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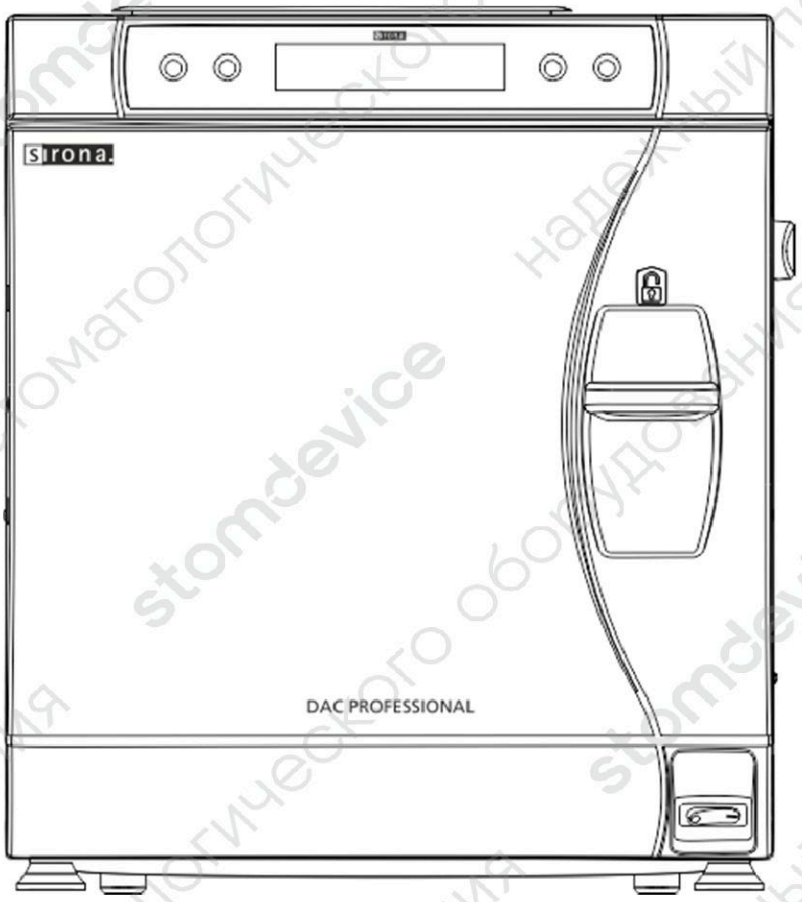
New as of: 03.2015

sirona
The Dental Company

DAC PROFESSIONAL
DAC PROFESSIONAL+

Operator Manual

English



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Dear customer

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

This autoclave was manufactured and checked in accordance with stringent quality criteria. Please read this operator manual thoroughly before using the autoclave for the first time. The functionality and value retention of your autoclave depends primarily on careful reprocessing of the instruments and the care taken with the device.

We wish you a great deal of success and enjoyment with DAC PROFESSIONAL / DAC PROFESSIONAL^{+}.

Your DAC PROFESSIONAL/ DAC PROFESSIONAL^{+} team

CE 0123

General notes

Please read this instruction manual before using the device for the first time. The manual includes important safety information. The functionality and value retention of your device depends on the care accorded to it.

Keep this instruction manual in a safe place near your device. It is a part of the product.

User Group

This manual is targeted at doctors, medical assistants and service.

Scope

This manual applies to the DAC PROFESSIONAL/ DAC PROFESSIONAL^{+} autoclaves.

About this manual

Symbols used

Symbol	Explanation
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Indicates a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Inidcates important information.

Formatting rules

Symbol	Explanation
`Universal Program`	Words or groups of words that appear on the display of the autoclave are identified as software quotes
Chapter 6 – Logging	Reference to another text section within these instructions.
Figure 1/5	Reference to a detail in a figure—in the example given, the reference is to part no. 5 in Figure 1.

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Symbols on the device

Symbol	Explanation
	The symbol of a crossed-out wheeled bin is used for a device that must not be disposed of in household waste. It must be sent for expert and proper disposal by the seller of the device. By labeling a device with this symbol, the manufacturer also declares that it has met all legal requirements for the device regarding selling, accepting returns, and environmentally friendly disposal of electrical and electronic equipment.
CE 0123	By labeling the device with this CE mark, the manufacturer declares that the medical device meets the essential requirements of the Medical Device Directive. The four-digit number indicates that an approved certification office monitors this compliance.
CE 0035	By labeling the device with this CE mark, the manufacturer declares that the medical device meets the essential requirements of the Pressure Equipment Directive. The four-digit number indicates that an approved certification office monitors this compliance.

Scope of delivery

Standard scope of delivery

- DAC PROFESSIONAL / DAC PROFESSIONAL^{+}
- Instruction sheet for downloading the technical documentation
- Factory test results
- Declaration of conformity with Medical Device Directive
- Declaration of conformity with Pressure Equipment Directive
- Rack for trays or cassettes
- Tray lifter
- 1 hose to drain the internal water storage tank
- 1 TORX key to remove the carrying strap
- 1 lever for emergency locking of the door
- 1 key for the sterilization chamber filter
- 2 replacement fuses on the inner door of the autoclave

Optional

- Trays
- Standard tray cassettes and lifter
- Additional racks

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⚠Safety Instructions

When operating the autoclave, please observe the following safety instructions as well as those contained in subsequent chapters.

Only use the device for the purpose stated in the instruction manual.

- Do not use this autoclave to sterilize any liquids.

Power cables and power plug

- Never damage or change power cables or power plugs.
- Never operate the autoclave if the power cable or power plug are damaged.
- Never pull on the power cable to remove the power plug from the socket. Always hold the power plug itself.

Setting up, installing, starting up

- Ensure the setting up, installation and initial start-up of the autoclave is only done by persons authorized by Sirona.
- The electrical connection and the connections to the feed and waste water must only be carried out by a skilled technician.
- In accordance with current VDE specifications, the autoclave is unsuitable for operation in areas exposed to the danger of explosion.
- The autoclave is conceived for use outside the patient environment. The device should be located a minimum of 1.5 m radius away from the treatment area.
- Observe all the information contained in the service handbook for the initial start-up.

⚠ **DANGER!**

Failure to comply with the set-up conditions can result in malfunctions or damage to the autoclave and/or human injury.

Preparation and sterilization

- Follow the instructions of the manufacturer of the textiles and instruments for preparing and sterilizing the textiles and instruments.
- Follow the relevant standards and directives for the preparation and sterilization of textiles and instruments, e.g., from Robert Koch Institute and the German Association for Supply of Sterile Goods (DGSV).
- Only use wrapping materials and systems that are suitable for steam sterilization according to the manufacturer.

Program terminated

- Note that when opening the door after a program is terminated, depending on when the program was interrupted, hot steam may escape from the sterilization chamber.
- Depending on when the program was terminated, the load may not be sterile. Follow the clear instructions on the display of the autoclave. If necessary, sterilize the affected load again after rewrapping the items.

Removing the sterilized load

- Never open the door with force.
- Use a tray lifter to remove the trays. Never touch the sterilized items, the sterilization chamber or the door with unprotected hands. These parts are hot.
- Check the wrapping of the sterilized items for any damage when removing them from the autoclave. If the wrapping is damaged, rewrap the item to be sterilized and sterilize it again.

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Maintenance

- Maintenance must only be carried out by authorized persons.

Carrying the autoclave

- The autoclave must only be carried by two persons.
- Use the supplied carrying belt to carry the autoclave.

Malfunctions

- If error messages occur repeatedly during operation of the autoclave, shut down the autoclave and inform your specialist supplier.
- The autoclave may only be repaired by authorized persons.

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Chapter 1 – Device description

Intended Use

The autoclave is designed for application in a medical context, e.g., hospitals and medical and dental practices. According to DIN EN 13060, this autoclave is a class B sterilizer. As a universal autoclave it is suitable for demanding sterilization tasks. You can, for example, sterilize narrow-bore instruments and handpieces — wrapped or unwrapped — and large quantities of textiles.

DANGER!

When sterilizing liquids, boiling can be retarded which may lead to damage to the autoclave and burns.

- Do not sterilize liquids with this autoclave. It is not approved for the sterilization of liquids.

WARNING

Failure to comply with the safety information can lead to damage and/or safety hazards.

- Only use the autoclave for the intended applications described in the accompanying technical documents and only together with the devices and components recommended by Sirona.
- As with the preceding instrument preparation, sterilization of instruments and textiles with this autoclave may also only be carried out by competent personnel as defined in §2 of the German Medical Device Operators Ordinance.
- Only use instruments, wrapping, and textiles for sterilization that are suitable for steam sterilization according to the manufacturer.

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Views of the device

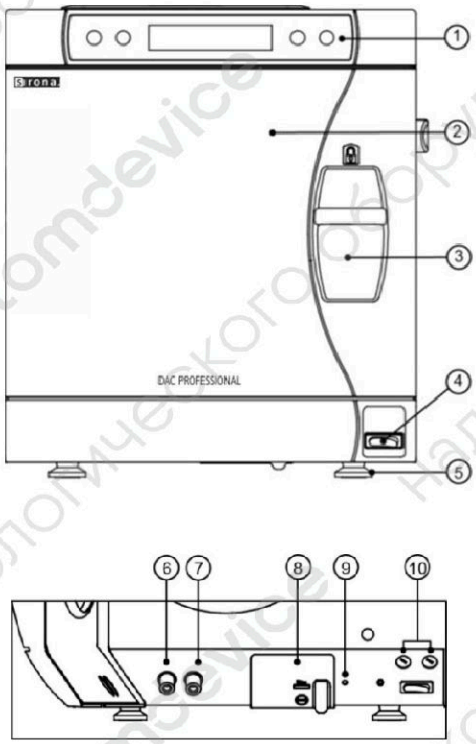


Fig. 1: Views of the front of the device

1. Control and display panel
2. Door, pivots open to the left
3. Sliding latch
4. Power switch
5. Front foot of the autoclave (adjustable)
6. Port for emptying the internal water storage tank—waste water
7. Port for emptying the internal water storage tank—feed water
8. Serial data and printer connection (RS232)*
9. Reset key for overheat protection
10. Autoclave fuses—2× 16 A / gRL

*covered by white panel

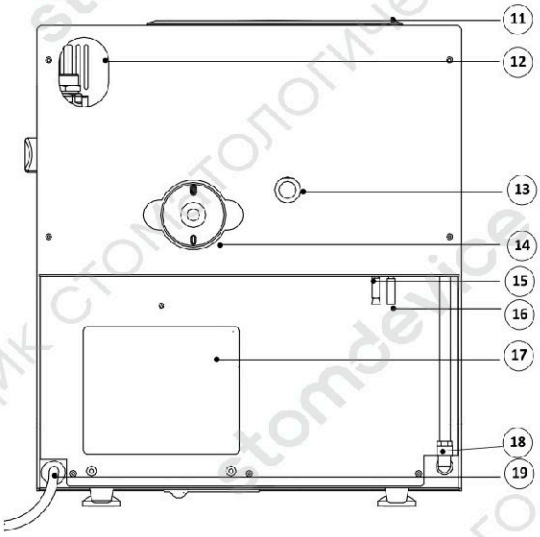


Fig. 2: Views of the back of the device

11. Tank cap
12. Elongated hole for optional fitting with the safety combination EN1717
13. Spring-loaded safety valve
14. Sterile filter
15. One-way drain (optional)
16. Emergency overflow hose
17. Cooler
18. Feed water inlet for water preparation unit
19. Power cable



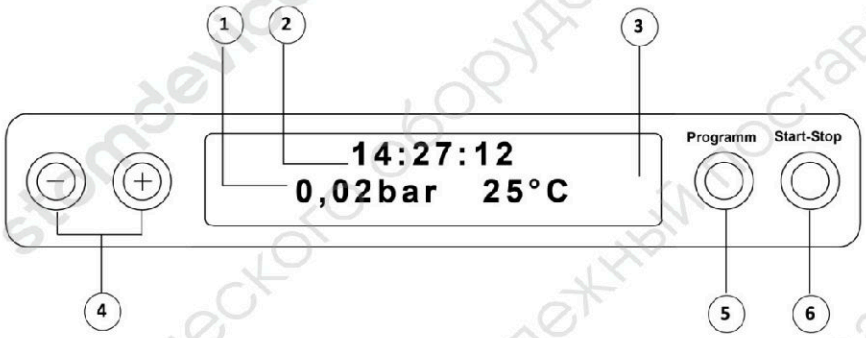
Fig. 3: Internal view

1. Rack to hold trays / cassettes
2. Chamber
3. Door lock pin
4. Door port
5. Door seal

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Control panel

The control panel is made up of a two-line alphanumeric LED display and four membrane keys.



