to set the Timer to "ON".
- Use the ▶ function button to move the cursor to the next number field.
- Select the period after which the machine should go into Energy save mode or Idle mode.

Start / Stop



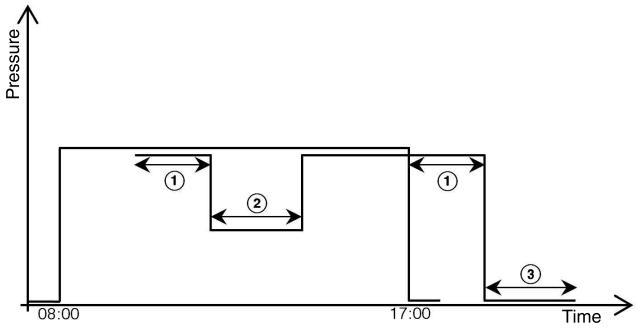
You can pre-select the time at which the sterilizer's steam generator heats up or switches off automatically. The mains switch must remain switched on for this function.

- Use the function buttons to set the Timer to "ON".
- Set the on and off times you require.

For the machine to actually switch into Idle mode or Energy save mode when the set switch off time is reached, a program must not be running and the machine must not have been operated for the time set in the timer. Otherwise the actual switch off time will be postponed by the value entered in the "Time" field. Please note that the "Start" and "Stop" settings can only be used in combination with the "Timer".

- Confirm your entries with the OK button. You will return to the "Settings" menu.

Example:



① Time period set under "Time"

② Energy save mode (120 kPa)

③ Idle mode (0 kPa)

The sterilizer start time ("Start" menu option) is set to 08:00. The sterilizer will start at this time with the heating-up phase. You can now start processes and use the machine. The timer ("Time" menu option) will begin to count down from the point in time when the machine is no longer being operated. Once the period set for the timer has elapsed the Energy save mode will begin and the display will go dark.

You can reactivate and use the sterilizer at any time.

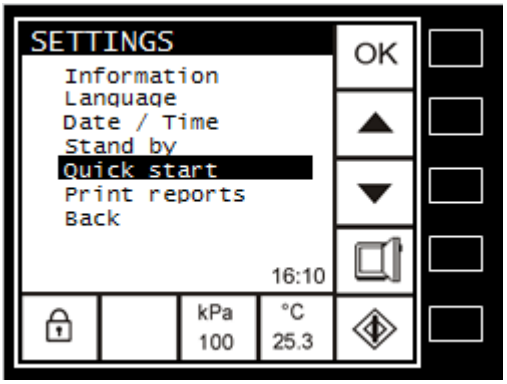
If the "Stop" option is set to 17:00, the machine cannot be operated from this time onwards and the timer will count down before the Idle mode, not the Energy save mode, begins.

Quick start function

◈ You can allocate the program you use most frequently to the Quick start button.

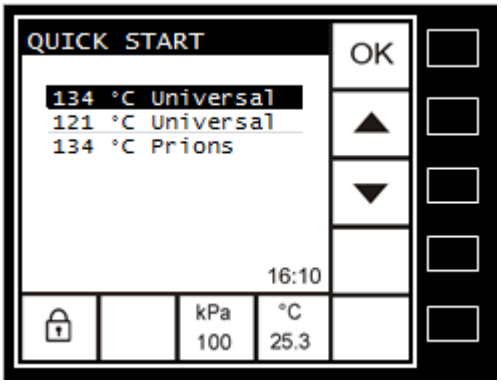
The Quick start function button in the main menu can be allocated to a program of your choice.

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Quick start".
- Confirm with the OK button.



- Press the ▲ or ▼ function button until the program you want appears.
- Confirm with the OK button.

Only sterilization programs can be pre-selected in this way. Test programs (Helix, Bowie-Dick tests and the vacuum test) cannot be pre-selected.



When the Quick start button in the Main menu is pressed, the sterilizer will start running the pre-selected program immediately.

Print reports

- Open the "Settings" menu.
- Use the ▲ or ▼ function button to scroll to "Print reports".
- Confirm with the OK button.

This option guarantees documentation of sterilization processes, should, for example, the printer or connected software fail. The last five reports are saved and can be printed, for example, after the problem has been resolved (printer cartridge / paper replenished).

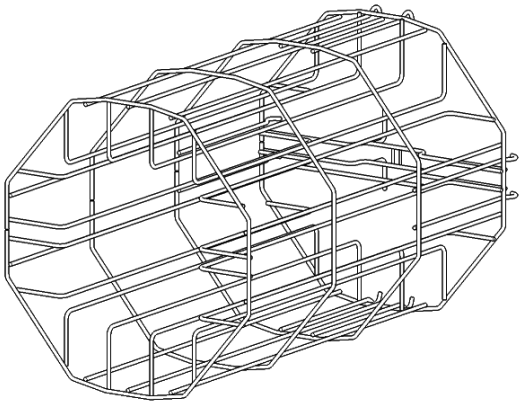
With this option the five most recent reports are sent to a connected printer and printed. If a printer has not been connected to the machine then the display will not show an error message and no reports will be printed. Where a Segosoft Miele Edition USB data logger has been connected to the machine, the same procedure will apply as for a printer connected to the machine.

5 reports are saved for process documentation software and can then be uploaded by the software. The function depends on the software product. Miele Segosoft Edition software can upload the 5 most recent reports from the machine automatically, i.e. without any intervention by the user.

For more information about report printing, please refer to "Process documentation".

The "Back" function in the "Settings" menu returns you to the main menu. Pressing the OK button will also take you a step back from the sub-menu.

Prerequisites



The steam-sterilizer is supplied as standard with a rack. The rack has a capacity of:

– 3 large instrument cassettes,

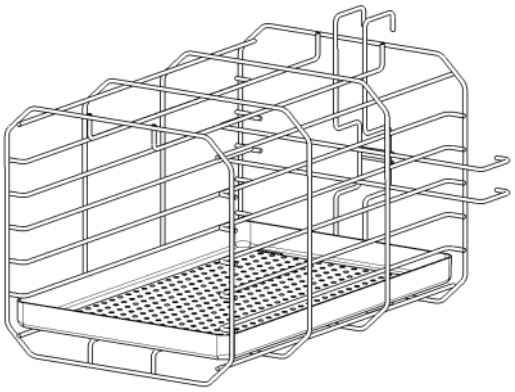
– or 6 small instrument cassettes,

– or 9 exam instrument cassettes,

– or 3 trays to sterilize pouches,

– or a mixed load of instrument cassettes

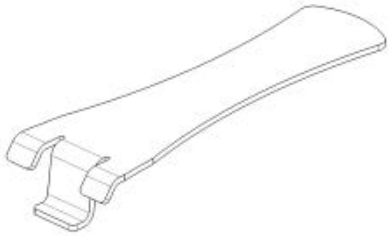
– and pouches loaded on a tray.



Rack ZS 111 for 6 trays is available as option from Miele. This rack is especially designed to sterilize pouches in up to 6 trays in total. Only use perforated Miele trays (ZS 131) for efficient steam penetration.

If the rack is turned 90° on their long axis, it holds 2 Oral surgery cassettes or can also be loaded up with the different sizes of instruments cassettes as well as trays to sterilize pouches. The rack is supplied with 3 perforated trays (ZS 131) and only use these perforated trays for efficient steam penetration.

The rack is locked in position at the end of the chamber. To detach the rack, pull it until you hear a click.



A handle is supplied for handling the trays. The handle can be used to remove the trays from and load the trays into the rack safely.

Items to be sterilized

Only load the steam-sterilizer with items which have been cleaned, disinfected and dried in accordance with correct procedures. The instruments must be visibly clean. There must be no deposits, e.g. dental impress compound, blood, composite etc. present on the items to be sterilized. These substances could cause inadequate sterilization.

– Instruments should be cleaned immediately after use. We recommend using a washer-disinfector to clean instruments. Please follow the washer-disinfector manufacturer's instructions as well as those of the instrument manufacturer.

– When cleaning manually, rinse the instruments thoroughly to remove any cleaning and disinfection agent residues and ensure that they are sufficiently dry. Residual substances can lead to corrosion over time.

– Clean and care for the instruments in accordance with the manufacturer's instructions.

– Cotton items must be washed and dried before sterilization.

⚠ Disposable instruments must not be reprocessed.

⚠ Ensure that no acid or solvent residues, especially hydrochloric acid or chlorides, are introduced into the sterilizer chamber.

Program selection

– A Helix/Bowie-Dick text should be carried out daily before the first batch is sterilized. The instructions of the test manufacturer must be followed. It is recommended to use the Miele Helix Test ZS150.

– The vacuum test must be run at least once a week.

– Check the type of item being sterilized before loading (e.g. risk evaluation with respect to infectious prions (Creutzfeldt–Jakob Disease, CJD or vCJD)) in order that the appropriate program can be selected.

– Only load each batch with items which are to be sterilized using the same program (e.g. 134 °C Universal) . Please follow the manufacturer's instructions.

– Some rubber and plastic items can only be sterilized at a temperature of 121 °C. Please follow the manufacturer's instructions.

– Sterilize solid instruments and porous items (cloths, laminate etc.) using the 134 °C program, if necessary. Please follow the manufacturer's instructions.

Test programs

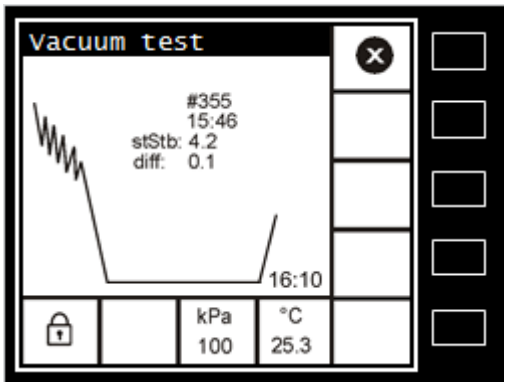
Vacuum test

This program is used to test the whole system for leaks. The vacuum test must be performed at least once a week. A successful test indicates that the system does not leak and that the technical precondition for safe sterilization has been assured.

