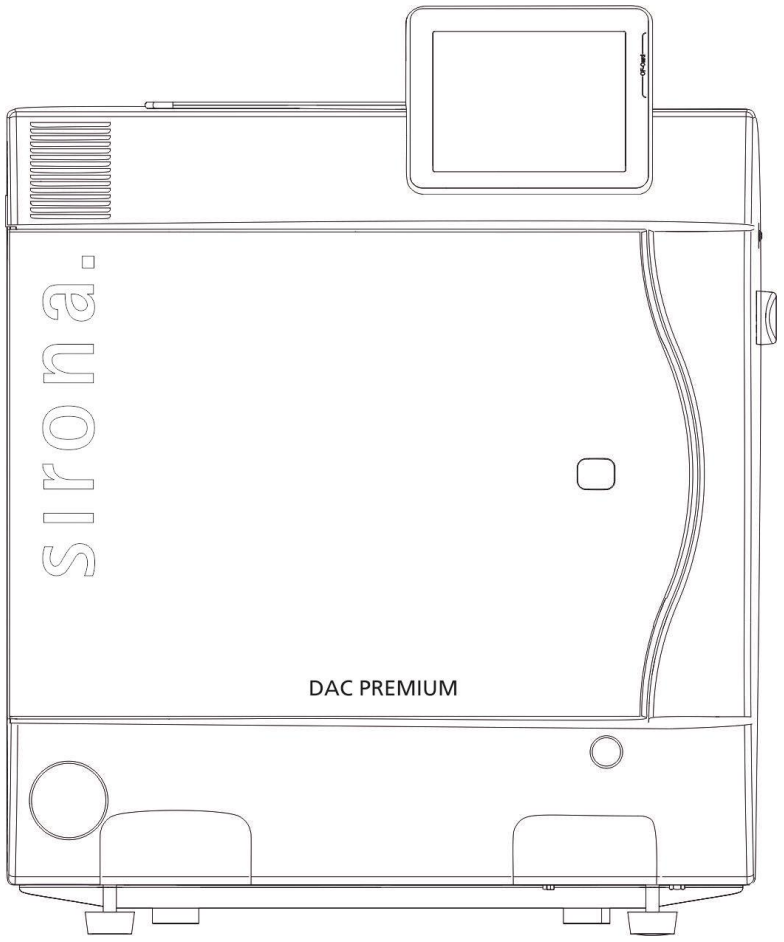
New as of: 03.2016

sirona
The Dental Company

DAC PREMIUM
DAC PREMIUM+

Operating Instructions

English



Dear customer, ...

We should like to extend our thanks for your purchase of this autoclave.

This autoclave was manufactured and checked according to strict quality criteria. However, please read this User Manual thoroughly prior to start-up. The long-term functional effectiveness and preservation of your autoclave depends above all on the careful preparation of instruments and the maintenance of the equipment.

We wish you success and enjoyment with the DAC PREMIUM/DAC PREMIUM^{+}.

Your DAC PREMIUM/DAC PREMIUM^{+} team

CE 0123

For doctors, doctor's assistants and service personnel

Please read this User Manual before operating the autoclave. The manual contains important safety information. Keep the User Manual in a safe place close to your autoclave. It represents a component of the product.

Preface

Thank you for purchasing this DAC PREMIUM/DAC PREMIUM^{+} autoclave from Sirona.

The DAC PREMIUM/DAC PREMIUM^{+} autoclaves are described together in this User Manual. They are alike except for their boiler depth and device depth.

System designation

In these instructions, the device name autoclave is used to refer to the DAC PREMIUM/DAC PREMIUM^{+} steam sterilizers.

User manual

The User Manual contains important precautions and information which you need to operate the autoclave. Read this manual completely.

Avoid dangers

Please read these operating instructions carefully before starting up the autoclave.

About this manual

Symbol	*Meaning*	*Explanation*
 **Danger!**	Health risk	Indicates a dangerous situation which, if not avoided, could entail slight to life-threatening injuries.
Caution!	Be sure to follow	Draws your attention to a situation which, if not avoided, could result in damage to the instruments, the practice fittings or the autoclave.
	Important information!	Draws your attention to important information.

Table 1: Meaning of the symbols used in the User Manual

Example emphasis	*Meaning*	*Explanation*
→double-jacketed steam generator	Glossary entry	Words or phrases marked with an arrow are explained in the glossary. The glossary is sorted alphabetically. It can be found at the end of this manual.
`Universal program`	Software citation	Words or phrases that appear on the →touch display of the autoclave are identified as a software citation.
Chapter 6 – Logging	Cross-reference	Reference to another text section within these instructions.
Figure 1/(5)	Cross-reference	Reference to a detail in a figure – in the example, to part no. 5 in Figure 1.

Table 2: Meaning of the highlighted text in the User Manual

Symbol	*Meaning*	*Explanation*
	Health risk	Indicates a hot surface. In the case of the failure of the radiator fan, the radiator fins may be hot.
	Health risk	Indicates that for the operation of the autoclave, the safety instructions in the User Manual must be observed.

Table 3: Meaning of the symbols on the autoclave

Safety Instructions

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

Term(s)

- Do not sterilize any liquids with this autoclave.