1. Chamber pressure (bar) and (steam) temperature (°C)
2. Time (h:min:s)
3. **2-line LC display**
   for program status indicators and parameter indicators
4. **Function keys (-) and (+)**
   For selecting, setting, and displaying special functions:
   printing, date / time, preheating, total number of sterilized batches, water conductivity, error message acknowledgement, (+) key to unlock the door.
5. **Program selection keys (P)**
   For selecting the sterilization and test programs and
   for selecting/setting options
   (submenus) for the special functions.
6. **Start/stop key (S)**
   For starting and stopping programs, for drying, and to control special functions.

Default setting

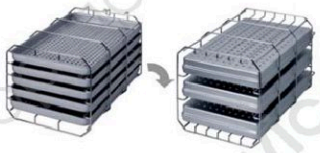
The display switches to the initial operating state each time the autoclave is switched; the initial operating state shows the current time and the chamber pressure in bar and the (steam) temperature in °C.

Racks for loading

Rack

The autoclave is always supplied with a rack for holding trays or cassettes.

Rack (A) is standard and can hold either five trays or, when rotated by 90°, three standard tray cassettes.



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Chapter 2 – Installation

NOTE
Please carefully follow the instructions for the installation given in the service manual. All requirements for the building installation are listed in detail in the service manual.

Electrical connections

DANGER!

Improperly made electrical connections can lead to a short circuit, fire, water damage, and/or electric shock.

Severe injuries may result.

- The electrical connection and the connections to the feed and waste water must only be carried out by a licensed electrician or plumber respectively.
- Also note the information regarding the installation and initial start-up in the service manual.

Please comply with the following precautionary measures when handling power cables and power plugs.

- Never splice or modify the power cable.
- Never bend or twist the power cable.
- Always hold the power plug itself to remove it from the power plug.
- Do not place heavy objects on the power cable.
- Ensure that the power cable is not compressed (e.g., between doors or windows).
- Do not place the power cable in front a heat source.
- Do not use any nails, staplers or similar objects to fix a cable.
- Should the power cable or the power plug be damaged, shut the autoclave down. The power cable or power plug may only be replaced by authorized persons.
- Failure to comply with this precaution can lead to damage to the cable or to the plug and/or to fire or an electric shock. Severe injuries may result.

Feed water connection

For steam sterilization, the use of distilled or demineralized water, referred to as feed water, is required. The DIN EN 13060 intends that feed water in accordance with the recommended values in Annex C is used. The feed water is supplied either via the internal water storage tank or via a separate water treatment unit; see **Chapter 3 – First steps**. Detailed information about the connection to a water treatment unit can be found in the service manual.

Waste water connection

The waste water can either be collected in the internal water storage tank on the waste water side (left) and manually drained or automatically drained via the one-way drain. To connect the autoclave to the waste water, a retrofit kit can be ordered for the tank drain.

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Chapter 3 – First steps

Switch on the autoclave

The autoclave is switched on at the power switch (page 8, Fig. 1/4).

After switching the autoclave on at the power switch, the display shows the message: **`Unlock the door with "+" key,`** if the door is closed, alternating with the initial operating state.

NOTE
Immediately after switching the autoclave on for the first time and before the initial start-up, all accessory parts must be removed from the chamber.

Opening and closing the door

The door can only be opened when the message: **`Acknowledge with "+" / Unlock door with "+" key`** appears on the display.

1. Press the (+) key. After an audible click, you can open the door.
2. To close the door, press it gently against the chamber flange while pushing the sliding latch down.

Preparing the feed water

Using the internal water storage tank

If the feed water is supplied via the internal water storage tank, this must be manually filled from time to time. The autoclave displays an appropriate message when this is necessary.

The internal water storage tank holds a maximum of 5 liters. This quantity of feed water is sufficient for up to 7 sterilization cycles.

To fill the water storage tank with fresh feed water, remove the lid and fill the tank (right chamber) up to the MAX mark with fresh feed water:



Setting the feed water supply to the autoclave

To supply the feed water via the internal water storage tank, the function **`INTERNAL`** must be set. To supply the feed water via a water preparation unit, the function **`EXTERNAL`** must be set.

1. Select the **`Function`** set-up menu by pressing the (+) and (-) keys at the same time. The display shows the message **`Function: Last batch no.`**
2. Navigate to the message: **`Function: Feed water supply`** on the display using the (+) or (-) keys.
3. Press the (P) key. The display shows the currently selected option.
4. Press the (P) key again to change to the desired setting (**`INTERNAL/EXTERNAL`**).
5. Press the (S) key to save the setting and exit the menu.

By pressing the (S) key again, you leave the menu completely and return to the initial operating state of the display.

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Using a water preparation unit

To use a water preparation unit, please follow the instructions in the service manual.

NOTICE

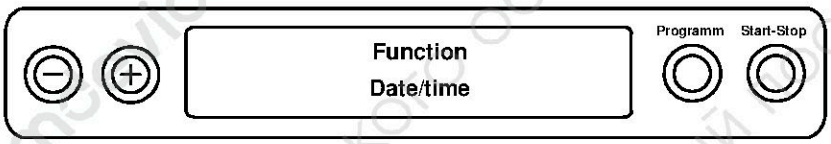
Please consult Sirona first if you would like to use a water preparation unit from another manufacturer.

Failure to comply with these instructions can damage the autoclave and/or the items to be sterilized.

Setting the date and time

For flawless batch documentation, the date and time of the autoclave must be set correctly. Please note the switch to and from daylight savings in spring and fall as this is not done automatically. Set the date and time as described below:

1. Select the **`Function`** set-up menu by pressing the (+) and (-) keys at the same time. The display shows the message **`Function: Last batch no.`**
2. Navigate in the "Function" menu using the (+) or (-) keys until you reach the message:



3. Press the (P) key to confirm. The current hour is shown.
4. Using the (+) or (-) keys, select between the following setting options: hour, minute, second, day, month, year.
5. To set the parameter "hour," for example, press the (P) key to confirm.

   The current value on the display flashes.
6. With the (+) and (-) keys, you can increase or decrease the value.
7. To save the value, confirm with the (P) key.

   The value currently set on the display no longer flashes.

   To adjust the other parameters, proceed as described above.
8. After the setting is complete, press the (S) key to leave the menu.

   The display shows the message **`Function: Date/time`**.
9. After pressing the (S) key again, you leave the menu completely and the display shows the initial operating state again.

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Chapter 4 – Sterilizing

Important information about routine operation

Please follow the current recommendations from the Robert Koch Institute (RKI) and the directions in DIN 58946-7 regarding routine operation.

Manufacturer's recommendation for routine operation of class B autoclaves

(in accordance with the current recommendations from the Robert Koch Institute)

When does testing need to be done?	How is testing done?
Once a working day	▪ Visual inspection of the door seal and the door closure for any leaks. ▪ Inspection of the operating media (electricity, feed water, water connection where applicable). ▪ Inspection of the documentation media (printer paper / computer / network). The steam penetration test with the Bowie - Dick test in the universal program is recommended (test system in accordance with EN 867-5).
Once a week	▪ Vacuum test Tip: In the mornings before starting work—the autoclave must be cold and dry.
Batch-related tests	For instruments in Critical B category: ▪ the test set Helix test should be done together with every sterilization cycle as a batch control. For instruments in Critical A category: ▪ a chemical indicator (class 5 as defined by ISO 11140) should be included together with every sterilization cycle as a batch control. For instruments in Critical A+B category: ▪ The test set Helix test should be done together with every sterilization cycle as a batch control. This simplifies the workflow and increases the reliability. A daily steam penetration test with the Bowie & Dick test (see above) can then be omitted. Another test system as defined by EN 867-5 can be used. Due to the variety of test systems available, it is not possible for Sirona to provide technical support for the use of another system.

WARNING

The results of the tests must be documented.

- The used indicator test strips themselves do not have to be stored.

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Preparing the items to be sterilized

Follow the cleaning and care instructions of the manufacturer to prepare the items to be sterilized. This is a prerequisite for both proper cleaning and disinfection and subsequent sterilization of the items to be sterilized. The materials, cleaning agents, and preparation methods used are of critical importance.

NOTE
Sterilize textiles and instruments separately if possible in separate sterilizer containers or sterilization wrap. This will achieve better drying results.

Preparing instruments

Pay attention to the following when preparing used and brand-new instruments:

- It is essential that you follow the instructions of the instrument manufacturer when preparing and sterilizing the instruments and comply with the relevant standards and directives, e.g., BGV A1, RKI, and DGSV.
- The instruments must be cleaned very thoroughly, e.g., with the help of a cleaning and disinfection unit.
- At the end of the disinfection and cleaning, rinse the instruments, preferably with demineralized or distilled water, and then thoroughly dry the instruments with a clean, lint-free cloth.
- Only use care products that are suitable for steam sterilization. Ask the manufacturer of the care product.

DANGER!
As a result of incorrect preparation of instruments any residual soiling can become loose during sterilization. Traces of disinfectant and cleaning agents lead to corrosion.

Unsuitable care agents, e.g., water-repellent care agents or oils that are impermeable to steam, can lead to non-sterile instruments. This places your health and the health of your patients at risk.

An increased need for maintenance and impaired function of the autoclave may result.

- Therefore, it is essential that you follow the preparation instructions described in this manual.

When using ultrasonic units, cleaning equipment for handpieces and turbines, and cleaning and disinfecting units, you must follow the preparation instructions of the instrument manufacturer.

Preparing textiles

When preparing textiles and when placing textiles in the sterilization containers, pay attention to the following:

- Follow the instructions of the textile manufacturer when preparing and sterilizing textiles and comply with the relevant standards and directives, e.g., from RKI and DGSV.
- Align the folds of the textiles parallel to one another.
- Stack the textiles as vertically as possible and not too close to one another in the sterilization container so that flow channels can form.
- Keep the stacks vertical when you pack the textiles into the sterilization container.
- If the textile packages do not stay together, wrap the textiles in sterilization paper.
- Only sterilize dry textiles.
- The textiles must not make direct contact with the floor and walls of the sterilization chamber because otherwise they become saturated with condensate.

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DANGER!

The penetration of steam into the washing package can be hindered and/or you obtain poor drying results. The textiles cannot be sterilized.

This could represent a risk to the health of the patient and the clinical team.

- It is therefore essential that you follow the preparation instructions in this manual.

Loading the autoclave

Effective sterilization and good drying results can only be achieved when the autoclave is loaded correctly.

You must therefore pay attention to the following during loading:

- Only place trays or cassettes with the corresponding rack into the chamber.
- Use perforated trays such as the trays from MELAG. This is the only way to ensure the condensate drains. If you use solid trays or open pans to hold the items to be sterilized, this may lead to poor drying results.
- Using tray inserts made of paper can also lead to worse drying results.

Wrapping

Only use wrapping materials and systems (sterile barrier systems) that comply with the DIN EN ISO 11607-1 standard.

The correct application of suitable wrapping is critical for the success of the sterilization.

You may use re-usable, rigid packaging such as standard tray cassettes or soft wrapping such as transparent sterilization wrap, paper bags, sterilization paper, textiles or non-woven fabric.

Closed sterilization containers

When using closed sterilization containers to hold the items to be sterilized, pay attention to the following:

- Use sterilization containers made of aluminum. Aluminum conducts and stores heat well and thus accelerates drying.
- Closed sterilization containers must have at least one side perforated—preferably on the bottom—or have vents.
- If possible, only stack sterilization containers of the same size on top of one another which allow condensate to drain on the side facing the walls.

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WARNING

Using sterilization containers that are not suitable leads to insufficient stem penetration and the sterilization may not be successful. The drainage of condensate may also be hindered.

Poor drying results are the consequence. This can ultimately lead to non-sterile instruments and thus endanger the health of patients and the clinical team.

- Closed sterilization containers must have at least one point—preferably on the bottom—with perforations or vents.

WARNING

If the sterilization containers are stacked incorrectly, the dripping condensate cannot drain to the floor of the chamber. It can saturate the items below.

Poor drying results are the consequence. Non-sterile instruments may result and these can endanger the health of patients and the clinical team.

- When stacking the containers ensure that the sterilization containers do not cover the perforation.

Soft sterilization wrapping

Soft sterilization packages can be sterilized both in sterilization containers and on trays. Pay attention to the following when using soft sterilization packages such as MELA*fol*:

- Arrange the soft sterilization packages vertically and close together.
- Do not lay several soft sterilization packages flat on top of one another on a tray or in a container.
- If a sealed seam tears during sterilization, the packaging may have been too small. If this is not the case, rewrap the instruments and sterilize them again.
- If a sealed seam tears during sterilization, use a longer sealing time on the sealer or use a double seam.

Multiple wrapping

Because the autoclave uses the fractionated pre-vacuum process, multiple wrapping can be used.