- Check that the pressure chamber is empty except for the rack.
- Close the pressure chamber door.
- In the main menu, use the ▲ or ▼ function button to scroll to "Testing" and then to "Vacuum test".
- Confirm with the OK button.

A vacuum of 2 kPa is generated in the pressure chamber during the preparation phase (no display is visible).

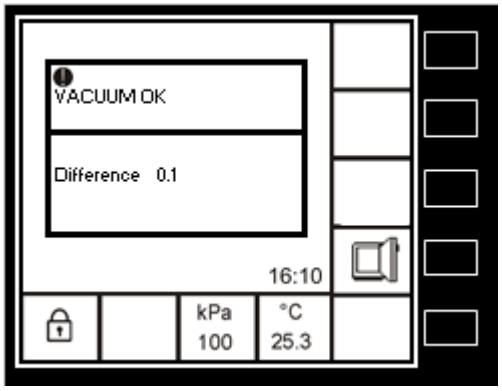
As soon as this value is reached, "Stabilisation", the first part of the vacuum test, will begin. The system will stabilize itself. During the stabilization period the display will show how high the pressure is at the beginning of the phase and how much it is expected to rise by the end of the phase (diff = difference Start / Finish). This phase lasts 5 minutes.



The different program stages are indicated by stStb = Start stabilization and stTst = Start test phase.

The vacuum test will finish after approx. 23 minutes and "VACUUM OK" will appear in the display as well as the rise in pressure

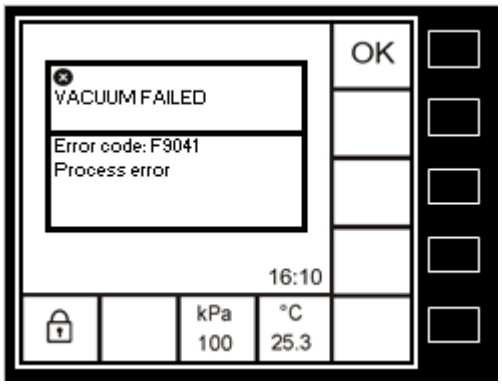
which has been measured (diff = difference Start / Finish) during the test period of, for example, 0.1 kPa.



- Use the "Open" button to open the door.

The main menu appears in the display. The steam-sterilizer is now ready for further use.

If leakage (greater than 1.3 kPa within 10 minutes) is detected during the test period, the program will be cancelled automatically. "VACUUM FAILED" will appear in the display. Error code “F9041" and "Process error" will also appear in the display.



- Confirm with the OK button.

The display will change to show the main menu.

- Open the door, remove any residual liquid and check whether there is any debris on the door seal.
- Where necessary, clean the door seal and the sealed surfaces. Close the door and restart the program.

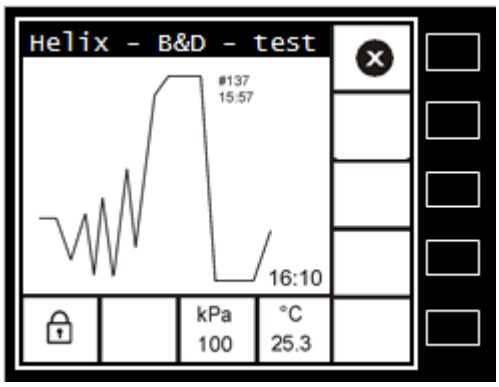
If the test is unsuccessful again, please contact the Miele Service Department.

Document each test carried out on the steam-sterilizer, e.g. using process documentation software (Segosoft Miele Edition) or a report printer.

Helix/B&D test

This program is used to test that steam penetration is efficient and to test the performance of the machine in order to ensure that hollow and porous material items are sterilized effectively. Tests are performed using a Process Challenging Device (PCD) like Helix or Bowie&Dick (B&D) test. The Helix or B&D tests are also known as "Air removal test". The Helix/B&D test must be carried out daily (please follow the manufacturer's instructions). A successful test means that all process parameters are correct and the basic technical requirements for safe sterilization are assured. The Helix/B&D test should carried outin compliance with “CSA Z 314.3-09 Effective sterilization in health care facilities by using the steam process”. It is recommended to use the Miele Helix Test ZS 150.

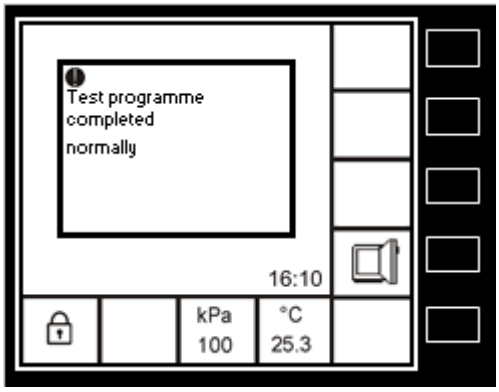
- Open the pressure chamber door.
- Place an appropriate test item (Helix or B&D test) on the lowest tray in the pressure chamber.
- Position the test in the middle of the tray. The other trays in the rack remain empty. Do not place any other items in the pressure chamber.
- Close the pressure chamber door. In the main menu, select "Testing" and then "Helix- B&D -Test".
- Confirm with the OK button.



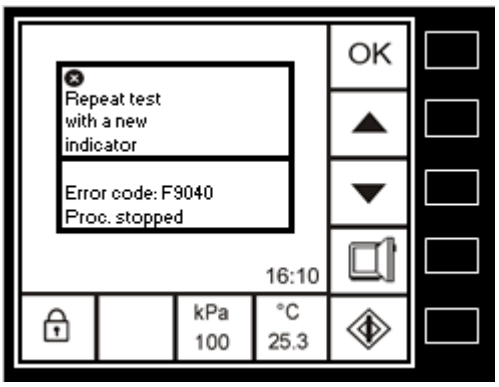
The program will finish after approx. 14 minutes and "Test programme completed normally" will appear in the display.

- Confirm with the OK button and you will automatically return to the Main menu.
- Open the pressure chamber door by pressing the "Open" button and remove the test item.

At the end of the program ("Test programme completed normally"), remove the process challenge device and evaluate it according to the manufacturer's instructions. If the indicator strip shows that the test has been completed successfully, the steam-sterilizer can be used for sterilization.



If problems occur during the test, this will be indicated in the screen.



Repeat the procedure if the test program has been cancelled ("Repeat test with a new indicator").

If the display continues to indicate that there are problems, please contact the Miele Service Department.

Useful tip:

Miele recommends to use the Helix Test ZS 150. As alternative to a Helix Test you can carry out a Bowie-Dick test in this program instead of a Helix test. The B&D test is referred to as a "steam penetration test". It gives information on efficient steam penetration of porous and wrapped items. This test must also be placed in the lowest tray in the empty pressure chamber. Please refer to the manufacturer's instructions on the B&D test packaging for information about how to use and evaluate the test.

Document each test carried out on the steam-sterilizer, e.g. using process documentation software (Segosoft Miele Edition) or a report printer.

Sterilization programs

Chronological sequence (phases) of a sterilization process

A sterilization program is composed of 14 phases which are listed individually in the process documentation report printout.

An example of a report is given in "Process Documentation - Example of a report printout". The individual phases of a sterilization program are listed in the following table.

Sequence of a sterilization program (134 °C Univ.)		
Phase/Process	Pressure 1)	Time 2)
Steam flow	Increase to approx. 120-135 kPa	Approx. 120 secs
1. Pre-fractioning: Vacuum	Reduction to approx. 50 kPa	Max. 240 secs
1. Pre-fractioning: Steam intake	Increase to approx. 140 kPa	Max. 240 secs
2. Pre-fractioning: Vacuum	Reduction to approx. 10 kPa	Max. 360 secs
2. Pre-fractioning: Steam intake	Increase to approx. 160 kPa	Max. 240 secs
3. Pre-fractioning: Vacuum	Reduction to approx. 25 kPa	Max. 360 secs
3. Pre-fractioning: Steam intake	Increase to approx. 180 kPa	Max. 180 secs
4. Pre-fractioning: Vacuum	Reduction to approx. 65 kPa	Max. 300 secs
Pressure increase (for sterilization)	Increase to approx. 200 kPa	Approx. 120 secs
Stabilization for sterilization	Increase to approx. 314 kPa	
Sterilization: Start of holding time	Approx. 314 kPa	Program dependent
Drying: Start (of phase)	Reduction to approx. 10 kPa	Max. 360 secs
Aeration: Start (of phase)	Reduction to approx. 4 kPa	420 secs
End of process	Increase to approx. 100 kPa	60 secs

1) Absolute pressure measured in the pressure chamber. Atmospheric pressure approx. 100 kPa (14.5 psi) depending on installation site (0 kPa equals absolute vacuum).

2) Generally the appropriate pressure is reached earlier. Several times are maximum values, i.e. if pressure is not achieved within the maximum time allocated to a phase, an error message is displayed.

Key to the graphs below:

The schematic graphs below show the pressure-time progression of the particular program. A schematic graph will also appear in the display of the steam-sterilizer.