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Mixed loads

Pay attention to the following when sterilizing mixed loads:

- Always place textiles on top.
- Sterilization containers on the bottom.
- Unpacked instruments on the bottom.
- Transparent sterilization wrap and paper packages on top—the exception is when combining with textiles, then on the bottom.
- The heaviest items are on the bottom.
- Stack transparent sterilization wrapping as upright as possible so that alternating paper side is against paper side and film side against film side but if this is not possible then with the paper side facing downwards.

Loading variations	DAC PROFESSIONAL		DAC PROFESSIONAL+	
	Instruments	Textiles	Instruments	Textiles
Maximum for each individual part	2 kg	1.8 kg	2 kg	1.8 kg
Maximum total quantity	5 kg	1.8 kg	5 kg	1.8 kg
Loading variations Rack A	Max. 5 trays, depth 420 mm Max. 6 sterilization containers 15K Max. 3 sterilization containers 15M Max. 2 sterilization containers 15G Max. 6 sterilization containers 17K Max. 3 sterilization containers 17M Max. 1 sterilization container 17G Max. 3 swab drums 17R Max. 1 sterilization container 23G Max. 2 sterilization containers 23M Max. 2 swab drums 23R Max. 2 sterilization containers 28M Max. 1 sterilization container 28G Max. 3 standard tray cassettes		Max. 5 trays, depth 290 mm Max 3. sterilization containers 15K Max. 3 sterilization containers 17K Max. 3 swab drums 17R Max. 2 swab drums 23R Max. 2 sterilization containers 28M Max. 1 sterilization container 28G Max. 3 standard tray cassettes	

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Program selection

Using the program select key (P), choose between the initial operating state and the desired program.

Then select the sterilization program based on whether and how the items to be sterilized are wrapped. You must also note the thermal stability of the items to be sterilized.

The following tables show which program you should use for particular items to be sterilized.

Table 1: Summary of the sterilization programs

	Universal program	Quick program B	Quick program S	Gentle program	Prion program
Sterilization temperature	134 °C	134 °C	134 °C	121 °C	134 °C
Sterilization pressure	2/29 bars/psi	2/29 bars/psi	2/29 bars/psi	1 bar	2/29 bars/psi
Sterilization time	5.5 min	3.5 min	3.5 min	20.5 min	20.5 min
Operating times					
Operating time*	30 min	28 min	15 min	45 min	45 min
The drying process	20 min	10 min	5 min	20 min	20 min

*without drying (full load with DAC PROFESSIONAL and DAC PROFESSIONAL$^+$: 5 kg) and depending on the loading and conditions set, e.g., mains voltage

Table 2: Summary of the use of the particular sterilization programs

Program	Packaging/suitability	Loaded quantity*
Universal program	single and multiple wrapped, mixed loads; handpieces, long narrow-bore hollow instruments (hollow A and B)	5 kg
Quick program S	only unwrapped (no textiles) simple solid instruments, simple hollow instruments (hollow B)	5 kg
Quick program B	single wrapped and unwrapped (no textiles) handpieces, long narrow-bore hollow instruments (hollow A and B)	single wrapped 1.5 kg or unwrapped 5 kg
Gentle program	single and multiple wrapped large quantities of textiles, thermolabile items (e.g., plastic, rubber items); mixed loads; narrow-bore hollow instruments (hollow A and B)	Textiles 1.8 kg or thermolabile items 5 kg
Prion program	single and multiple wrapped instruments for which there is a suspected risk of infection due to pathologically altered proteins (e.g., Creutzfeld-Jacob, BSE); narrow-bore hollow instruments (hollow A and B)	5 kg

*valid for DAC PROFESSIONAL and DAC PROFESSIONAL$^+$

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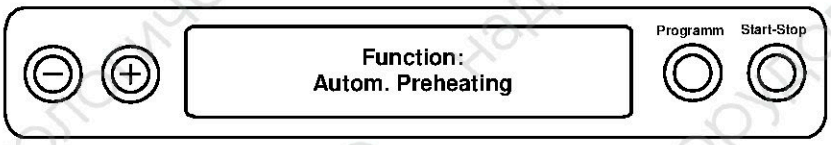
Select automatic preheating

In the factory setting the automatic preheating is activated. This function heats the chamber of the autoclave to the preheat temperature for that particular program prior to starting a program or holds the chamber at this temperature between two program steps. This shortens the cycle times.

NOTE
The autoclave must remain switched on to use the automatic preheating function.

To change this setting, please proceed as follows:

1. Select the "Function" set-up menu by pressing the (+) and (-) keys at the same time until the message **`Function: Last batch no.`** appears on the display.
   Using the (+) or (-) keys, navigate to the message:



2. Press the (P) key to confirm. The display shows the currently set option, e.g., Preheating yes.
3. If you press the (P) key again the message on the display switches to **`Preheating no`**. The preheating function is deactivated.
4. To leave the **`Function: Auto. preheating`** menu and return to the initial operating state, press the (S) key 2×.

NOTE
Sirona recommends activating automatic preheating.

Start program

WARNING
Unsupervised operation of electrical equipment, such as this autoclave, is done at your own risk. Sirona does not accept liability for any damage occurring as a result of unsupervised operation.

If you have selected a program using the program selection keys, the sterilization temperature is shown on the display in addition to the program you have selected. You can also see whether the particular program is suitable for wrapped or unwrapped items.



1. Press the (S) key to start the program.
   The autoclave checks the pumping of the feed water and its conductivity.

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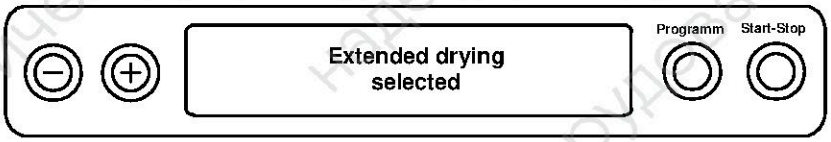
NOTE
If the Quick Program S is started, the warning message **`Attention: Unwrapped instruments only`** appears on the display.
If the load contains unwrapped instruments only, press the (S) key again to confirm and to start the program.

Select extended drying

For difficult drying tasks, you can extend the drying time of a program by 50% using the **`Additional drying`** function.

To do this, proceed as follows:

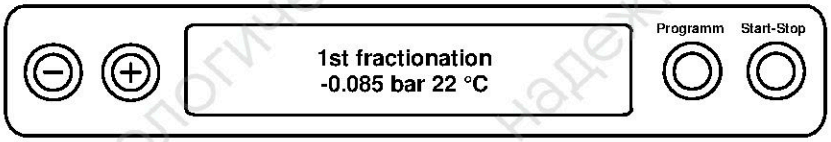
- When starting the program, press the (S) and the (+) keys. The display shows the message:



The program starts once you have made your selection.

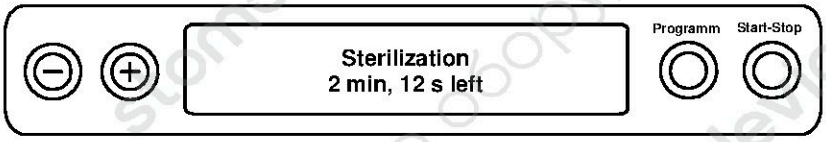
Program running

After a program starts, you can track the progress of the program on the display. The chamber temperature and pressure as well as the time until the end of the sterilization cycle or the drying time that has elapsed are also shown.



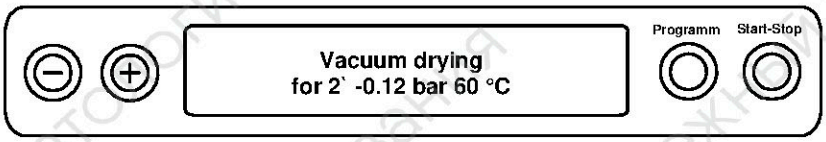
Sterilization phase has ended

On the display you can see whether the sterilization phase has successfully ended.
The remaining time for the sterilization phase is shown alternating with the pressure and temperature information.



Drying phase

The normal drying time is 5 minutes for the Quick Program S, 10 minutes for the Quick Program B, and 20 minutes for all other programs. During the drying phase the display shows an appropriate message.



The autoclave dries the items to be sterilized very thoroughly. However, should it be necessary to dry the items again for difficult drying tasks, the following will help to further improve the drying:

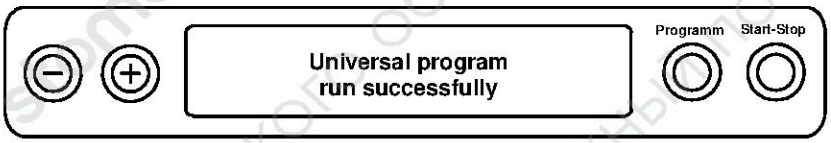
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- Load the autoclave to maximise drying performance. For example, stack transparent sterilization wrap and paper packages like index cards. Follow the instructions in the section **Loading the** autoclave on page 15. Use the film holder if necessary.
- Activate the **`Additional drying`** function. Follow the instructions in the section Select extended drying on page 20.

Program has ended

If the program has successfully ended, the display shows the message:



If immediate output at program end has been activated in the "Function" set-up menu **`Last batch no.`**, the log for the completed program is issued on the activated output media after the door is opened (see page 25, Chapter 5 – Logging).

Manual termination of a program

You can interrupt a running program in all phases. However, if you terminate a program before the start of the drying, the load is still **non-sterile**. The program is considered not to have run successfully.

WARNING

Terminating a running program by switching the power switch off can lead to hot steam escaping from the sterile filter resulting in its contamination.

- Never terminate a running program by switching the autoclave off at the power switch.

DANGER!

The sterilization chamber, the door, and the items that have been sterilized are hot. After a program has been interrupted, hot steam may also escape when the door is opened depending on when the program was terminated.

Burning hazard due to hot steam.

- Only remove the trays using the tray lifter.
- Never touch the items that have been sterilized, the sterilization chamber or the inside of the door with unprotected hands.

Manual termination during the drying phase

During the drying phase you can interrupt the program using the (S) key without the autoclave reporting a malfunction.

You must then expect inadequate drying, particularly for wrapped items. The sterilized items must be sufficiently dry before proper sterile storage is possible. For this reason, you should allow the program to run through to the end of the drying phase when possible for programs with wrapped items.
In a quick program, sterilized unwrapped instruments dry after being removed from the autoclave because of their own heat.

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During the drying phase the drying time that has elapsed is shown on the display. This alternates with the message:



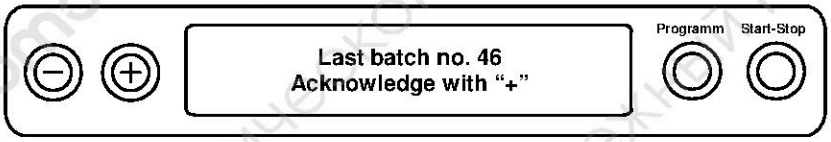
To terminate a program, proceed as follows:

1. Press the (S) key.
2. Then acknowledge the subsequent confirmation prompt **`Immediate removal "Stop"`** by pressing the
(S) key.

The terminated program is confirmed on the display with “Drying interrupted.”

NOTE!
The confirmation prompt remains on the display for about 5 seconds. If the (S) key is not pressed again, the program continues with the normal sequence.

After ventilating the chamber, the display shows the message **`Universal Program successfully ended`** alternating with the message:



If a log printer or another output medium is connected to the autoclave and the immediate output is set to **`Yes`**, a note with “Drying interrupted” is recorded in the log.

Manual termination before starting the drying phase

If you terminate a program before the drying has started, the load is still **non-sterile**. The program is considered not to have run successfully.

To terminate a program, proceed as follows:

1. Press the (S) key.
2. Acknowledge the subsequent confirmation prompt “Terminate program?” by pressing the (S) key again.

NOTE!
The confirmation prompt remains on the display for about 5 seconds. If the (S) key is not pressed again, the program continues with the normal sequence.

Depending on when the program was interrupted, the pressure in the autoclave is released or the the unit is ventilated. The appropriate message is shown on the display.

After the pressure is released or the autoclave is ventilated, the user is requested to confirm the termination of the program.

On the display the message **`Termination end`** alternates with **`Acknowledge with "-" key`**.

3. Press the (-) key.

The display shows the message **`Unlock door with "+" key`** alternating with the display of the previously selected program.

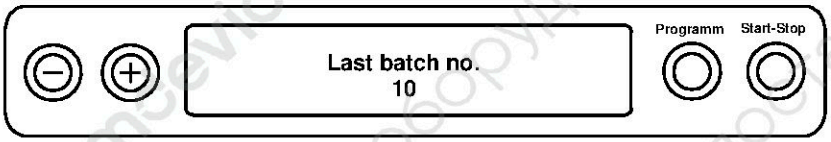
4. After pressing the (+) key, you can open the door.

The log includes the note “Program interrupted / Load not sterile!”.

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Display daily batch counter

After each program has run, you will automatically see the last run batch number for the day on the display.



You can also manually display the last batch number:

1. Select the “Function” set-up menu by pressing the (+) and (-) keys at the same time. The display shows the message **`Function: Last batch no.`**
2. Press the (P) key to display the current daily batch number.

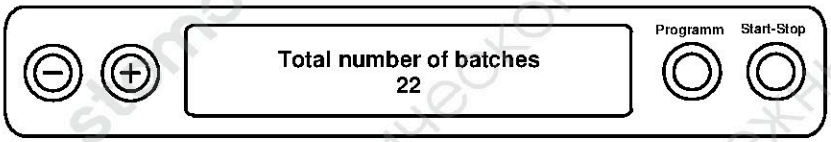
To return to the initial display, press the (S) key 2×.

Displaying the contents of the total batch counter

You can change the counter status to display the total batches completed to date:

Select the “Function” set-up menu by pressing the (+) and (-) keys at the same time.
The display shows the message **`Function: Last batch no.`**

Navigate using the (+) or (-) keys until the corresponding message appears on the display:



1. Press the (P) key.

You can see the current counter status for the total number of batches on the display.

2. To return to the initial display, press the (S) key 2×.

Removing the sterilized items

DANGER!

Metal parts and loads are hot at the end of the program and hot steam may escape from the autoclave.

Risk of burns!

- It is essential to follow the instructions below for removing the sterilized items from the autoclave.

DANGER!

If any packaging has been damaged or burst during a program run, the instruments may not be sterile.

The health of the patient and the clinical team is at risk.

- Damaged or burst packages must be rewrapped and sterilized again.

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At the end of a program, note the following when removing the sterilized items:

- Never open the door with force. The autoclave may be damaged and/or hot steam may escape.
- Use the tray lifter to remove the trays from the autoclave.
- Never touch the sterilized items, the chamber or the inside of the door with unprotected hands. These parts are hot.
- Check the packaging of the sterilized items when removing them from the autoclave.
- If packaging is damaged, rewrap the items to be sterilized and sterilize them again.

When you remove the sterilized load from the autoclave at the end of the program, small amounts of moisture may be present on the sterilized items.

According to the Instrument Reprocessing Working Group (AKI; Red Booklet; 10th edition; p. 57) the following applies: “In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated but actual pools of water are not acceptable.”

Storing sterilized items

Only use packaging compliant with standards to store the sterilized items. Do not store the sterilized items in the reprocessing room. Comply with DIN 58953, part 8 and the criteria listed below for storing sterilized items.

Ensure the following criteria are met for the storage location and the length of time the sterilized items are stored:

- Protected against dust, e.g., in closed instrument cabinet
- Protected against damage on smooth surfaces
- Protected from large temperature variations
- Protected from moisture (e.g., alcohol, disinfectants)
- Storage period corresponds to the type of packaging
- The maximum storage period is determined by the packaging and the storage conditions. For sterilized items packaged in accordance with the standard, presuming dust-protected storage, the storage period is up to six months.

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Chapter 5 – Logging

Documentation of batch results

Batch documentation is essential as evidence of successful completion of the sterilization process and is a mandatory component of quality assurance (MPBetriebV, German Medical Device Operators Ordinance). Data such as program type, batch, and the process parameters for programs that have run are automatically saved in the internal log memory of the autoclave.

For batch documentation you can read the internal log memory and transfer the data to various output media. This can be as soon as a program is finished or subsequently, e.g., at the end of the working day.

Capacity of the internal log memory

The internal memory is sufficient to store 40 logs.
If the internal log memory is full, when the next program starts the oldest log is automatically overwritten.

If you have connected a log printer and the option Immediate output “No” is set (see also page 26, Immediate automatic output of logs), before overwriting the saved logs, a confirmation prompt is displayed. For more information about connecting the printer, please read the operating instructions for the particular printer.

Output media

You can print out and appropriately archive the logs for programs that have run using the following output media. Follow the operating instructions for the particular device.

- NITRAprint log printer
- NITRAflash CF card printer onto CF card
- Computer, e.g., using the MELA*trace*/MELA*view 3* software

There is no option set for output of the logs in the factory settings.

Using the computer as an output medium (no network connection)

In the following example you can read how to use a computer as an output medium.

You can connect a computer to the autoclave if the following conditions are satisfied:

✓ *The computer has a serial interface or a USB serial adapter is connected.*

NOTE
To connect to the (clinic) network, the MELA*trace*/MELA*view* software is needed.

To use a computer as the output medium, the computer must be connected to the autoclave via the serial interface. To read the logs you can use the MELA*trace*/MELA*view* software.

To register the computer on the autoclave, you must make the following setting once on the autoclave:

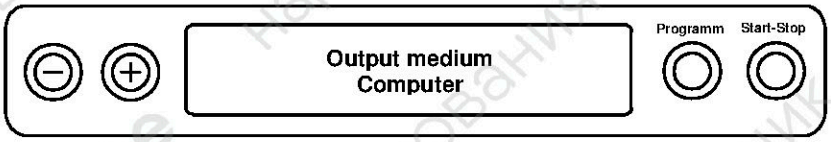
1. Switch the autoclave on.
2. Wait until the display shows the initial operating state.

Select the “Function” set-up menu by pressing the (+) and (-) keys at the same time. The display shows the message **`Function: Last batch no.`**

3. Navigate using the (+) or (-) keys in the “Function” menu until you can see the **`Function: Log output`** display.
4. Press the (P) key to select the log output submenu – output medium.
5. Press the (P) key again. The display shows the message **`Log output – No output medium`** if no output medium has been selected.

   Navigate using the (+) or (-) keys until the following message appears on the display:

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6. Press the (P) key to confirm. The display returns to the **`Log output – Output medium`** menu.
7. Press the (S) key to return to the set-up menu **`Function: Log output`**.

After pressing the (S) key again, the display shows the initial operating state again.

Immediate automatic output of logs

Text logs

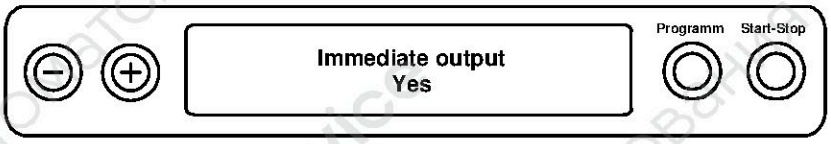
The following conditions must be satisfied for automatic output of logs as soon as a program has ended:

- ✓ *In the set-up menu* **`Function: Log output`** *immediate output is set to* **`YES`**.
- ✓ *At least one output medium (computer, NITRAprint log printer) must be selected as the output medium.*
- ✓ *The activated output medium must be connected and initialized.*

If you would like to output the text log for a program as soon as the program is finished, use the **`Immediate output yes`** function. This is not preset in the factory settings.

To set the option for immediate output of the log when the program has finished:

1. Switch the autoclave on at the power switch.
2. Select the “Function” set-up menu by pressing the (+) and (-) keys at the same time.
   The display shows the message **`Function: Last batch no.`**
3. Navigate using the (+) or (-) keys until the message: **`Function: Log output`** is displayed and press the (P) key.
4. Navigate using the (+) or (-) keys to the message.



5. Press the (P) key to change from immediate output no or yes.

To immediately output logs, the immediate output must be set to yes.

6. To save the setting and leave the menu, press the (S) key.

   The display shows the message **`Function: Log output.`**

By pressing the (S) key again, you leave the menu completely and return to the initial operating state.

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NOTE!
If immediate output of a log is not possible, e.g., because the activated output medium is not connected, a warning appears. Sirona recommends that you use the immediate log output.

Delayed log output

You can output logs later and independent of when a program ended. You can choose whether selected or all saved logs (up to 40 logs) should be printed. Use the connected output medium, e.g., the log printer.

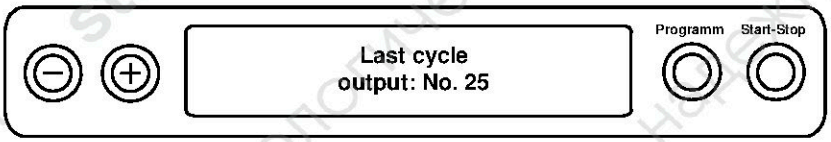
Print selected logs

To print selected logs from particular programs at a later point, proceed as follows:

1. Select the "Function" set-up menu by pressing the (+) and (-) keys at the same time. The display shows the message **`Function: Last batch no.`**
2. Navigate using the (+) or (-) keys until the message: **`Function: Log output`** is displayed and press the (P) key.

   The display shows the **`Log output – Output medium`** menu.
3. Navigate using the (+) or (-) keys until you see the message: **`Output last cycle: No. 40`** (as an example for no. 40).
4. Press the (P) key. The current log number flashes.
5. To output a log from a different cycle, navigate using the (+) or (-) keys until you reach the desired number, 25 in this example.
6. Press the (P) key to start the output of the selected program. The display shows the message **`Output.`**

After successful output, the display again shows the previous setting with the message:



To output additional logs, repeat the last three steps.

7. To leave the submenu without outputting the log, press the (S) key.
8. To leave the menu after successful output, press the (S) key. The display shows the message **`Function: Log output.`**

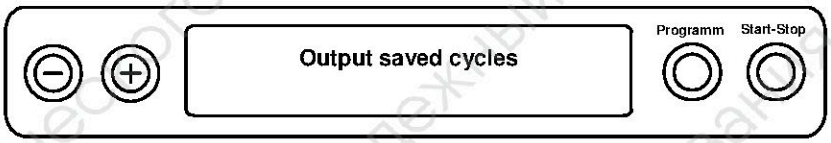
By pressing the (S) key again, you leave the menu completely and return to the initial operating state of the display.

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Output all saved logs

To output all saved logs at a later time, proceed as follows:

1. Select the “Function” set-up menu by pressing the (+) and (-) keys at the same time.
   The display shows the message **`Function: Last batch no.`**
2. Navigate using the (+) or (-) keys until the message: **`Function: Log output`** is displayed and press the (P) key.
3. Navigate using the (+) or (-) keys to the message: **`Output saved cycles`**.
4. Press the (P) key to start the output of the selected program. Once the output is complete the display shows the message:



If you would like to leave the submenu without outputting the log, press the (S) key.

NOTE!
Interrupting the log printer **during** the log output is only possible by switching the device off at the power switch or by interrupting the power supply to the printer.

5. To leave the menu, press the (S) key. The display shows the message of the set-up menu **`Function: Log output.`**

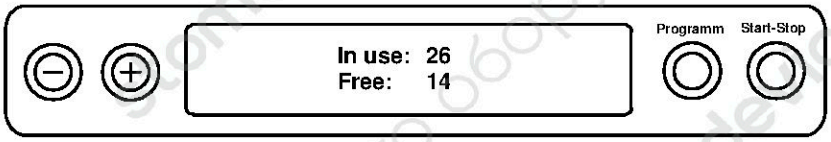
By pressing the (S) key again, you leave the menu completely and return to the initial operating state of the display.

Displaying the log memory

If the printer or another output medium is connected and initialized, you can check how many logs have already been saved in the log memory of the autoclave.

Proceed as follows:

1. Select the Function set-up menu by pressing the (+) or (-) keys at the same time.
   The display shows the message **`Function: Last batch no.`**
2. Navigate using the (+) or (-) keys until the message: **`Function: Log output`** is displayed and press the (P) key.
3. Navigate using the (+) or (-) keys to the message for the assignment of memory.



To leave the menu again, press the (S) key 2×.

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Deleting logs in the internal log memory

To suppress the warning Log memory full, for example, if the option **`Immediate output no`** is set, you can manually delete the saved logs. The following example shows how you can delete all saved logs.

1. Select the Function set-up menu by pressing the (+) or (-) keys at the same time.
   The display shows the message **`Function: Last batch no.`**
2. Navigate using the (+) or (-) keys until the message: **`Function: Log output`** is displayed and press the (P) key.

Navigate using the (+) or (-) keys until the following message appears on the display:



3. Press the (P) key to delete all logs now.
4. To leave the submenu without deleting the logs, press the (S) key.
5. To leave the menu after deleting the logs, press the (P) key.

   The display shows the message **`Function: Log output.`**

By pressing the (S) key again, you leave the menu completely and return to the initial operating state of the display.

Reading logs correctly

Log type	File extension	Explanation
Text log	.PRO	Log of a successfully run program
Error log	.STR	Log for a program that failed to run successfully
Standby log	.STB	Log for errors when in standby
Demo log	.DEM	Log for a simulated program run. No sterilization has actually been done.

Log header

The header of the program log includes the general information on the program that has run such as the date, the program selected, the daily batch number, and the autoclave type.

Values for the program steps

During the program the program phases are recorded with the corresponding values for the steam pressure, the temperature, and the time (relative to the start of the program).

Summary

The summary states whether the program was successfully completed. The values for the required sterilization time, sterilization temperature, and pressure including their maximal deviations are also shown.