① Start

② Steam

③ Pre-fractioning

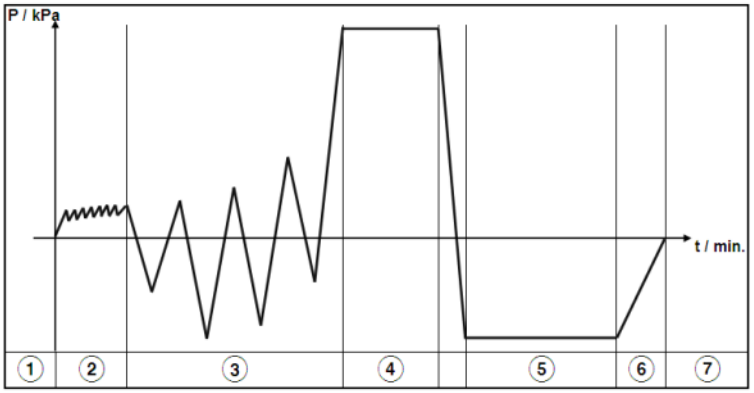
④ Sterilization

⑤ Drying

⑥ Aeration

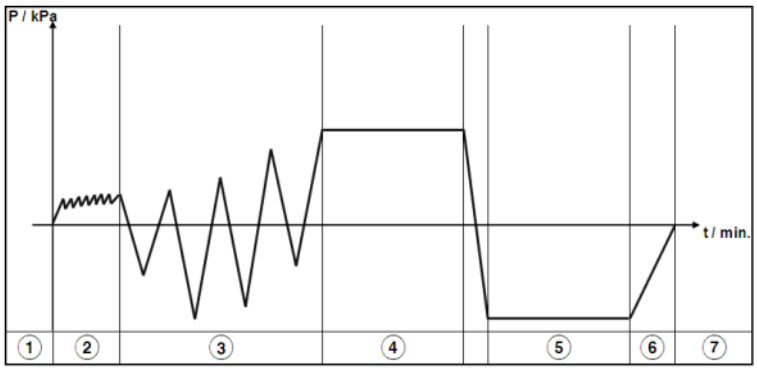
⑦ Finish

134 °C Universal



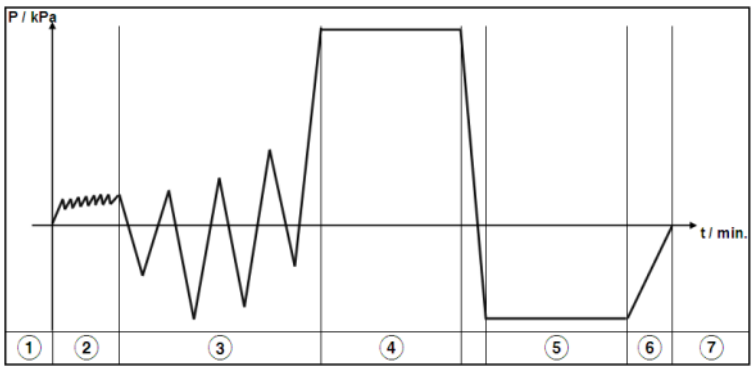
This program is intended for the sterilization and subsequent drying of unwrapped and wrapped sterile supplies. It can only be used to sterilize solid instruments and hollow and porous items which are suitable for sterilizing at a temperature of 134°C. Please refer to the item manufacturer's instructions.

121 °C Universal



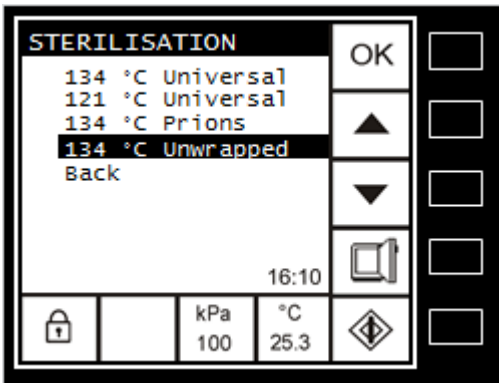
This program is intended for the sterilization and subsequent drying of unwrapped and wrapped sterile supplies. It can only be used to sterilize solid instruments and hollow, rubber, plastic and porous items which are suitable for sterilizing at a temperature of 121°C. Please refer to the item manufacturer's instructions.

134 °C Prions

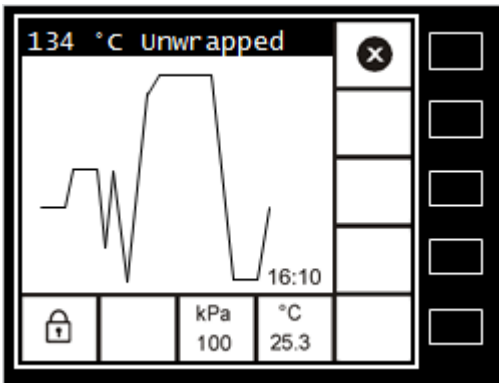


This program is intended for the sterilization and subsequent drying of unwrapped and wrapped items. It can only be used to sterilize solid instruments and hollow and porous items which are suitable for sterilizing at a temperature of 134 °C. Please refer to the item manufacturer's instructions. This program has an increased holding time of 18 minutes. This is the holding time advised by guidelines and recommendations regarding the risk of Creutzfeldt–Jakob Disease (CJD or vCJD) transmission in some countries. The program is used to inactivate prions related to Creutzfeldt–Jakob Disease (CJD or vCJD).

134°C Unwrapped



The "134 °C Unwrapped" program is only suitable for sterilizing unwrapped items.



This program is intended for the sterilization and subsequent drying of items which are not wrapped. Only dental instruments and hand pieces which are suitable for sterilizing at a temperature of 134 °C may be sterilized. Please refer to the item manufacturer's instructions. This program only has two pre-fractioning stages, therefore the total running time, with a holding time of 4 minutes, is 12 minutes including drying.

⚠ The "134 °C Unwrapped" program has reduced aeration and drying times and is therefore unsuitable for sterilizing wrapped goods or porous items (e.g. textiles).

⚠ After the machine door has been opened, unwrapped items are no longer "sterile" and should be used immediately.

Switching on

- Insert the mains plug into the socket.
- Open the faucet.
- Switch on with the mains switch.

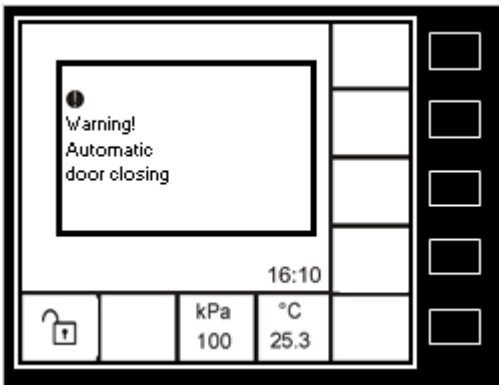
If the steam-sterilizer is cold, it will take approx. 30 minutes after switching on the mains switch to reach its operating temperature. A program can only be started once the operating temperature has been reached.

Pressure chamber door

To close the pressure chamber door, you need to close it by hand until it touches the spindle.

The door motor will start running (audible) and close the door automatically.

"Warning. Automatic door closing" will appear in the display.



To open the pressure chamber door, press the "Open" function button (see "Using the machine").

The door motor will start running and open the door approx. 2 cm. The motor will then switch off. You can now open the pressure chamber door further by hand. The maximum opening angle of the door is 180°.

To save energy, please keep the pressure chamber door shut during short pauses.

If the steam-sterilizer is to remain switched off for a long period of time or when it is in standby mode or idle, we recommend leaving the door slightly ajar and not to close it completely. This will increase the life of the door seal and prevent the seal from sticking to the door.

⚠ Do not open the door by force, and only use the emergency release when absolutely necessary. Caution - danger of scalding. Please contact the Miele Service Department to arrange for the emergency release of the door.

Notes on loading and unloading

- Only load the steam-sterilizer with items which have been cleaned, disinfected and dried in accordance with correct procedures.
- If possible, sterilize textiles and instruments separately in different containers or trays.
- If possible, place large instruments in the lower trays or instrument cassettes.
- Items of different materials (unalloyed steel, stainless steel etc.) must be placed in separate trays or instrument cassettes if they are not wrapped individually.
- Items which are being sterilized unwrapped must only be placed in trays. It is recommended to use a layer of sterilization paper between the tray and the unwrapped instruments.
- Porous items should be placed in the upper trays or instrument cassettes, if possible.
- Hollow items and unperforated dishes must always be placed with the opening facing downwards. Hinged instruments (forceps, scissors etc.) should always be sterilized in the open position.
- Ensure that lumened items (hoses etc.) are not kinked and can be accessed by steam without hindrance.
- Check that the packaging of wrapped items is intact.

– Check that items to be sterilized are wrapped correctly and positioned on the trays correctly. When using cassettes, check that cassettes to be sterilized are wrapped correctly and positioned in the rack correctly.
– Instruments can be wrapped and sterilized in paper-foil pouches or in instrument cassettes wrapped in sterilization fleece or paper.
– The foil side of paper-foil pouches should face upwards. This allows condensate (water) to drain off more freely.
– Wrapped items must be loaded so that they do not touch one another. For more capacity slide in additional trays (ZS 131) or use optional rack (ZS 111) for a capacity of 6 trays.
– The items to be sterilized or the packaging must not touch the chamber walls or the door of the pressure chamber.
– Textile packs can be double-wrapped in sterilization fleece or paper, if necessary.
– The trays must not be overloaded. This would compromise the drying result (see "Sterilization programs").
– In order to guarantee good steam circulation, only use the rack and trays supplied.
– Items to be sterilized must be placed in the rack loaded in instrument cassettes or on trays. Only use perforated Miele tray ZS 131 for sufficient steam penetration.
– Make sure that sterilized items are dry after reprocessing.
– In accordance with “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” use packages (e.g. pouches, wrapped cassettes) with internal and external chemical indicators in each load. For additional information refer to “Routine monitoring”.
– In accordance with “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” perform a biological indicator test once a day. Testing is performed with the first sterilization program (typically in the morning). The indicator is placed on the lowest tray or cassette. Run the cycle with a full sterilizer load. For additional information refer to “Routine monitoring”.