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Table 3: Example of a text log for a successfully completed program

`----------`
`DAC PROFESSIONAL+`
`----------`
	Autoclave type

`Program : Universal program`
`134 °C wrapped`
`Datum : 2013-12-19`
`Time : 09:14:19 (start)`
`Batch no. : 2`
	Program started
	Current date
	Time at the start of the program
	Daily batch number

`Preheating 127.5 °C` `AIN6: Conductivity 15 µS/cm`	Preheat temperature Conductivity of the feed water

`Program step Pressure Temp. Time`
`bar °C min`
`Start 0.01 77.0 00:00`
`1st fractionation`
`Evacuation -0.92 58.2 02:23`
`Steam intake 0.41 108.7 04:53`
`2nd fractionation`
`Evacuation -0.82 71.3 06:45`
`Steam intake 0.41 109.2 08:33`
`3rd fractionation`
`Evacuation -0.82 66.7 10.35`
`Steam intake 0.41 109.3 12:24`
`Pressure rise 2.06 134.0 14:40`
`Steril. start 2.06 134.0 14:40`
`Steril. end 2.20 135.9 20:10`
`Press. release 0.20 105.2 20:55`
`Vacuum drying`
`Drying start -0.31 94.4 21:03`
`Drying pressure -0.91 75.1 23:01`
`Drying pressure -0.91 85.9 25:01`
`Drying pressure -0.92 84.3 27:01`
`Drying pressure -0.93 81.4 29:01`
`Drying pressure -0.93 79.2 31:01`
`Drying pressure -0.93 77.6 33:01`
`Drying pressure -0.94 76.3 35:01`
`Drying pressure -0.94 75.4 37:01`
`Drying pressure -0.94 74.5 39:01`
`Drying pressure -0.94 73.9 41:01`
`Drying end -0.86 73.8 41:03`
`Ventilation -0.29 77.3 41:12`
`End 0.00 79.2 41:24`
	Values for the program steps
	During the program, the program phases with the corresponding values for steam pressure, temperature, and time (relative to the start of the program) are recorded.
	
	Program phases with corresponding values for pressure, temperature and time (relative to start of program).

`----------`	Summary The summary shows whether the program was successfully completed. The values for the required sterilization time, sterilization temperature, and pressure including their maximal deviations are also shown.
`PROGRAM SUCCESSFULLYCOMPLETED!`	Control message

`Temperature : 135.6 +0.4 /-0.3 °C`
`Pressure : 2.17 +0.03/-0.03 bar`
`Sterilization time : 5 min 30 s`
`Time : 09:55:43 (end)`
`==========`
	Mean sterilization temperature with max deviations
	Mean sterilization pressure with max. deviations
	Sterilization time adhered to
	Time at the end of the program

`305 2015PRO+1234 5.11 5.05`	Info line showing total batch counter, factory number, and device software version no.

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Chapter 6 – Functional testing

Automatic functional testing

The electronic parameter control continuously and automatically monitors the interaction between those parameters relevant for the sterilization, namely pressure, temperature, and time. The process evaluation system of the autoclave compares the process parameters during the program with each other and monitors these in terms of their thresholds. The autoclave monitoring system tests the device components in terms of the functionality and their plausible interaction. If the thresholds defined for the parameters are exceeded, the autoclave issues a warning or an error message. If necessary, it interrupts the program with an appropriate message. If the program was successfully completed, an appropriate message is shown on the display.

Manual functional testing

You can track the progress of the program on the display using the values shown. In addition, you can determine whether a program was successful using the log recorded for every program (see Chapter 5 – Logging).

Batch-related tests

Test set for Helix test

The Helix test set is an indicator and batch monitoring system that satisfies the DIN EN 867-5 standard. It comprises a process challenge device, the Helix, and an indicator strip.

If you are sterilizing Critical B category instruments, the Helix test set should be included in every sterilization cycle for cycle monitoring.

You can conduct a steam penetration test with the Bowie & Dick test in the Universal Program at any time independent of the Helix test.

If the Helix process challenge system is used properly, staining of the plastic surface may occur. This staining does not have any effect on the functionality of the Helix process challenge system.

Vacuum test

The test is used to detect any leaks from the autoclave. The leak rate is determined in the test.

Carry out a vacuum test in the following situations:

- Once a week during routine operation
- At the initial start-up
- After longer periods of disuse
- In case of a relevant error (e.g., in the vacuum system)

Carry out the vacuum test with a cold and dry autoclave as follows:

1. Switch the device on at the power switch. The display shows its initial operating state.
2. Hold down the (P) key until the message **`Vacuum test`** appears on the display.
3. Close the door.
4. Press the (S) key to start the vacuum test.

The evacuation pressures and the equilibration time or measurement period are shown on the display. After the measurement period has elapsed, the chamber is ventilated (corresponding message on the display). A message showing the leak rate is then shown on the → display. If the leak rate is too high, that is, it is greater than 1.3 mbar, a corresponding message is shown on the display. The display also shows the current batch number for the day alternating with the message **`Acknowledge with "+" key`**. After pressing the (+) key, you can open the door.

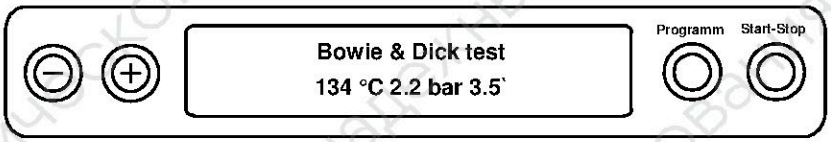
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NOTE
If a log printer or another output medium is connected and “Immediate output” has been set to “yes”, a log is printed out at the same time.

Bowie & Dick test

The Bowie & Dick test is used to determine the steam penetration of porous materials such as textiles.

Various test systems for the Bowie & Dick test are available from specialist suppliers. Carry out the test in accordance with the instructions provided by the manufacturer of the test system.



Start the program for the Bowie & Dick test as follows:

1. Switch the device on at the power switch.
2. Select the Bowie & Dick test by repeatedly pressing the (P) key.
3. Press the (S) key to start the Bowie & Dick test.

After the test program has been successfully completed, the display shows the current batch number for the day and the message Acknowledge with “+”. After pressing the (+) key, you can open the door.

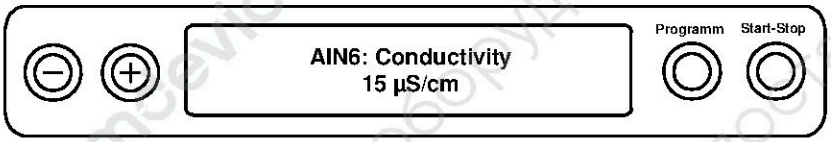
NOTE
If a log printer or another output medium is connected and “Immediate output” has been set to “yes”, a log is printed out at the same time.

NOTE
The intensity of the color change of the treatment indicator tape often varies between batches due to different storage periods or other influences. What is critical when assessing the Bowie & Dick test is not the intensity of the color change but instead the uniformity of the color change on the test strip.
If the treatment strips or treatment indicator tape has changed color evenly, the ventilation of the sterilization chamber is functioning correctly.
If the center of the star on the treatment indicator strips or treatment indicator tape has not changed color or the color change is less than on the ends, the ventilation was inadequate. In this case, contact your supplier’s customer service.

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Checking the water quality of the feed water

Whenever the autoclave is switched on, including when a program is running, you can show the water quality on the display.



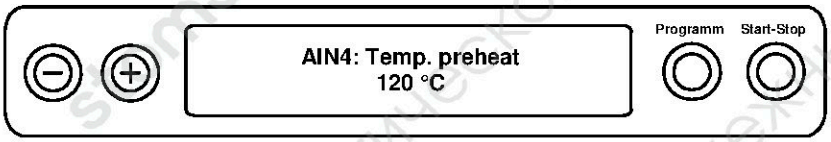
To do so, hold down the (-) key until the message **Conductivity** appears on the display. The conductivity is shown in µS/cm.

As soon as you release the (-) key, the display returns to its previous status (e.g., the initial operating state).

Checking the preheat temperature of the chamber

If preheating is activated, the autoclave preheats the cold chamber or maintains the temperature between two sterilization cycles. This is used to shorten the program times and to reduce the formation of condensation in order to improve the drying results.

If you press the (-) key 2×, first briefly and then holding it down the second time, instead of the conductivity the preheat temperature of the chamber is shown.



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Chapter 7 – Maintenance

Checks and cleaning

Door seals, chamber, chamber sealing surface, racks, trays

Inspect the chamber including the door seal and chamber sealing surface and the racks for loading once a week for any soiling, deposits or damage. If you detect any contamination, remove any trays or cassettes and the rack from the chamber. Clean the contaminated parts.

Pay attention to the following when cleaning the chamber, the racks for loading, chamber sealing surface, and door seal:

- Switch off the autoclave before cleaning and remove the power plug from the socket
- Ensure that the chamber is not hot
- Use a soft and lint-free cloth
- Use cleaning agents that do not contain chlorine or acetic acid
- First soak the cloth with cleaning alcohol or spirits and try to remove the soiling with the cloth
- For stubborn soiling only on the chamber, rack or chamber sealing surface use a mild stainless steel cleaning agent with a pH between 5 and 8
- To clean the door seal use a neutral liquid cleaning agent
- Cleaning agent must not enter the pipes that exit the autoclave chamber
- Do not use hard objects such as pot cleaners made of metal or steel brushes

WARNING

Surfaces may be scratched or damaged and sealing surfaces may develop leaks. Dirt deposits and corrosion in the sterilization chamber would be encouraged.

- It is essential that you follow the directions for cleaning the affected parts.

Internal water storage tank

NOTE

Ensure that any soiling is removed from the tank using a cloth without leaving any residue. If dirt particles are only detached but not removed, when the waste water tank is emptied they may enter the dirt particle filter that is integrated into the drain hose.

Failure to comply with this instruction could impair the service life of the dirt particle filter and require replacement within a short period.

If you supply the feed water manually from the internal water storage tank, check the feed water side (right side) for any contamination before adding water. If necessary, clean the tank before filling with a cloth and clean feed water.

Clean the waste water side (left chamber) of the internal water storage tank every two weeks.

Empty both chambers of the water storage tank as follows:

1. Plug the drain hose onto a quick coupling (drain tank on the left, feed water tank on the right) until it perceptibly snaps into place.
2. Drain the water into a vessel or container with a capacity of at least 5 liters.
3. Repeat this procedure for the other chamber.

To remove the drain hose, press the gray release key on the quick coupling. The hose automatically disengages from the coupling.

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WARNING

Please note the following when removing the quick coupling:

- When emptying the storage chambers, stand to one side of the connection.
- When pushing the gray release key of the quick coupling, be sure to hold the hose securely in place with your other hand in order to absorb the spring force of the catch.

Failure to observe this precaution may result in injury.

Preventing spotting

Only if you correctly clean instruments prior to sterilization can you avoid residues from the load or the instrument preparation detaching under the steam pressure during sterilization. Residual soiling (e.g., traces of disinfectant) that become detached can block up the filter, nozzles, and valves of the autoclave and become deposited as spots and residue on the instruments and in the chamber (see page 14).

All parts of the autoclave that come into contact with steam are made of non-corrosive materials. This prevents any corrosion caused by the autoclave. If corrosion spots do occur, this is external corrosion. If instruments are incorrectly prepared, corrosion can occur even on stainless steel instruments of renowned manufacturers. A single instrument with corrosion is often all that is necessary to cause external corrosion on the other instruments or the autoclave itself.
Remove external corrosion from instrument sets using a chlorine-free stainless steel cleaning agent (see page 34, Cleaning) or send the damaged instruments to the manufacturer for reprocessing.

Changing the door seal

The door seal must not be greased or oiled. It must be kept clean and dry. If the door seal has shrunk or become uneven, it must be replaced. Otherwise leaks can develop that lead to steam escaping or the leak rate in the vacuum test being too high.

Proceed as follows to change the door seal:

1. Open the door of the autoclave and remove the old door seal. The door seal is only sitting in the groove of the door port (page 8, Fig. 3/5). Place the new door seal in the groove so that the **wider sealing surface is facing the chamber**.



Fig. 4: Internal view

IMPORTANT!
You must observe the different widths of the sealing surfaces. The door will only close properly and the chamber will only be tight if the seal is seated correctly in the groove.

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Cleaning the filter in the chamber

1. Remove the filter for inspection and cleaning by rotating it counterclockwise out of the opening.
2. Rinse the filter with water to clean.
3. Screw the filter back into the opening by rotating it clockwise.

Please use the key supplied for the chamber filter to unscrew the chamber filter (Fig. 6/c).