Starting the program

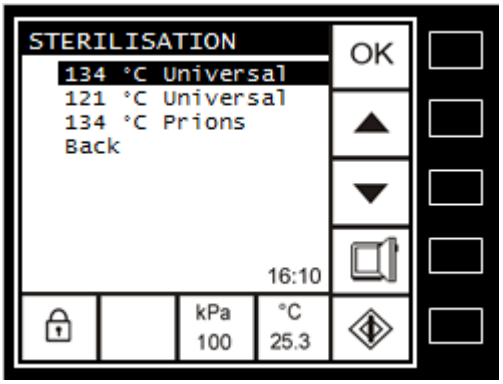
It is essential to follow the instructions of the instrument / textile manufacturer with regard to machine reprocessing and sterilization and to observe the relevant standards, regulations and guidelines.

When loading and unloading the steam-sterilizer, please note that the walls of the pressure chamber and the trays can be hot. Use the tray handle or temperature resistant gloves to avoid injury.

■ Open the pressure chamber door. Place the items to be sterilized on the trays.
■ Close the pressure chamber door.

The total duration of the sterilization program can vary depending on the load.

■ Press the OK button to access the Sterilization menu.
■ Select the program you want by scrolling to it with the ▲ or ▼ function button.

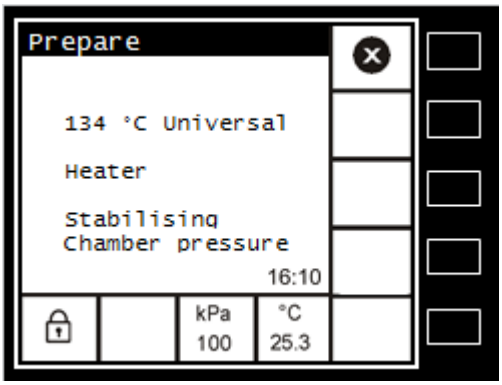


See "Application technology" for an exact description of the programs.

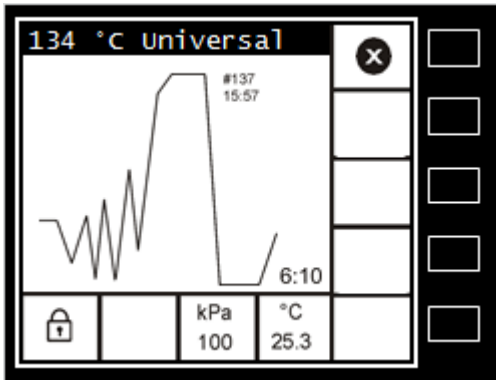
■ Press the OK button to start the program.

The program will only start when the operating pressure in the boiler is reached.

The sterilizer waits until the operating pressure has been reached and then starts automatically.



Example of a program sequence display



End of program

– Check that the "Process OK" message is showing in the display. Check the following in order that the items can be validated and approved as sterile.

– Open the pressure chamber door with the "Open" button and remove the sterilized items.

– There must not be any residual condensate present in the pressure chamber.

– Do the following visual check of the sterilization result: The packaging of wrapped sterile items must not be damaged. Check the join or bonded seam on pouches.

– There must be no residual condensate visible on the packaging or the load items.

– All sterile items must be in trays. Any items which have fallen to the bottom of the chamber should be regarded as "unsterile". These must be repackaged and sterilized again.

– Remove the biological indicator (where applicable) from the load and incubate it according to the indicator manufacturer's instruction. For additional information refer to "Routine monitoring".

– If a report printer or process documentation software is being used, check the printout or the software display to ensure that the relevant process parameters/process curves have been maintained.

– If no errors are identified, the items should be approved and documented as sterile in accordance with the on-site quality management system. To confirm that the parameters are "OK", the print-out or electronic record should be initialed or signed manually or electronically.

If "Process failed" appears in the display at the end of a program, the sterilizer will need to be checked. Exception: Error code F9040 (manual cancellation).

Items in damaged or wet packaging must be repackaged and sterilized again. Items which are not wrapped are not considered sterile after sterilization.

Instruments which must be sterile when used must be wrapped when being sterilized.

■ If "Process failed" appears in the display, confirm the message with the OK button and then open the pressure chamber door and remove the items.

Label all items immediately as "Not sterile".

■ Repackage and sterilize the items again.

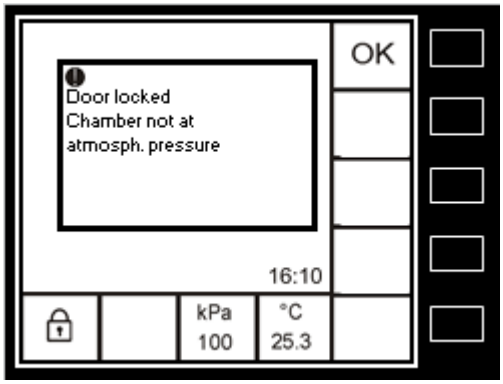
Before loading the sterilizer again, check that the machine is functioning correctly by running a vacuum test and a Helix/B&D test.

Document the result of every cycle, e.g. using process documentation software (Segosoft Miele Edition) or a report printer. Also document batches where the process parameters have not been met, but never release a batch where the process failed.

Cancelling a program manually

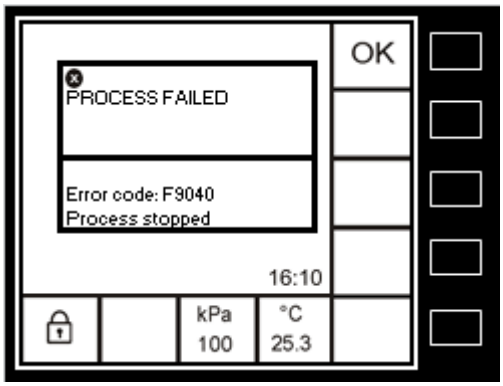
A program can be cancelled manually whilst it is running at any time by pressing the program cancellation button.

Cancelling a program while it is under pressure will activate a cancellation routine. The following message will appear:



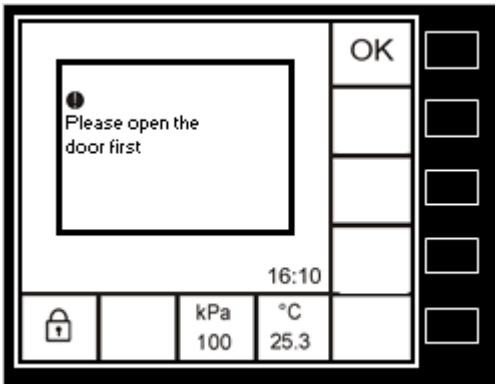
This is a safety measure. The cancellation routine ensures that the chamber is at atmospheric pressure before it can be opened.

When the cancellation routine is finished, "PROCESS FAILED" will appear in the display as the sterilization cycle has not been completed.



- Confirm the message with OK to return to the main menu.
- Open and close the pressure chamber door so that you can restart the program.

If you do not open and close the door, the following message will appear:



- Confirm with the OK button.
- Open and close the pressure chamber door.

A program is not started until the operating pressure is reached, so when the program is cancelled you will be taken back to the main menu.

According to “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” physical parameters as well as chemical and biological indicator need to be monitored in a sterilization process.

Physical parameters

After the cycle has finished, the physical parameters (e.g. time, temperature, pressure) are verified by examining the printout or electronic record of each cycle before the load is released. To confirm that the parameters have been met and checked, the print-out or electronic record is initialed or signed manually or electronically. The steam-sterilizer can be connected to a printer or electronic record. For additional information refer to “Process documentation”.

Chemical indicator

Chemical indicators react to specific sterilization parameters and they usually respond by a color change after being exposed for a certain time to steam. For further information regarding indicators refer to the manufacturer's instructions. The indicator typically can be used to differentiate between processed and unprocessed items and to demonstrate items inside a package have been exposed to steam.

– Internal indicator:

  According to “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” internal indicators are placed in each package (e.g. pouch, wrapped cassette) to demonstrate that the load was exposed to steam. For proper use please refer to indicator manufacturer’s user manual.

– External indicator:

  According to “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” each package (e.g. pouch, wrapped cassette) that is sterilized carries a visible external chemical indicator to differentiate between “Processed” and “Unprocessed" packages, unless the internal indicator is visible without opening the sterile package. The external indicator could be either an autoclave tape or an indicator printed on the packaging material itself. For proper use please refer to indicator manufacturer’s user manual.

Biological indicator

According to “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” the sterilization process needs to be monitored once a day with a biological indicator. Biological indicators consist of spores on a carrier plus incubation media. After sterilization the biological indicator is incubated to define if growth of micro-organisms exists after the sterilization process. For proper use please refer to biological indicator manufacturer’s user manual.

Testing is performed with a sterilization program (typically in the morning) and the indicator is placed on the lowest tray or cassette. Run the cycle with a full sterilizer load. After the cycle finished the indicator is removed from the load and the following aspects are documented to link the indicator to a specific load: Indicator location, date, time, sterilizer number and cycle number.

Routine Monitoring

After the documentation the biological indicator is incubated according to the instructions of the biological indicator manufacturer. Sterilized loads should not be released before the incubation results of the biological indicator are known.

If the incubation results do not show any growth of micro-organism the previous sterilized loads can be released for use. In case of any growth of micro-organism the previous loads are kept under quarantine and are labeled “Not sterile”. Repack and sterilize the items again. Before loading the steam-sterilizer again, check that the machine is functioning correctly by running a vacuum test and a Helix/B&D test. If the biological test fails again contact your Miele Service.

The following spreadsheet provides an overview for daily and weekly routine monitoring tests.

Test	Performance...	Program selection...
Vacuum test	Once a week	Vacuum test
Helix test or Bowie&Dick (B&D) test	Once a day before first batch is sterilized	Helix/B&D test
Biological indicator	Once a day used in sterilization programs, typically placed in first batch of the day that is sterilized	Standard program
Chemical indicator	Used in each load and package	Standard program
Check of physical parameter	After each cycle	Standard or test program

Report printer and software for process documentation

The steam-sterilizer is capable of documenting sterilization processes (process documentation). This can be carried out either by using process documentation software (Segosoft Miele Edition) or via an external printer (PRT 100).

Process documentation using software

The process documentation can be transferred for digital archiving by connecting the steam-sterilizer directly to a PC via a cable (cable length max. 13 m). The data is transferred to a PC loaded with the process documentation software.

Process documentation via USB stick

Process data is saved temporarily on a USB stick via a USB data logger connected to the steam-sterilizer. The data can then be transferred from the USB stick to a PC loaded with process documentation software (Segosoft Miele Edition).

Process documentation using report printer PRT100

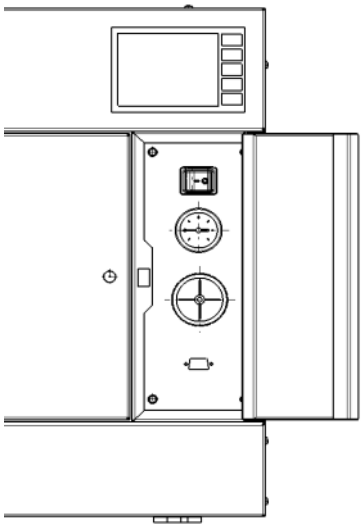
The process reports are printed on a report printer connected to the machine and then archived in paper form.

Only printers which are certified in accordance with EN/IEC 60950 may be used.

The machine is equipped with an RS 232 serial interface for connecting to a computer with suitable software or a printer. This is located behind the service panel on the front of the machine. If a PC loaded with process documentation software is to be connected directly to the steam-sterilizer (direct connection), a serial cable is connected to the machine. The serial cable can then be connected directly with a USB serial adapter cable to the USB interface of the PC.

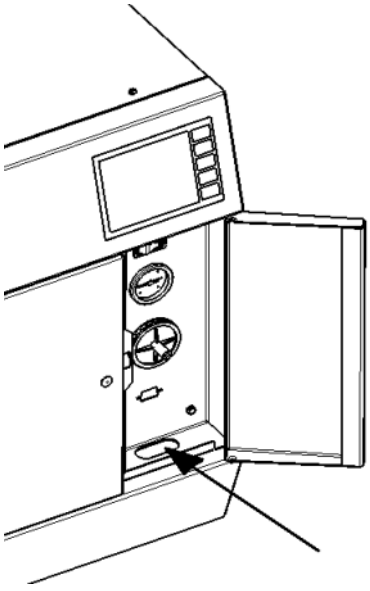
Please only use the report printer listed in "Optional extras". The control unit is pre-programmed for connection to this printer.

The printer or the documentation software once loaded will function automatically after being connected to the interface.



Please observe the printer manufacturer's installation instructions and read the operating instructions for the printer before use.

Pull the machine forwards so that it protrudes slightly over the worktop. Guide the cable from below through the opening provided for it in the base behind the service panel (see illustration).



Connect the cable to the interface. Place the machine carefully back in position and guide the interface cable out to the side, making sure it does not become trapped.

Specially designed software and printer solutions for process documentation are available from Miele Professional. Segosoft Miele Edition software is particularly suitable for documentation. Please contact Miele for further information.

If the cable is disconnected from the steam-sterilizer or from the receiver while data is being transferred, the machine must be restarted and the procedure repeated.

Example of a report printout

Below is an example of a report printout of a sterilization program and a test program.

Example program: 134 °C Universal

```
=======================================
Miele PS 1201B
=======================================
Serial number:      111500014
software version:   T2.2
Language:           english
Programme:          134°C Universal
Batch number:       388
Start:              09:56:09 17-02-2011
Stop:               10:20:19 17-02-2011
Result:             PROCESS OK
Error code:         No error
=======================================
Phases
=======================================
Steam flow
01:30Min:Sec     144.0kPa    101.9°C
1. Pre-fractioning: Vacuum
02:37Min:Sec      50.2kPa    102.3°C
1. Pre-fractioning: Steam intake
03:03Min:Sec     139.1kPa    103.1°C
2. Pre-fractioning: Vacuum
03:45Min:Sec      10.5kPa     77.8°C
2. Pre-fractioning: Steam intake
04:33Min:Sec     159.3kPa    106.4°C
3. Pre-fractioning: Vacuum
05:03Min:Sec      25.3kPa     86.4°C
3. Pre-fractioning: Steam intake
05:51Min:Sec     175.8kPa    110.4°C
4. Pre-fractioning: Vacuum
06:06Min:Sec      69.2kPa    107.1°C
Evacuation for sterilisation
06:14Min:Sec     181.9kPa    104.6°C
Stabilisation for sterilisation
07:45Min:Sec     309.2kPa    134.0°C
Sterilisation: Start of holding time
07:59Min:Sec     315.0kPa    135.0°C
Sterilisation: End of holding time
12:03Min:Sec     312.8kPa    135.5°C
Drying: Start
13:45Min:Sec       9.3kPa     98.3°C
Aeration: Start
20:46Min:Sec      11.8kPa    117.5°C
End of Process
21:27Min:Sec      89.6kPa    118.8°C
=======================================
Sterilisation temperature (target)
Min.:134°C      Max.:138°C
Sterilisation temperature (Min.)
135.0°C
Sterilisation temperature (Max.)
135.5°C
Sterilisation Pressure (Min.)
311.9kPa
Sterilisation Pressure (Max.)
315.0kPa
Steriliation duration
04:04Min:Sec
Drying Pressure (Min.)
  3.0kPa
=======================================
End of report
=======================================
```

The report starts with the description of the machine.

The second section contains information about the machine: Serial number, software version and the language set. Next process parameters are listed, such as program selected, current cycle number, program

start and stop time, program sequence result and whether an error message has occurred or not.

Correct program sequence

With a correctly carried out program sequence, depending on the program selected, the following results are documented in the report.

– "PROCESS OK" with the "121 °C Universal" and "134 °C Universal", "134°C Unwrapped" and "134 °C Prions" programs

– "TEST PROGRAMME OK" with the "Helix-B&D test" program

– "VACUUM OK" with the "Vacuum test" program

– In addition "No error" is listed under "Error code".

"PROCESS OK" appears in the display. It is essential to observe the instructions in "Application technology" before releasing a cycle load as sterile.

Incorrect program sequence

With an incorrectly carried out program sequence, depending on the program selected, the following results are documented in the report.

– "PROCESS FAILED" with the "121 °C Universal" and "134 °C Universal", "134°C Unwrapped" and "134 °C Prions" programs

– "TEST PROGRAMME FAILED" with the "Helix-B&D test" program

– "VACUUM FAILED" with the "Vacuum test" program

– In addition the corresponding error is listed under "Error code".

"PROCESS FAILED" appears in the display. The load is not sterile and must not be released. It is essential to observe the information on how to proceed given in "Application technology".

For sterilization programs as well as the Helix-B&D test, time, temperature and pressure values are documented in detail in the "Phase" section. Please refer to "Application technology" for an explanation of the phases.

With the vacuum test only pressure values are documented in the "Phase" section. The maintenance of the vacuum and the permitted alteration in pressure are listed (see "Application technology, Vacuum test" for more information).

The critical target and actual values are summarized, depending on the program, in the last section of the report. The actual values are given as minimum and maximum values (Min./Max.).

The end of every report is indicated by the words "End of report".

Example program: Vacuum test

```
=======================================
Miele PS 1201B
=======================================
Serial number:      111500014
software version:   T2.2
Language:           english
Programme:          Vacuum test
Batch number:       389
Start:              09:40:57 17-02-2011
Stop:               10:04:13 17-02-2011
Result:             VACUUM OK
Error code:         No error
=======================================
Phases
=======================================
Stabilisation: Start
07:26Min:Sec       2.5kPa
Vacuum test: Start
12:25Min:Sec       2.6kPa
Vacuum test: End
22:22Min:Sec       2.5kPa
Vacuum test: Pressure variation
-0.1kPa
Permitted pressure variation
 1.3kPa
=======================================
End of report
=======================================
```

Please store all printouts or electronic process documentation software files of tests and sterilization programs carried out carefully.

The report printer will provide the print-outs as shown in this manual.

Process documentation

Reports can be digitally archived using process documentation software (Segosoft Miele Edition). The software also documents temperature and pressure curves during the entire process sequence.

Temperature and pressure curves cannot be documented via a USB stick.

The steam-sterilizer is manufactured with the greatest care and precision. Despite this, errors during operation can occur in isolated cases.

Messages

– Hardware error:

  Error codes 9000 to 9026

If a hardware error occurs, please make a note of the number in the display and switch off the sterilizer.
Inform the Miele Service department and leave the machine switched off until a technician arrives.

– Process error:

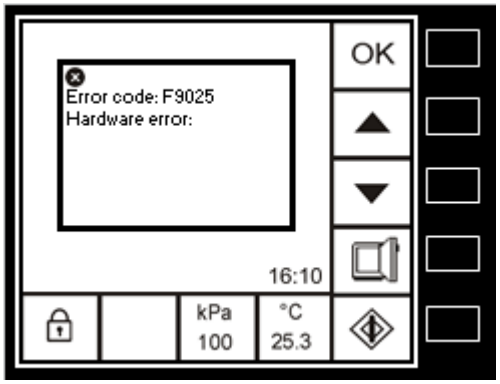
  Error codes 9027 to 9041

– Notes

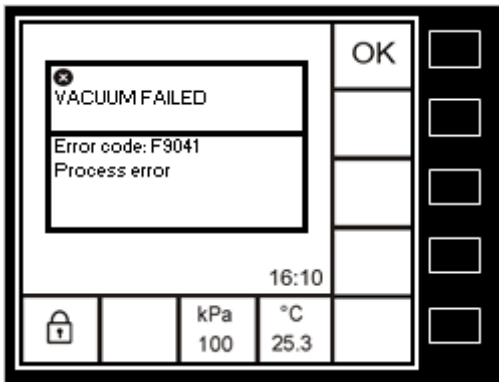
Errors or instructions are displayed as an error code and/or in clear text. Instructions are indicated by an exclamation mark "!" and errors by an "X".