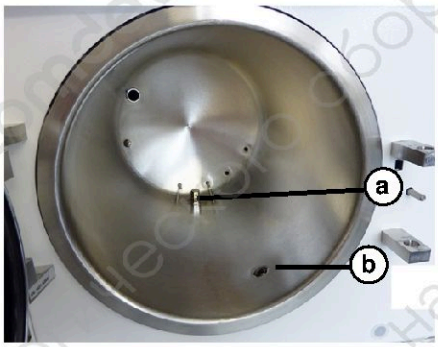


Fig. 5 Chamber internal view

(a) Filter condensate drain
(b) Chamber filter
(c) Key for chamber filter



Fig. 6Unscrewing the chamber filter

Maintenance

WARNING

Continuing operation despite maintenance messages can result in malfunctions in the autoclave.

- Maintenance should only be performed by trained technicians from customer service or your specialist supplier. Contact your specialist supplier for any maintenance.
- Adhere to the specified maintenance intervals.

To preserve the value of your autoclave and to ensure it continues to function reliably, regular maintenance is essential.
This maintenance includes all testing and replacement where necessary of all components and electrical systems that are relevant for function and safety. The autoclave must undergo maintenance after every 1000 program cycles or 2 years. The autoclave shows a maintenance message at the relevant time.

NOTE ABOUT THE INDUSTRIAL HEALTH AND SAFETY ORDINANCE

According to the German industrial health and safety ordinance (BetrSichV §15), facilities operating pressure devices (such as autoclaves) are obliged to have their device inspected to ensure proper condition. For this purpose we provide you with an appropriate guideline for downloading from our Internet site under the “Service” menu. This shows you our recommendations regarding which components must be inspected at which intervals.

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Chapter 8 – Periods of disuse

Sterilization frequency

Pauses in operation between individual programs are not necessary. At the end of or after interrupting the drying time and removing the sterilized load, you can immediately reload the autoclave and start a program.

Periods of disuse

Depending on the length of the period of disuse, the following measures must be adhered to:

Length of the period of disuse	Measure
Between two sterilization cycles, longer than one hour	▪ Switch the autoclave off (saves energy)
Overnight or on the weekend	▪ Switch the autoclave off ▪ Leave the door ajar to prevent the door seal sticking ▪ If present, close the cold water intake of the water preparation unit
Longer than two weeks	▪ Carry out a vacuum test ▪ Then run an empty sterilization in the Quick Program B (see page 31, chapter 6 – Functional testing).

Carry out the tests described in chapter 6 – Functional testing after pauses depending on the length of the pause.

Shutdown

If you want to shut the autoclave down for a longer break for holidays or you plan to move the autoclave, for example, proceed as follows:

1. Switch the autoclave off at the power switch.
2. Remove the power cable from the socket.
3. Empty both chambers of the water storage tank.
4. Close the water intake if you use a water preparation unit.

NOTICE

Please follow the instructions in the service manual regarding transport. All the requirements are listed there in detail.

Starting up the autoclave again after changing location

When starting the autoclave up again after changing location, proceed as for the initial start-up (see page 11, chapter 3 – First steps).

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Chapter 9 – Function descriptions

Sterilization procedure

The autoclave sterilizes using the fractionated pre-vacuum method. This ensures complete removal of air and effective wetting or penetration of the items to be sterilized with saturated steam. This method can be used to sterilize all types of loads in a medical practice.
The autoclave uses a separate steam generator to generate the sterilization steam. At the start of the program steam is generated and fed into the sterilization chamber. In this way a defined pressure and prescribed temperature are ensured.
The items being sterilized are dried using the post-vacuum method (vacuum drying). This ensures that optimal drying results are achieved even when wrapped items are sterilized.

Type of feed water supply

The autoclave works using a feed water one-way system. This means that it uses fresh feed water for every sterilization cycle. The quality of the feed water is monitored by an integrated conductivity meter.

Internal process monitoring

The electronics of the autoclave has an integrated process evaluation system. It monitors process parameters such as temperature, time, and pressure during a program. Opening the door while there is positive pressure in the sterilization chamber is therefore not possible. The sterilization chamber is protected against overheating and the total operating time of a program is optimized depending on the load.
It also monitors the parameters in terms of their thresholds when controlling and regulating and ensures reliable and successful sterilization. If one or more parameters deviate from the defined thresholds, the autoclave issues a warning or error message and, if necessary, interrupts the program.

Programs

Program sequences

Normal sterilization program

Program phase	Description
1. Venting phase	In the venting phase (fractionation), the air is repeatedly suctioned off until the pressure defined for the program is reached. This is achieved by alternating with the influx of steam until a slight positive pressure is reached. Depending on the program selected and the current chamber temperature at the start of the program, the fractionation may be repeated.
2. Heating phase	After the venting phase, the heating phase starts. The steady influx of steam into the chamber increases the pressure and the temperature until the sterilization parameters are reached.
3. Sterilization phase	After reaching the parameters for the sterilization pressure and temperature, the sterilization phase starts.
4. Drying phase	After the pressure has been released, the drying phase starts. At the end of the drying phase, the chamber is ventilated while the pressure is equilibrated.
5. Ventilation	At the end of a program the chamber pressure is equilibrated to the atmospheric pressure. A corresponding message “Ventilation” is shown on the display.

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Vacuum test

Program phase	Description
1. Evacuation	The chamber is evacuated until the pressure for the vacuum test is reached.
2. Equilibration time	This is followed by an equilibration time of five minutes.
3. Measurement period	The measurement period is ten minutes. In this time the pressure increase in the chamber is measured. The evacuation pressure and the equilibration time or measurement period are shown on the display.
3. Ventilation	After the measurement period has elapsed, the chamber is ventilated. A message with the details of the leak rate is then shown on the display. If the leak rate is too high, that is, it is greater than 1.3 mbar, the message also indicates this.
4. End of test	On the display the current batch number for the day alternates with "Acknowledge with "+" key". After pressing the (+) key, you can open the door.

Summary of the sterilization programs

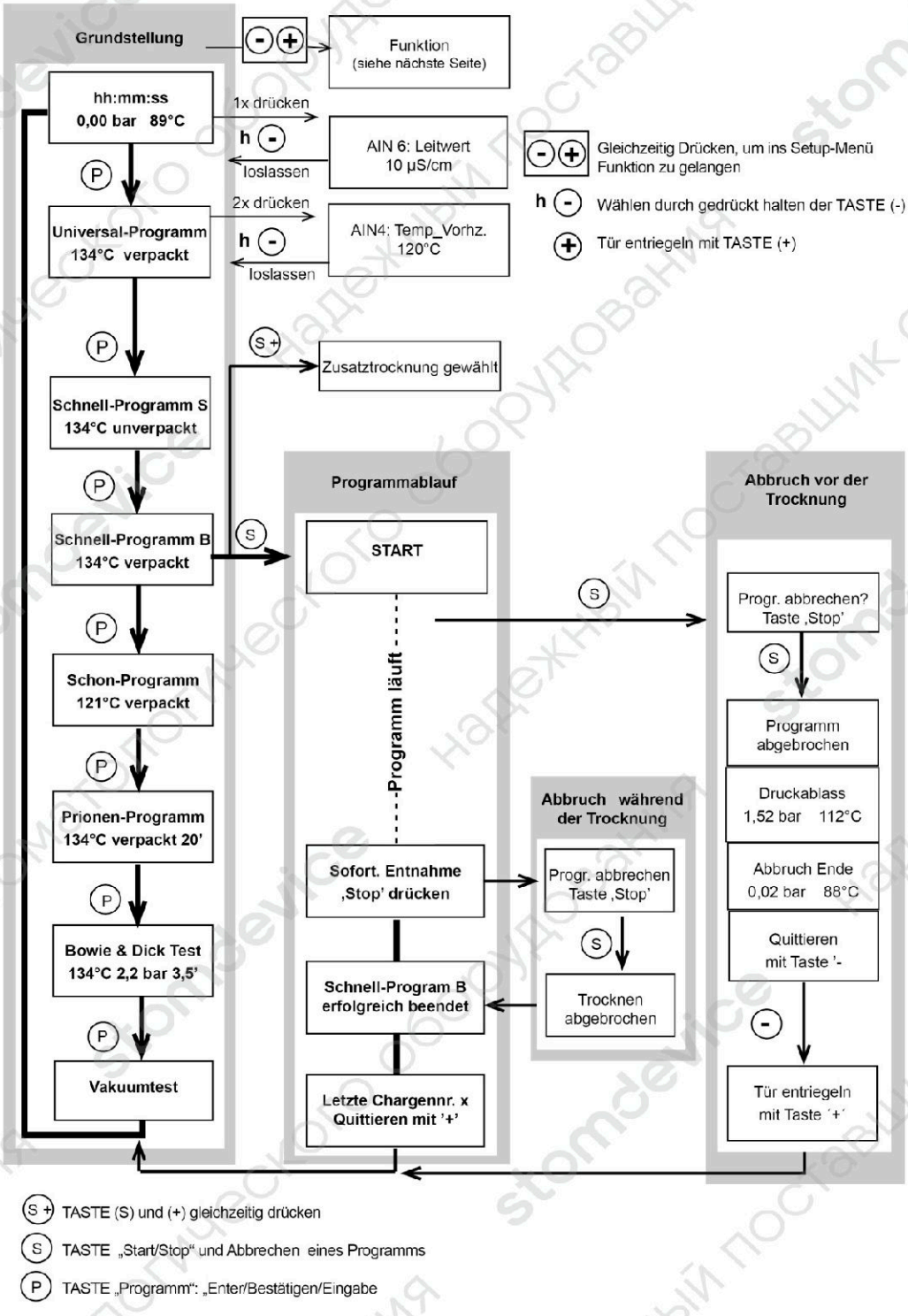
The results in this table show which tests the autoclave underwent. The labeled fields indicate compliance with all the applicable sections of the
DIN EN 13060 standard.

Type testing	Universal program	Quick program B	Quick program S	Gentle program	Prion program
Program type as defined by DIN EN 13060	Type B	Type B	Type S	Type B	Type B
Dynamic pressure testing of the sterilization chamber	X	X	X	X	X
Air leak	X	X	X	X	X
Empty chamber test	X	X	X	X	X
Solid load	X	X	X	X	X
Porous partial load	X			X	X
Porous full load	X			X	X
Hollow body B			X		
Hollow body A	X	X		X	X
Single wrapping	X	X		X	X
Multiple wrapping	X			X	X
Drying solid load	X	X	X	X	X
Drying porous load	X			X	X
Sterilization temperature	134 °C	134 °C	134 °C	121°C	134 °C
Sterilization pressure	2/29 bars/psi	2/29 bars/psi	2/29 bars/psi	1 bar	2/29 bars/psi
Sterilization time	5.5 min	3.5 min	3.5 min	20.5 min	20.5 min

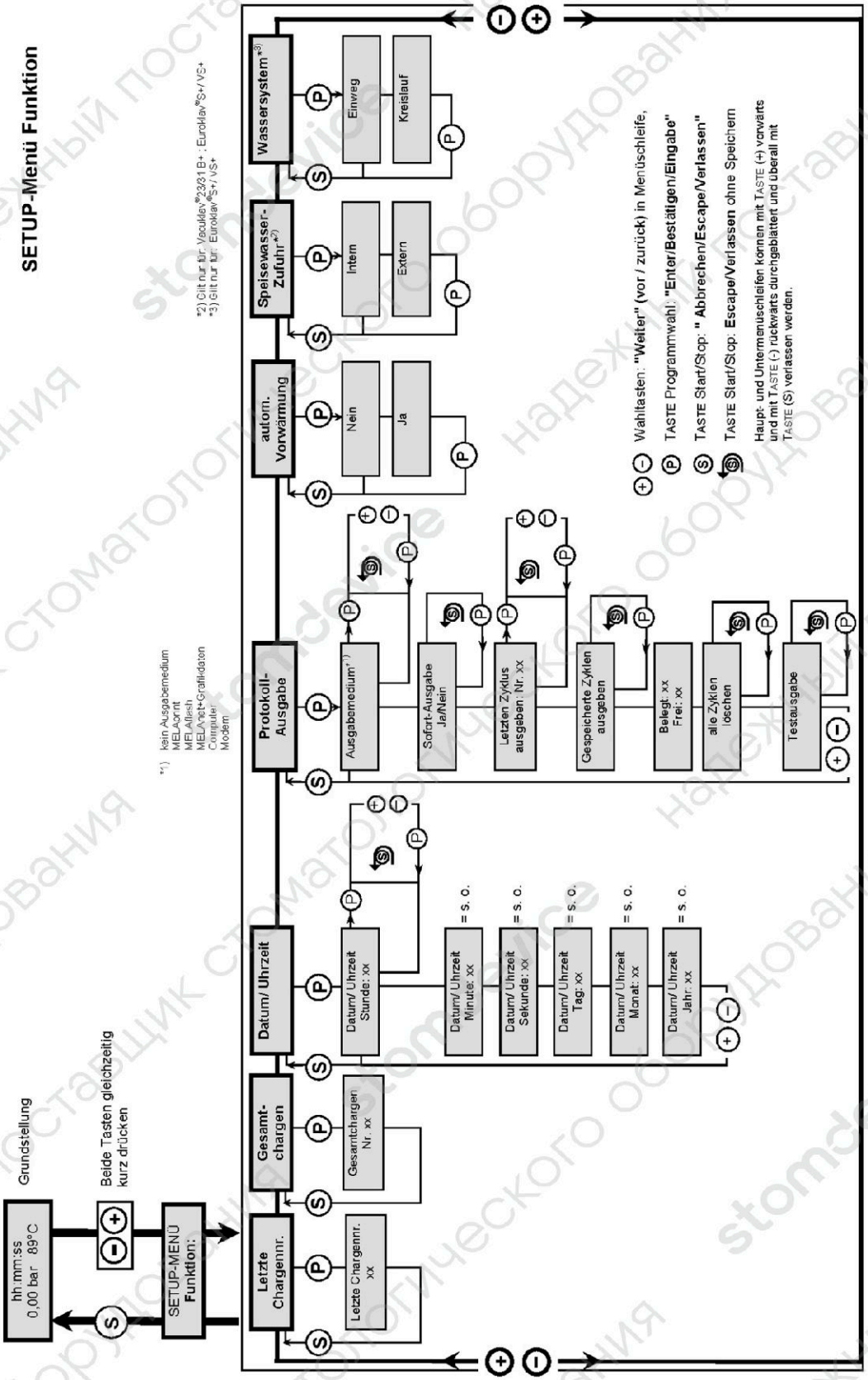
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Program overview

MAIN menu



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Chapter 10 – Malfunctions

Warnings

Warnings are not error messages. They help you to ensure your autoclave functions trouble free and to identify undesirable conditions. Pay prompt attention to these warnings to avoid errors.

Error messages

Error messages are shown on the display with an incident number. This number is used for identification.
If the safe operation or reliable sterilization cannot be assured, error messages are displayed.
These may appear on the display shortly after switching the autoclave on or while the program is running.

If an error occurs while a program is running, the program is ended.

RISK OF INFECTION

If a program is interrupted before the drying, the load is not sterile.
This endangers the health of your patients and the clinical team.

- Wrap the items again if applicable and repeat the sterilization for the affected items.

Before calling customer service

Follow the instructions for dealing with a warning or error message shown on the display of the autoclave. You can also find the most important incidents in the following table. The possible causes and the possible corresponding operating instructions are listed for the incidents.

If you cannot find the particular incident in the table below or your efforts have not been successful, please contact your specialist supplier. Please ensure you have the serial number of your autoclave and a detailed description of the fault in the error message ready.

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General incidents

Incident	Possible cause	What you can do:
No reading on the display	No power (item 2)	Check that the power plug is correctly inserted into the socket. Check the mains voltage at the socket. If necessary, change the device fuses on the lower front of the autoclave (see page 8, Fig. 1/10). Follow the instructions in the service manual under “Change device fuses.”
Door will not open	Door seal adheres to the sealing surface.	Switch the autoclave on, press the “+” key to open the door, and pull forcibly on the door to open it.
Feed water consumption too high	Autoclave has been loaded incorrectly Autoclave is not positioned correctly. The condensate drain is blocked.	Pay attention to the load size (page 15, “Loading the autoclave”). Check that the autoclave is positioned correctly. If necessary, unscrew the leveling feet by a max. of 2 rotations. Remove any instruments, filter paper or similar that have been dropped.
Poor drying results	Autoclave has been loaded incorrectly. Autoclave is not positioned correctly. The condensate drain is blocked.	Pay attention to the load sizes (page 15, “Loading the autoclave”). Textiles must not make direct contact with the walls or floor of the chamber. Check that the autoclave is positioned correctly. If necessary, unscrew the leveling feet by a max. of 2 rotations. Remove any instruments, filter paper or similar that have fallen down. Check the chamber filter and the filter of the condensate drain for any blockages. Activate pre-heating (see page 19, Select automatic preheating) Activate additional drying (see page20, “Additional drying”).

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Warnings

Warning	Possible causes	What you can do
Warning: Door is open and autoclave cannot start	The door contact was not closed when the autoclave was started.	Push the sliding latch down to the stop.
Warning: No feed water / add feed water – autoclave cannot start	Only with feed water supply from the internal water storage tank: Insufficient feed water in the internal water storage tank.	Check the level of the feed water in the internal water storage tank and add feed water if necessary.
Warning: No feed water / check feed water inlet	The warning appears after a program has started. The integrated flow sensor does not close.	**Feed water supply from the internal water storage tank** If this message occurs repeatedly, have your specialist supplier's customer service inspect the unit. **Feed water supply from the NitraDem Direct Connect** Check the water preparation unit, if necessary, open the inlet to the unit. If this message occurs repeatedly, have your specialist supplier's customer service inspect the unit.
Feed water quality poor / replace cartridge/module	Conductivity of the feed water too high. Conductivity ≥ 40 µS NitraDem filter must be replaced.	**Cannot start the autoclave by pressing the (S) key again** **Feed water supply is off:** **NitraDem Direct Connect:** Change the NitraDem filter, see instructions for use, item 2.5.
Feed water quality inadequate / cannot start autoclave	Conductivity of the feed water is too high. Conductivity ≥ 65 µS	**Can no longer start the autoclave:** See warning: Feed water quality poor / replace cartridge/module.
Please wait pre-heating chamber	Message appears during the program start phase. The autoclave has not yet reached the start temperature.	The autoclave starts automatically after reaching the start temperature.
Warning/Change the sterile filter	Min./max. pressure during ventilation drying has fallen below/exceeded, sterile filter dirty or torn.	Replace the sterile filter. **NOTE!** Message appears at the end of the program and in the last line of the log output.
Output medium is not ready	The autoclave is being operated without an output medium but an output medium has been registered. Output medium is not correctly connected.	In the log output menu, set the option no **`Output medium`**. Check that the data cable is correctly connected to the autoclave and the output medium.

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Warning	Possible causes	What you can do
	Power supply to the printer has been disconnected. Printer is offline.	Ensure there is power to the printer; the red LED “P” on the NITRAprint log printer must light up. Set the printer to online (press the “SEL” key on the NITRAprint;. the green “SEL” LED must light up).
Log memory full	The internal log memory of the device is full (max. 40 logs possible). An output medium is registered and in the **Log output** menu the option **Immediate output no** is set.	The message is shown at the start of a program. By pressing the (S) key repeatedly, the message disappears and the program starts as follows. The oldest log is deleted in the process. Set the autoclave to **Immediate output yes** (see page26, Immediate automatic output of logs). Delete printer memory (see page 29, Deleting logs in the internal log memory), if necessary, output all saved logs first (see page 28, Output all saved logs). In the **Log output** menu, remove the output medium by setting the option **No output medium**.
Please carry out maintenance	The maintenance message is activated because the device has reached the specified number of batches.	The message is shown every time a program is started. By repeatedly pressing the (S) key the message disappears and the program starts. Keep message: Press the (S) key 2× at the start. Have your specialist supplier’s customer service carry out the maintenance. **NOTE!** The maintenance counter will be reset by customer service.
Test not successful Leak rate: 3.2	The leak rate determined in the vacuum test is greater than the maximum permitted value of 1.3 mbar. Door seal, chamber flange soiled. Door seal not correctly seated.	Check that the door seal and the chamber flange are clean and if necessary clean them; see page 34. Inspect the door seal for damage and replace it if necessary; see page 35. Repeat the vacuum test while the autoclave is completely cold. Check that the door seal is correctly seated. Repeat the vacuum test while the autoclave is completely cold.
Caution! Battery empty	The battery voltage monitor for the internal battery detected an insufficient voltage value.	The battery must be replaced by your specialty supplier’s customer service.

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Error messages

Error message	Possible causes	What you can do
Error 1: Vacuum system	Door seal, sealing surface on the chamber soiled or faulty.	Check the door seal and the sealing surface of the chamber for faults and soiling and clean, see page 34. Inspect the door seal for faults and replace it if necessary; see page 35.
	Door seal incorrectly seated.	Check that the door seal is correctly seated. Check that the autoclave is positioned correctly; page 10. Check for any instruments, filter paper or the like that may have fallen onto the floor of the chamber.
	The chamber filter is blocked.	Inspect the chamber filter for contamination and clean if necessary. Use the chamber filter key for this purpose (see page 36, “Cleaning the chamber filter”).
Error 2: Steam generator	Autoclave is overloaded.	Ensure the load sizes are correct (page 15, “Loading the autoclave”).
	Reduced heating capacity because the mains voltage is too low.	Check the building’s electrical installation; try operating the autoclave on another circuit. Contact your specialist supplier if this message occurs repeatedly.
Error 4: Pressure release	The condensate drain filter is contaminated.	Unscrew the filter for the condensate drain (in the floor of the chamber towards the back) and inspect for contamination; page 36. If this error occurs repeatedly, please contact your specialist supplier.
Error 6: Ventilation	The sterile filter is contaminated and a corresponding warning appeared beforehand.	Change the sterile filter. Remove the sterile filter and insert a new one.
Error 8: Time base	The maximum limit for the difference between the program run time and the internal computer clock has been exceeded.	If this error occurs repeatedly, please contact your specialist supplier.
Error 9: Door open	The sliding latch was pushed upwards when a program was running.	Push the sliding latch down to the stop. Correct message on the display: **`Door locked`**. If this error occurs repeatedly, please contact your specialist supplier.
Error 10: Overheated steam generator	Error on the temperature regulator on the overheat control	After terminating the program and starting a program immediately this error message may occur; after a pause of 2 minutes repeat the program start again. If this error occurs repeatedly, please contact your specialist supplier.
Error 12: Door locking	The locking pin of the door is hard to move.	Check the smooth movement of the door locking pin. Do so by pressing the door locking pin (see page 8, Fig. 3/3) If this error occurs repeatedly, please contact your specialist supplier.

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Error message	Possible causes	What you can do
Error 14: No feed water	This error message appears after starting a program.	See the warning message **`Warning No feed water`**.
Error 21: Preheating	The monitoring period between activating the preheating function and reaching the required preheating temperature was exceeded.	If this error occurs repeatedly, set the **`Automatic preheating`** function to "No" (see Section 19, Select automatic preheating) and contact your specialist supplier.
Error 22: Preheating too hot	The maximum preheating temperature has been exceeded.	If this error occurs repeatedly, set the **`Automatic preheating`** function to "No" (see Section 19, Select automatic preheating) and contact your specialized dealer.
Error 31: System leak	During the vacuum test program, the maximum permissible pressure was exceeded after the evacuation pressure had been reached (very large leak).	Repeat the vacuum test; if the error message appears again, please contact your specialist supplier.
Error 32: Power failure/ Sterilize sterile filter	After starting a program there was a failure in the operating voltage. The error message appeared after the operating voltage was restored. If a power failure occurs when a program has started and has positive pressure, a message will also be shown requesting that the sterile filter be sterilized because this has become moist and possibly contaminated with micro-organisms. Autoclave was switched off while a program was running.	Check the building's electrical installation. If you cannot detect a fault, please contact the customer service of your specialist supplier. Replace the sterile filter at the rear of the autoclave. Sterilize the filter using Quick Program B, after the program is finished, insert the filter again. Only terminate a running program using the (S) key (see also page 21, Manual termination of a program).
Error 34: Sterilization TU1	The temperature has fallen below the minimum permissible sterilization temperature (temperature sensor 1).	Operate device with a smaller load; if necessary, carry out a vacuum test. Check the door seal for wear. If this error occurs repeatedly, please contact your specialist supplier.
Error 35: Sterilization TO1	The temperature has exceeded the maximum permissible sterilization temperature (temperature sensor 1).	Carry out the vacuum test. If this error occurs repeatedly, please contact your specialist supplier.
Error 36: Sterilization PU	The sterilization pressure has fallen below the minimum permissible limit.	Operate device with a smaller load; if necessary, carry out a vacuum test. Check the door seal for wear. If this error occurs repeatedly, please contact your specialist supplier.
Error 51: Sterilization TU2	The temperature has fallen below the minimum permissible sterilization temperature (temperature sensor 2).	Operate device with a smaller load; if necessary, carry out a vacuum test. Check the door seal for wear. If this error occurs repeatedly, please contact your specialist supplier.
Error 52: Sterilization TO2	The temperature has exceeded the maximum permissible sterilization temperature (temperature sensor 2).	Carry out a vacuum test. If this error occurs repeatedly, please contact your specialist supplier. See also error 35.

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Door emergency open in case of power failure

DANGER!

The autoclave must be completely decompressed!

Failure to observe this precaution may result in severe burns or injuries.