Make a note of the error code or text and check whether it is a hardware error, a process error or an instruction.

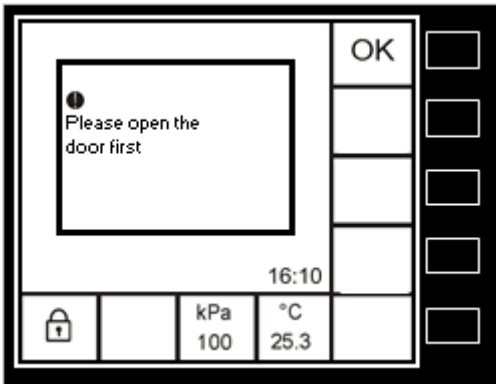
Example of a hardware error code:



Example of a process error code:



Example of an instruction:



"System not ready" message

This message will appear if a problem occurs during data transfer or the data cable is removed too early. Proceed as follows if this message appears:

- Switch the machine off at the mains switch.
- Disconnect the data cable and check it.
- Reconnect the data cable to the sterilizer.
- Close the Segosoft program on the computer.
- Switch on the sterilizer.
- Start the Segosoft program.

If reports are missing after following this procedure, confirm the "Print reports" command.

Steps to take after an error message has appeared

– Delete the message (errors and instructions)

  Press the OK button at the end of the program. The error message will go out and you will return to the main menu.

– Check the batch

  Remove an item and check it for visible moisture. Label the item as "Unsterile". Check the load. The sterilizer may have been overloaded.

– Measures required

  Test the machine using a vacuum test and then carry out a Helix or Bowie-Dick test. If both programs run without any problems, reload the item, making sure that the maximum load is not exceeded and repeat the sterilization cycle.

If the error occurs again, switch the machine off at the mains electricity supply and inform the Miele Service Department.

Service instruction

A spanner symbol will appear in the display to indicate that the sterilizer is due to be serviced.

Service required!

Either 12 months have elapsed or 2000 cycles have been run since the last service.

Please contact the Miele Service Department to arrange a service visit.

Hardware error:

Error code	Problem	Cause
F9000	**Hardware error**	The output voltage of the 1N1/10 power unit is too low.
F9001	**Hardware error**	The control unit did not recognize demineralized water valve 20Y63.
F9002	**Hardware error**	The control unit did not recognize steam inlet valve 1Y24.
F9003	**Hardware error**	The control unit did not recognize ejector valve 1Y27.
F9004	**Hardware error**	The control unit did not recognize ventilation valve 1Y54.
F9005	**Hardware error**	The control unit did not recognize vacuum valve 1Y68.
F9006	**Hardware error**	The pressure in the pressure chamber is too high.
F9007	**Hardware error**	The water tank level low float switch 1B1/14 has been activated. The WPS water inlet valve 1Y40 or the mechanical float switch in the water tank is closed.
F9008	**Hardware error**	The control unit did not recognize demineralised water pump 1M7.
F9009	**Hardware error**	The control unit did not recognize relay 1K12.
F9010	**Hardware error**	The control unit did not recognize inner chamber pressure measuring transducer 2B9.
F9011	**Hardware error**	The control unit is indicating that inner chamber pressure measuring transducer 2B9 is at the maximum value.
F9012	**Hardware error**	The control unit did not recognize outer wall pressure measuring transducer 1B9.
F9013	**Hardware error**	The control unit is indicating that outer wall pressure measuring transducer 1B9 is at the maximum value.
F9014	**Hardware error**	The control unit is indicating that inner chamber temperature sensor 1R30 (PT 100) is not functioning correctly.

Error messages and instructions

Error code	Problem	Cause
F9015	**Hardware error**	The door did not close as specified or the water intake temperature is too high.
F9016	**Hardware error**	The control unit did not recognize door motor 1M19.
F9017	**Hardware error**	Pressure in the jacket is too high. Outer wall pressure measuring transducer 1B9 has reached the maximum pressure.
F9018	**Hardware error**	Filling the jacket with demineralized water has taken too long.
F9019	**Hardware error**	The water level in the jacket is too low.
F9020	**Hardware error**	There is a transmission problem between control unit 1N1 and circuit board 2N1 for controlling the immersion heater element.
F9021	**Hardware error**	Current consumption in heating element 1 1R25 and heating element 2 2R25 is too high.
F9022	**Hardware error**	Heating circuit board 2N1 has too high a temperature.
F9023	**Hardware error**	Heating elelment 1 1R25 or heating element 2 2R25 is faulty.
F9024	**Hardware error**	The heater element control unit is faulty.
F9025	**Hardware error**	The water tank level low float switch 1B1/14 is activated. Water is not getting into the tank.
F9026	**Hardware error**	Control unit 1N1 is too hot to function safely.

Process error

CODE	Problem	Possible cause and remedy
F9027	**Process error**	Phase 2. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9028	**Process error**	Phase 3. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is securely locked. ■ Check whether the jacket is under a pressure of +230 kPa (the manometer is located behind the service panel). ■ Check whether there is water on the floor of the pressure chamber.
F9029	**Process error**	Phase 4. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9030	**Process error**	Phase 5. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly. ■ Check whether the jacket is under a pressure of +230 kPa (the manometer is located behind the service panel).

Error messages and instructions

CODE	Problem	Possible cause and remedy
F9031	**Process error**	Phase 6. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9032	**Process error**	Phase 7. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly. ■ Check whether the jacket is under a pressure of +230 kPa (the manometer is located behind the service panel).
F9033	**Process error**	Phase 8. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9034	**Process error**	Phase 9. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly. ■ Check whether the jacket is under a pressure of +230 kPa (the manometer is located behind the service panel).

CODE	Problem	Possible cause and remedy
F9035	**Process error**	Phase 10. Pressure, vacuum not achieved in the pressure chamber. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9036	**Process error**	Pressure not achieved in the sterilization phase. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly. ■ Check whether the jacket is under a pressure of +230 kPa (the manometer is located behind the service panel).
F9037	**Process error**	There is an impermissible deviance between pressure and temperature in the pressure chamber. ■ Contact the Miele Service Department.
F9038	**Process error**	Pressure of 10 kPa (vacuum) was not achieved during the drying phase. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9039	**Process error**	A rise in pressure of 10 kPa per 10 minutes was exceeded during the drying phase. ■ Check whether the load is too large or heavy. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.
F9040	**Process error**	The process was cancelled by the operator. ■ This is not a fault.

Error messages and instructions

CODE	Problem	Possible cause and remedy
F9041	**Process error**	A rise in pressure of 1.3 kPa per 10 minutes was exceeded during the vacuum test. The test was cancelled. ■ Check whether there is water on the floor of the pressure chamber. ■ Check whether the door seal is damaged. ■ Check whether the door is closed properly.

General errors

Problem	Possible cause and remedy
You cannot switch the sterilizer on.	The connector plug at the rear of the machine is not inserted correctly. ■ Insert the connector plug correctly.
	The mains connection cable is not connected properly. ■ Check the connector plug on the sterilizer. ■ Check the plug in the on-site socket.
	There is no power supply to the on-site socket. ■ Check the fuse for the on-site wall socket.
Water is leaking out of the sterilizer.	There is a leak in the area around the door. ■ Check and clean the door seal (see "Maintenance").
	There is a leak in the machine. ■ Contact the Miele Service Department.
At the end of the cycle there is still water in the pressure chamber and / or the load is still wet.	The sterilizer is not level. ■ The machine must be placed on an even surface. Realign it.
	The chamber is overloaded. There are too many items to be sterilized in the pressure chamber. ■ Please observe the instruction on the maximum load in "Application technology".
	The items to be sterilized have been loaded incorrectly. ■ Please observe the instructions on loading in "Application technology".
Oxidation or stains on the surface of instruments.	There were organic and / or chemical deposits on the instruments. ■ Thoroughly clean, rinse, disinfect and dry all the items to be sterilized before sterilizing them. Check the sequence of operations work flow.
	Different materials have been touching each other. ■ Wrap or bag instruments according to type of metal (aluminium, unalloyed steel, stainless steel, etc.).
	Limescale in the sterilizer pressure chamber. ■ Clean the sterilizer pressure chamber. Arrange for a service technician to test the water processing in the machine (reverse osmosis) (see "Maintenance").
Instruments have become discoloured and are brown or black.	Incorrect choice of program ■ Please follow the instrument manufacturer's instructions.

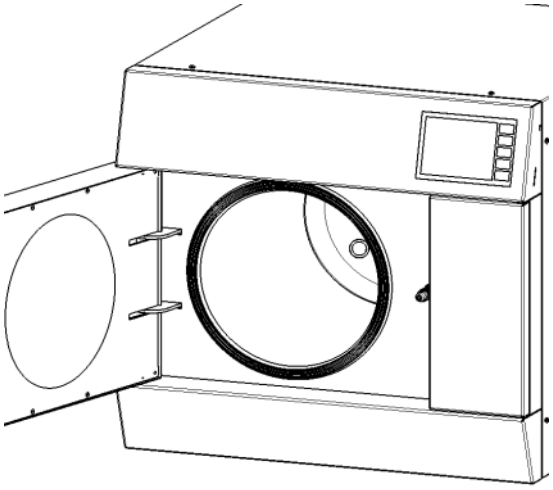
Ensure that the sterilizer is disconnected from the mains electricity supply and has cooled down before starting any routine checks or maintenance work.

Routine checks

With the pressure chamber door open, check if there is any residual condensate (water) present in the pressure chamber. If necessary, remove residual condensate with a dry cloth. Take the trays and rack out of the chamber to do this. Place the rack only back in the chamber and close the pressure chamber door.