- Steam must not escape between the sterile filter and the rear of the autoclave.
- The sliding latch must be easy to move up and down.
- The door must be able to be pushed inwards about 2 mm using slight pressure.
- The autoclave must be left to cool down. Metal parts such as the door and the chamber can be hot.

If the door cannot be opened, because of a power failure for example, please proceed as follows while complying with the above safety instructions:

1. Switch the autoclave off at the power switch and pull the power plug out from the socket.
2. Insert the lever for emergency unlocking of the door with the long side between the door and the side wall of the autoclave. The kink faces forwards and the lever is located at the same height as the sliding latch.

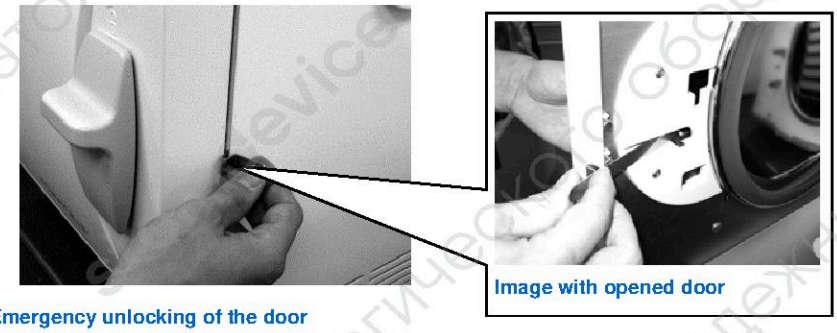


Fig. 7 Emergency unlocking of the door

3. If the lever is in the guide, pull it forward with your right hand. With the other hand, push the sliding latch upwards.
4. Open the door.

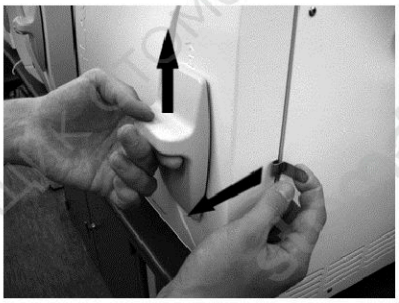


Fig. 8 Opening the door

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Replacing the fuses

If the fuses have blown (see page 8, Fig. 1/10), proceed as follows to replace them:

1. Switch the autoclave off at the power switch and pull the power plug out from the socket.
2. Open the door manually as described in the section “Door emergency open in case of power failure”. Unscrew the two screw caps of the fuse holder (page 8, Fig. 1/10) on the bottom front of the autoclave using a screwdriver or a coin.

On the inside of the door there are two replacement fuses (see marking).

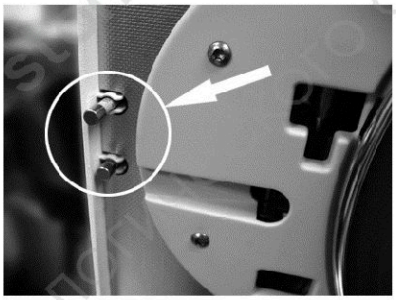


Fig. 9 Replacement fuses on the inside of the door

3. Remove the faulty fuses and insert the new replacement fuses firmly into the fuse holder.



Fig. 10 View front, bottom right

4. Screw the caps of the fuse holder on the bottom front of the autoclave on again.
5. Insert the power plug of the autoclave back into the socket and switch the autoclave on again at the power switch.

If the fuses fail repeatedly, please contact the customer service of your specialist supplier.

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Glossary

aqua dem
-> demineralized water

aqua dest
-> distilled water

Heating time
Time after switching the autoclave on or after starting a sterilization program that is required to heat the double-jacket steam generator before the sterilization procedure starts; the length of time required depends on the temperature used for sterilization.

Authorized persons
Technician from the depot or employee of a customer service nominated by Sirona who has been trained by Sirona.

BGV A1
German Guidelines for Occupational Health and Safety – Principles of Prevention

Bowie - Dick test
Steam penetration test with a standard test package; described in DIN EN 285; test is validated for large sterilizers.

CF card
CompactFlash card; memory card for digital data.

Batch
Load of sterilized items that have jointly undergone the same sterilization program.

Demineralized water
Water without the minerals that are normally present in spring or tap water; obtained from normal tap water using an ion exchange process. It is used here as feed water.

Distilled water
Also referred to as aqua dest from the Latin aqua destillata; is generally free of salts, organic material, and microorganisms and is obtained from normal tap water or pre-purified water using distillation (vaporization and subsequent condensation). It is used here as feed water.

DGSV
Deutsche Gesellschaft für Sterilgutversorgung [German Society for Sterile Supply]; the training guidelines of the DGSV are listed in DIN 58946, part 6 as “Requirements for personnel.”

DIN 58953
Standard – Sterilization, sterile supply

DIN EN 867-5
Standard – Non-biological system for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for smaller sterilizers Type B and Type S

DIN EN 868-8
Standard – Packaging for terminally sterilized medical devices

DIN EN ISO 11140-1
Standard – Sterilization of health care products – Chemical indicators – Part 1: General requirements

DIN EN ISO 11607-1
Standard – Requirements for materials, sterile barrier systems, and packaging systems; this standard is a harmonization of DIN EN 868 Part 1 and the international standard DIN EN ISO 11607.

DIN EN 13060
Standard – Small steam sterilizers

DIN EN 285
Standard – Sterilization – Steam sterilizers – Large sterilizers

Dynamic sterilizer chamber pressure test
Used to verify that the rate of pressure changes in the sterilizer chamber during a sterilization cycle does not exceed a value that could lead to damage of the packaging material [DIN EN 13060].

Dynamic sterilizer chamber pressure test
Used to verify that the rate of pressure changes in the sterilizer chamber during a sterilization cycle does not exceed a value that could lead to damage of the packaging material [DIN EN 285].

Single wrapping
Instruments wrapped in a single package—contrasted with multiple wrapping

Evacuation
Creation of a vacuum in a container

Fractionated vacuum procedure
Technical procedure for steam sterilization; involves repeated evacuation of the sterilizer chamber alternating with steam intake.

FTP
(File Transfer Protocol) is a data transfer protocol used to transmit files via the Internet. These data can contain files or even information. Special FTP programs (FTP clients) are used to upload the data to a server.

Mixed load
Wrapped and unwrapped items to be sterilized in a single load

Hollow A
Object open on single end for which:
$1 \leq L/D \leq 750$ and $L \leq 1500$ mm or
an object open on both ends for which:
$2 \leq L/D \leq 1500$ and $L \leq 3000$ mm and which is not a hollow B object
L...length of the cavity
D...diameter of the cavity
[DIN EN 13060]

Hollow B
Object open on single end for which:
$1 \leq L/D \leq 5$ and $D \geq 5$ mm or
an object open on both ends for which:
$2 \leq L/D \leq 10$ and $D \geq 5$ mm
L...length of the cavity
D...diameter of the cavity [DIN EN 13060]

Initialize
Production of a certain initial state for software when starting up

Condensate
Liquid (e.g., water) that is produced upon cooling from the vapor state and thus condenses.

Corrosion
Chemical change or destruction of metallic materials by water and chemicals

Contamination
Here: Soiling of the sterilizer load with undesired or harmful substances

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Empty-chamber test
Test with no load; carried out to assess the performance of the sterilizer without the influence of a load; allows the temperatures and pressures reached to be checked against the specified settings. [DIN EN 285]

Conductivity
The reciprocal of the electrical resistivity; its unit is microsiemens/centimeter (µS/cm); the more material dissolved in the water, the better it conducts electrical current and therefore the higher its conductivity. Distilled water ideally has a conductivity of zero.

Conductivity test
Measurement of the conductivity

Air leak—Testing for leakage of air
Air leakage is a leaky point through which unwanted air can penetrate or escape; the air leak test is used to verify that the volume of the air penetration into the sterilizer chamber during the vacuum phase does not exceed a value that prevents the penetration of steam into the sterilizer load and that the air leakage is not a possible cause of renewed contamination of the sterilizer load during drying.

Solid
Without hollow cavities or spaces, compact, dense, closed

Solid load—Testing with a solid load
Used to verify that for the values set on the controls the required sterilization conditions are reached within the entire load. The load must represent the greatest mass of solid instruments that the sterilizer as defined by DIN EN 285 is designed to sterilize. [DIN EN 285]

Multiple wrapping
For example, instruments sealed or wrapped in film are also in a container or a container wrapped in textiles.

MPBetrieb
German Medical Device Operators Ordinance that applies to setting up, operating, using, and maintaining medical devices in accordance with §3 of the German Medical Devices Act with the exception of medical devices for clinical trials or performance evaluations

Standard compliant
Compliance with all relevant standards

Porous
Permeable to liquids and air, e.g., textiles

Porous small elements
Made of materials that can absorb fluids (e.g., liquids)

Porous part load—Testing with porous part load
Used to verify that for the values that are set on the controls the steam rapidly and evenly penetrates the defined process challenge device [DIN EN 13060]

Porous complete load—Testing with porous complete load
Used to verify that for the values set on the controls the required sterilization conditions are reached within porous loads with the maximum density that the sterilizer as defined by DIN EN 285 is designed to sterilize [DIN EN 285]

Process evaluation system
Also self-monitoring system—observes itself, compares sensors during a running program with each other

Self-monitoring system
Process evaluation system

Separate steam generator
The steam generator is located outside the sterilization chamber. This protects the sterilization chamber from overheating.

Retardation of boiling
The phenomenon whereby under certain conditions liquids can heat up to temperatures above their boiling point without boiling; this state is unstable; only a slight vibration can lead to the very rapid formation of a large gas bubble which expands explosively.

Feed water
Required to generate the steam for the sterilization; guide values for the water quality defined in DIN EN 13060, Annex C

Sterile barrier system
Closed minimum packaging that prevents the penetration of microorganisms; e.g., by sealing of closed bags, closed re-usable containers, folded sterilization wraps, etc.

Sterile load
Also referred to as a batch, items that have been sterilized, therefore sterile items

Sterilization chamber
Interior of a sterilizer, holds the items to be sterilized

Items to be sterilized
Non-sterile, items that are yet to be sterilized

TCP
Transmission **C**ontrol **P**rotocol; refers to a standard protocol for connecting computers and networks.

Vacuum
Colloquial: space without material;
in the technical sense: volume with reduced gas pressure (at least air pressure)

Vacuum drying
Gentle drying; the items to be dried are subjected to negative pressure which lowers the boiling point and thus leads to evaporation of the water even at low temperatures.

VDE
Verband der Elektrotechnik, Elektronik und Informationstechnik e.V., German Association for Electrical, Electronic and Information Technologies

Soft sterilization wrapping
For example, paper bag or transparent sterilization wrap

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Technical Data

Model name	DAC PROFESSIONAL+	DAC PROFESSIONAL
Device dimensions (H×W×D)	48.5 × 42.5 × 75.5 cm	48.5 × 42.5 × 63 cm
Sterilization chamber (diameter×D)	Ø 25 cm × 45 cm	Ø 25 cm × 35 cm
Volume of the sterilization chamber	22.6 liter	17 liter
Volume of the storage tank	Feed water side (left chamber): 5 liter (approx. 7 cycles); waste water side (right chamber): 3 liter	
Weight (empty)	50 kg	45 kg
Electric power	2100 W	
Electrical connection	220–240 V (max. voltage range 207–253 V), 50/60 Hz, building's electrical installation recommendation: Separate electric circuit with 16 A fuse, additional FI circuit breaker 30 mA	
Noise emissions	Sound pressure level @ 1 m distance, < 65 db (A)	
Waste heat (with max. solid load)	0.9 kWh	
Ambient temperature	16–26 °C	
Relative humidity	30–60 %	
Length of the power cable	1.35 m	
Quality of the feed water	Distilled or demineralized feed water as defined by DIN EN 13060, Annex C (for central ion exchanger max. conductivity 5 µS)	
CE mark	CE 0123, CE 0035	
Degree of protection (defined by IEC 60529)	IP20	

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Accessories

	Article	Order no.*	
		DAC PROFESSIONAL +	DAC PROFESSIONAL
Holders	A for 5 tablets or 3 standard tray cassettes	65 32 233	64 86 133
Process challenge device system	Test set for Helix test	58 92 042	
	Additional indicators for Helix test set (100 pieces)	59 03 641	
Water preparation unit	NitraDem Direct Connect	62 59 852	
	NitraDem filter	61 98 431	
	SIRODEM	58 86 168	
	NitraDem installation kit	62 59 076	
	Water pistol	62 59 084	
	Cartridge for SIRODEM	58 92 026	
For the documentation	NITRAflash CF card incl. card reader	61 34 394	
	NITRAprint log printer	61 17 324	
Miscellaneous	Main fuse 16 A	61 26 752	
	Door seal	65 32 241	
	Sterile filter	61 26 093	

*All items listed can be purchased from specialist suppliers

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Subject to changes resulting from further technical developments.

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