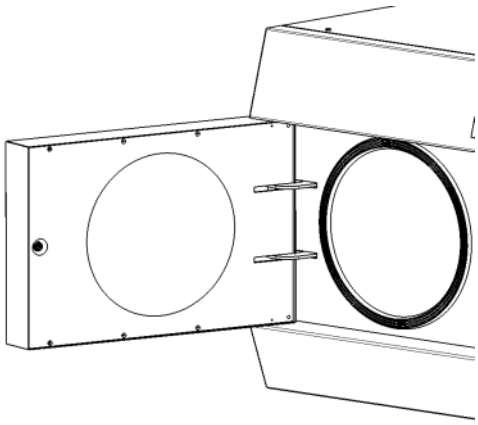
To ensure safe operation day after day the following routine checks must be carried out by the operator:

Visual check of the door seal (pressure chamber seal)



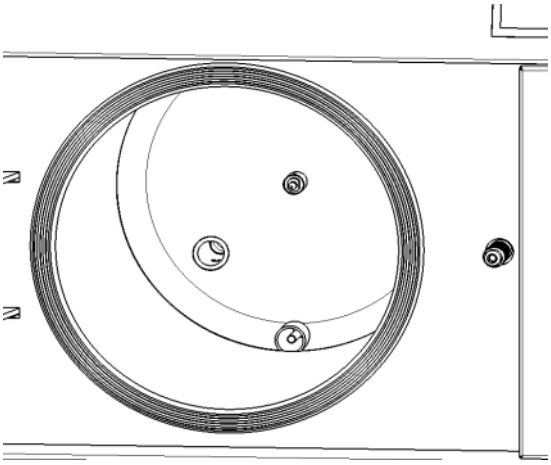
- Check for any deposits and if necessary clean with a soft cotton cloth. Do not remove the seal from the groove when doing this.
- Check that the seal is sitting correctly in the groove after every 50 cycles or at least once a month. If necessary, press the seal carefully and evenly back into its groove.
- Replace the door seal annually (see "Maintenance carried out by the operator").

Visual check of the inner door panel (pressure chamber door)



- Check for deposits and if necessary, clean carefully with a sponge and clean water. Avoid using any sharp utensils which could cause deep scratches. Then dry the door with a soft cotton cloth.

Visual check of the interior of the chamber (pressure chamber)



- Remove the trays from the rack and check the pressure chamber for any foreign objects or debris. Remove these.
- After 50 cycles or at least once a month, check the chamber for signs of corrosion. Clean the pressure chamber if necessary.

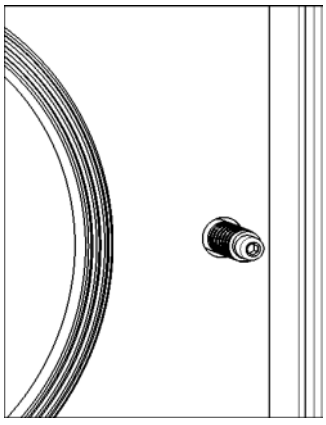
- To do this remove the interior rack and clean the chamber carefully with a sponge and clean water. Avoid using any sharp utensils which could cause deep scratches.

⚠ Continuous corrosion caused by debris can damage the pressure chamber. This type of damage is not covered by the guarantee or service contract. After cleaning the pressure chamber properly, wipe it with a dry cotton cloth to remove any traces of water. Replace the interior rack after cleaning.

Monitor the sterile air intake filter

- Open the service panel on the front of the machine. Check whether the filter is free of dust. The sterile air intake filter should be changed every 6 months or after 400 cycles (see "Maintenance to be carried out by the operator").

Monitor the door spindle



- Check the door spindle regularly. The spindle should always be lightly lubricated. Only use special lubricant ZS 173.
- Re-lubricate the spindle at least every 4 weeks.
- Wear a rubber glove. Place a pea sized amount of lubricant on your index finger and rub this into the threads of the door spindle.
- Now open and close the pressure chamber door twice. Remove any superfluous lubricant with a soft cloth. When doing this be careful not to remove the lubricant from the threads of the spindle.

Document each inspection of the steam-sterilizer. See the relevant document in "Appendix".

Maintenance to be carried out by the operator

The following maintenance can be carried out by the operator:

Replace the sterile air intake filter

- Open the service panel on the front of the machine. Turn the air filter anti-clockwise to remove it. Insert a new air filter and move it gently clockwise into position.

⚠ Make sure that the filter is positioned correctly. Do not overtighten it.
The sterile air filter must not be rotated. Once removed, it must always be replaced with a new sterile air filter.

Replace the door seal

- The door seal needs to be replaced after 2,000 cycles or at least once a year. Open the pressure chamber door. Pull the door seal out of its groove. Do not use any sharp utensils which could damage the seal. Use a sponge and clean water to carefully remove any deposits from the groove before fitting a new seal. Avoid using any sharp utensils which could cause scratches. After cleaning, wipe the groove with a soft cotton cloth. Now fit the new seal. Make sure that it goes on smoothly without any ridges.

⚠ Caution. The steam-sterilizer can be hot. Put on temperature resistant gloves before starting to replace the door seal or replace it when the machine is cold.

Do not use any sharp utensils to fit the seal as these could damage it.

- Close the pressure chamber door and carry out a vacuum test. If the vacuum test is not completed successfully, check that the seal fits properly and then repeat the vacuum test.

Document all maintenance work on the steam-sterilizer. See the relevant document in "Appendix".

Cleaning the pressure chamber

Please observe the following safety instructions with regard to cleaning:

- During operation the walls of the pressure chamber can reach temperatures of up to 140 °C. Before starting to clean the chamber, ensure that the sterilizer has cooled down. This is important to prevent the risk of burning and also irritation of the respiratory tract. The risk of inhaling any harmful gases which could be created by the cleaning agent evaporating will also be avoided.
- Observe manufacturers' instructions on the use of cleaning agents (protective clothing, goggles, gloves, etc.).
- Do not allow cleaning agent to come into contact with plastic parts (e.g. the door seal).
- Seal off the chamber drain in order to protect the pipework, valves and pump.
- Only use soft and lintfree cloths for cleaning purposes.
- Scouring agents can be used to remove localised deposits. Apply scouring cream with a soft cloth and rinse with copious amounts of demineralized water (<15 µS/cm). Scouring agents should not be used on a large scale.
- After cleaning, always rinse surfaces liberally with demineralized water. Rinse water should not be allowed to enter the pipework. When using acidic agents or cleaning agents containing acids, check

the pH value on the internal walls of the chamber after cleaning (this should ideally be between 6 and 7).

- After cleaning carry out a Helix-B&D test with the chamber empty.
- Use a neutral liquid cleaning agent to clean the door seal.
- Do not use any hard metal implements such as metal pot scourers or steel brushes.

Failure to observe this instruction could cause scratches and damage on the surfaces being cleaned, damage the sealing surface and cause it to leak. This would promote dirt deposits and corrosion in the pressure chamber.

Observe the following instructions when cleaning the pressure chamber:

- Switch the sterilizer off before cleaning (door in the open position).
- Disconnect the machine from the electricity supply.
- Allow the chamber to cool down to room temperature.
- Wipe the surfaces with a lintfree cloth which has been dampened with demineralized water.
- Use demineralized water to make solutions of cleaning agent.
- When carrying out cleaning, always wear the protective clothing prescribed by employers for such tasks.
- Do not use cleaning agent solutions containing chlorides, hydrochloric acid or flammable substances.

Cleaning the outer casing

- Use a soft cotton cloth to clean the casing.
- Clean the casing with a neutral liquid cleaning agent.
- Do not use cleaning agent solutions containing chlorides, hydrochloric acid or flammable substances.

Contact with solutions or steam containing acid or alkali can damage the surfaces.

Inspection and service by the manufacturer

The manufacturer must carry out an inspection/maintenance after 2000 cycles or at least once a year. This preventative service is carried out in accordance with a maintenance schedule and is documented accordingly.

The manufacturer must carry out an extended inspection/maintenance after 4000 cycles or at least every three years. This extended service is carried out in accordance with a maintenance schedule and is documented accordingly.

The Miele service technician will inform you of any maintenance/repairs which are necessary before beginning any work or repairs.

Please arrange for a service visit in good time so that you can plan for machine down-time on the day of the service.

Regular servicing of your steam-sterilizer will increase its availability by avoiding unforeseen problems.

Maintenance - annual service

Standard checks

General

– Determining the water hardness level
– Process safety tests including a test run without a load
– Safety tests including functional test of safety devices, thermometric measurement and pressure test
– Downloading and documenting of error memory and program data

Visual inspection and function of mechanical components

– Water inlet / drainage test (on-site)
– Water processing test
– Leak test of the pressure chamber and connected hoses
– Test of the doors and door lock
– Test of the pressure chamber

Visual inspection and function of electrical components

– Test of the settings / programmable functions
– Test of the heating elements
– Temperature regulation function test
– Documentation function test
– Test of the pressure sensors and pressure control valve

The following components must be replaced when the machine is serviced after 2000 cycles:

– Steam valve (piston)
– Vacuum valve (piston)

The following components must be replaced when the machine is serviced after 4000 cycles or at least every three years:

– Steam valve (piston)
– Vacuum valve (piston)
– Reverse osmosis system

Maintenance carried out by the manufacturer

Maintenance or repairs may only be carried out by Miele.

⚠ Unauthorised work and alterations carried out on the machine will invalidate the service contract or guarantee. The same applies to the use of non-original replacement or spare parts.

Document all service and maintenance work carried out on the steam-sterilizer (see "Appendix").

⚠ Repairs may only be carried out by the Miele Service Department.
Repairs and other work by unqualified persons could be dangerous.

To avoid unnecessary service call-outs, check that the fault has not been caused by incorrect operation when an error message first appears.

An overview of all error messages that can appear in the display are given in "Error messages and instructions".

If, having followed the advice in the operating instruction manual, you are still unable to resolve a problem please call the Miele Service Department (see the end of this booklet for contact details).

Please quote the model and serial number of your sterilizer.

You will find these on the data plate on the inside of the service panel.

Technical data

Ambient conditions	
Permissible ambient temperature / Air humidity	+5 °C to +40 °C / 0 % - 80 %
Permissible storage temperature / Air humidity	-10 °C to +60 °C / 0 % - 80 %
Maximum height above sea level	2000 m
Minimum air pressure	80 kPa (12 psi)
Dimensions	
Maximum pressure / temperature, pressure chamber	350 kPa / 140 °C
Pressure chamber (diameter x length)	Ø 250 mm x 400 mm
Pressure chamber volume	20 l
Cabinet, external dimensions (L x W x H)	620 mm x 565 mm x 542 mm
Weight when empty (with jacket and water tank filled)	73 kg
Capacity	
Large instrument cassettes (LxWxH) 204x280x32 mm	3
or Small instrument cassettes (LxWxH) 204x140x32 mm	6
or Exam cassettes (LxWxH) 204x76x32 mm	9
or Oral surgery cassettes (LxWxH) 204x368x32 mm	2
or trays (ZS 131) to sterilize pouches (LxWxH) 285x184x20 mm	3
Unwrapped instruments	max. 6 kg
Wrapped instruments	Max. 6 kg including instruments, cassettes, packaging
Textiles and bindings	Max. 2 kg including packaging
Maximum weight individual item	0.5 kg
Cycle duration (with load)	
121 °C Universal cycle duration	Approx. 34 mins / cycle
134 °C Universal cycle duration	Approx. 22 mins / cycle
134 °C Prions cycle duration	Approx. 36 mins / cycle
134 °C Unwrapped cycle duration	Approx. 12 mins / cycle

Holding time	
121 °C Universal	Approx. 16 mins
134 °C Universal	Approx. 4 mins
134 °C Prions	Approx. 18 mins
134 °C Unwrapped	Approx. 4 mins
Consumption data	
Energy consumption	0.5 - 0.65 kWh / cycle
Demineralized water	0.33 l / cycle
Emissions	
Maximum heat output	3000 kJ / h
Sound power level (EN ISO 3746)	< 70 dB(A) re 1pW
Electrical data	
Total connected load	3200 W
Current draw	15 A
Fuse rating	20 A (surge-proof)
Voltage	208 VAC (+/- 6 %)
Frequency	60 Hz
Protection	IP 20
Overvoltage category	II
Pollution level	2
Water inlet connection	
Threaded union	3/4" internal thread
Length of inlet hose with WPS	1.50 m
Drain hose	
Connection / Pipe coupling	22.5 mm
Length of drain hose	1.50 m
Other	
Serial interface	RS 232

Technical data

Water quality

The steam-sterilizer PS 120xB has an integrated reverse osmosis unit. This generates demineralized water to supply the steam generator. It is important to ensure that the mains water meets the following quality requirements:

Mains water temperature	Max. 25 °C
Mains water pressure	150 - 1000 kPa (22 - 145 psi)
Mains water conductivity level	375 µS / cm*

*) The integrated reverse osmosis unit can guarantee a demineralized water conductivity level of max. 15 µS/cm for up to this mains water conductivity level. An ion exchanger (ZS135) may also be necessary if the conductivity is above 375 µS / cm.

Using water containing sediment, particulate matter etc. or water with a high mineral content will reduce the performance and useful life of the reverse osmosis unit.

Optional extras for the steam-sterilizer are available to order from Miele:

– ZS 111 rack
– ZS 131 tray
– Segosoft Miele Edition process documentation software
– PRT 100 report printer
– ZS 135 ion exchanger LC 117 (Set)

The following consumables and parts which are subject to wear and tear are also available:

– ZS 150-1 Helix test
– ZS 171 door seal
– ZS 172 Sterile air intake filter
– ZS 173 Special spindle lubricant
– Micronfilter 0,2µm for ophthalmic applications

Disposing of your old appliance

Please contact Miele Service to arrange for the technical decommissioning of the sterilizer and for it to be disposed of in accordance with regulations.

Old electrical and electronic equipment often still contain valuable materials. However, they may also include harmful substances that were essential for proper functioning and safe use. Improperly disposing of these items in your household waste can be harmful to your health and the environment. Therefore, please do not dispose of your old appliance in your regular household waste.

Instead, use your local community waste collection and recycling centre for electric and electronic appliances.

If the appliance is being stored prior to disposal, please make sure it is child-proof.

Templates for documenting various processes are shown on the following pages. If you do not have process documentation software available, the templates can be copied for your own use.

Templates:

– Documentation of sterilization cycles

– Maintenance to be carried out by the operator

– Log book for services and repairs

– Daily checks

Make sure you make enough copies of the original. Fill out the top part of the copied document in print that is easy to read. All the other columns and rows should be filled out by the appropriate persons so that they can be read easily. Store the documents in a safe place. After any service and maintenance work is carried out, ensure that the service technician makes the appropriate entry in the "Log book" document.

By using documentation software you can optimise the organisational process in your practice and ensure that sterilization processes are securely documented and archived. Please contact Miele for more detailed information. See also "Optional extras".

Appendix

Documentation of sterilization cycles

Operator:.....(Op. No.=1) Operator:.....(Op. No.=2)

Operator:.....(Op. No.=3) Operator:.....(Op. No.=4)

Steam-sterilizer model number:..... Serial number:.....

Date	Batch number	Op. No.	Program	Notes / Indicator	Batch released or Test passed	Signature

Documentation of sterilization processes, maintenance and service work can be documented electronically using Segosoft Miele Edition documentation software.

Maintenance to be carried out by the operator

Operator:.....(Op. No.=1) Operator:.....(Op. No.=2)

Operator:.....(Op. No.=3) Operator:.....(Op. No.=4)

Steam-sterilizer model number:..... Serial number:.....

Date	Batch number	Op. No.	1. Sterile air intake filter replaced 2. Door seal replaced 3. Door spindle lubricated	Signature

Documentation of sterilization processes, maintenance and service work can be documented electronically using Segosoft Miele Edition documentation software.

Appendix

Log book

Steam-sterilizer model number:..... Serial number:.....

Date	Batch number	Service technician	Content of service/maintenance/ repairs carried out. See Report No.:	Signature

Documentation of sterilization processes, maintenance and service work can be documented electronically using Segosoft Miele Edition documentation software.

Daily checks

To ensure safe operation day after day the following routine checks must be carried out by the operator and recorded in the following chart:

– Visual check of the door seal (pressure chamber seal)

  Check for any deposits and if necessary clean with a soft cotton cloth. Do not remove the seal from the groove when doing this.

  Check that the seal is sitting correctly in the groove after every 50 cycles or at least once a month. If necessary, press the seal carefully and evenly back into its groove.

  The door seal must be replaced annually. See "Maintenance to be carried out by the operator" in the operating instructions.

– Visual check of the inner door panel (pressure chamber door)

  Check for deposits and if necessary, clean carefully with a sponge and clean water. Avoid using any sharp utensils which could cause deep scratches. Then dry the door with a soft cotton cloth.

– Visual check of the interior of the chamber (pressure chamber)

  Remove the trays from the rack and check the pressure chamber for any foreign objects or debris. Remove these.

  After 50 cycles or at least once a month check the chamber for signs of corrosion. Clean the pressure chamber where necessary. Remove the interior fittings from the chamber and then clean the chamber carefully with a sponge and clean water. Avoid using any sharp utensils which could cause deep scratches. Continuous corrosion caused by foreign objects or debris can damage the pressure chamber. This type of damage is not covered by the guarantee or service contract. After cleaning the pressure chamber properly wipe it with a dry cotton cloth to remove any residual water.

– Deposits/foreign objects in the pressure chamber

– Visual inspection of the door spindle (lock)

  Check the door spindle regularly. The spindle should always be lightly lubricated. Re-lubricate the spindle at least every 4 weeks. Only use special lubricant ZS 173. Wear a rubber glove. Place a pea sized amount of lubricant on your index finger and rub this into the threads of the door spindle.

– Monitor the sterile air intake filter

  Open the service panel on the front of the machine. Check whether the filter is free of dust. The sterile air intake filter should be changed every 6 months or after 400 cycles (see "Maintenance to be carried out by the operator").

– Helix/B&D test

  This program is used to test that steam penetration is efficient and to test the performance of the machine in order to ensure that hollow and porous materials are sterilized effectively. It should be carried out daily (please note manufacturer instructions on the various tests). If this test is passed, it can be presumed that all process parameters are correct and the basic technical prerequisites for safe sterilization have been met.

– Vacuum test

  This program is used to test the whole system for leaks. It should be performed once a week. A passed test indicates that the system does not leak and that the technical precondition for safe sterilization has been assured.

– Biological indicator

  According to “CSA Z314.3-09 Effective sterilization in health care facilities by using the steam process” the sterilization process is monitored once a day with a biological indicator. Biological indicators consist of spores on a carrier plus incubation media. After sterilization the biological indicators are incubated to define whether or not micro-organism survived the sterilization process. For proper use please refer to biological indicator manufacturer’s user manual.

Operator:.....(Op. No.=1) Operator:.....(Op. No.=2)

Operator:.....(Op. No.=3) Operator:.....(Op. No.=4)

Serial number:..... Month:.....

	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
Door seal																
Inner door panel																
Chamber interior																
Pressure chamber																
Door spindle																
Sterile air intake filter																
Helix test																
Biological indicator																
Vacuum test																
Signature																
	17.	18.	19.	20.	21.	22.	23.	24.	25.	26.	27.	28.	29.	30.	31.	
Door seal																
Inner door panel																
Chamber interior																
Pressure chamber																
Door spindle																
Sterile air intake filter																
Helix test																
Biological indicator																
Vacuum test																
Signature																

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M.-Nr. 09893480 / 07
Valid for software version: V2.4

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