Power cord and connector

- Never damage or alter the power cord or plug.
- Never operate the autoclave if the power cord or plug is damaged.
- Never pull on the power cord to remove the plug from the electric outlet. Always hold directly onto the plug.

→Double-jacketed steam generator

- After turning off the autoclave, it will remain under pressure for some time. Check the pressure gauge of the manometer below on the front of the autoclave.

Set up, installation and initial start-up

- Only have the autoclave set up, installed and commissioned by individuals who are →authorized by Sirona.
- Only operate the autoclave in non-hazardous areas.
- Only have the electrical connections and connections for the water supply and drainage established by a professional.

Preparation and sterilization of textiles and instruments

- For the preparation and sterilization of textiles and instruments, follow the instructions of the textile and instrument manufacturer.
- For the preparation and sterilization of textiles and instruments, comply with the relevant standards and guidelines, such as RKI →and →DGSV.
- Only use wrapping materials and systems which, according to manufacturer data, are suitable for steam sterilization.

Program interruption

- Be aware that when you open the door after a program interruption, depending on the time of the program interruption, hot water vapor may come out from the boiler.
- Depending on the time of the program interruption, the load may not be sterile. Please follow the clear instructions on the →display of the autoclave. If necessary, re-sterilize the respective →item to be sterilized after re-wrapping.

Removing the sterilized items

- Never open the door by force.
- To remove the tray, use a tray lifter.
  Never touch the sterilized items, the boiler or the inside of the door →with your bare hands. The parts are hot.
- Check the wrapping of the sterile items for damage when removing them from the autoclave. If a wrapping is damaged, rewrap the sterilized item and sterilize it once again.

Maintenance

- Only have the maintenance conducted by →authorized individuals.
- Maintain the specified servicing intervals.

Moving the autoclave

- Only carry the autoclave with two people.
- Use suitable carrying straps for moving the autoclave.

Malfunctions

- If repeated error messages appear during the operation of the autoclave, shut off the autoclave.
- Only have the autoclave repaired →by authorized personnel.

Table of contents

Chapter 1 – Performance Specifications

In this chapter, you will see

- **under what conditions and for what purpose you can use this autoclave**
- **what benefits you can achieve by using this autoclave**
- **which sterilization programs you can use**

Intended Use

Area of application

The autoclave is designed for use in the medical field: for example, in general medical and dental practices.

Sterilization procedures

According to →DIN EN 13060, the autoclave is a -B-Class sterilizer. Being a universal autoclave, it is suitable for demanding sterilization procedures. For example, you can sterilize narrow-bore instruments and transmission instruments – wrapped or unwrapped – as well as larger quantities of textiles.

Danger

Observe the following information when using the autoclave:

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

Doing so may lead to a delay in boiling, which could result in damage to the autoclave as well as to burns.

!

Caution

- Only use the autoclave for the usage stated in the technical documentation and only in connection with the equipment and components recommended by Sirona.
- As with the above-mentioned instrument preparation, the sterilization of instruments and textiles with this autoclave is also, pursuant to Section 2 MPBetreibV, only to be performed by qualified personnel.
- During sterilization, only use instruments, wrapping and textiles which, according to the manufacturer, are suitable for steam sterilization.

Failure to do so may result in damage and/or safety issues.

User benefits

Universal application

The autoclave sterilizes on the basis of the → fractionated vacuum process. This ensures the full and effective wetting and penetration of the →items to be sterilized with saturated steam. With this method, the entire sterilization is possible within a medical practice.

Large quantities
Limited time required
No pause times
Overheating protection

For the generation of the sterilizing steam, the autoclave uses a →double-jacketed steam generator. Permanent steam is present there upon heating. As a result, the walls of the →sterilization chamber have a defined temperature. The sterilization chamber is protected from overheating and you can sterilize large loads of instruments or
textiles in a very short time, along with achieving very good drying results.

Clean feed water

The autoclave operates with a disposable feed water system. This means that fresh →feed water is used for each sterilization. The quality of the feed water is continuously monitored via an integrated →feed water measurement. As a result, stains on instruments and soiling of the auto-

clave is prevented – as long as the instruments are carefully prepared.

Automatic feed water supply
The supply of →feed water for steam generation occurs automatically via the internal storage tank or water treatment system (e.g., NitraDem Direct Connect, SIRODEM).

Optimal drying of wrapped items to be sterilized
The drying of the →items to be sterilized occurs via the →vacuum. (→ vacuum drying). As a result, you have optimal drying results even with wrapped items to be sterilized.

Optimized total operating time
The autoclave works with an → electronic parameter control. As a result, the autoclave optimizes the total operation time of a program according to the load.

High degree of safety through comprehensive safety devices
At any time, the autoclave can verify the pressure and temperature in the sterilization chamber and does not allow the door to be opened in case of overpressure in the boiler. The motorized automatic door lock opens the door slowly by rotating the spindle lock and holds the door upon opening. Even in the case of pressure differences, a pressure compensation would occur up to the complete opening of the door.
The quantity and quality of the →feed water is tested.
A process evaluation system is integrated in →the electronics of the autoclave. During a program, it compares process parameters such as temperatures, times and pressures with each other. It monitors the parameters in terms of their limit values for control and regulation and ensures safe and successful sterilization.
A control system checks the components of the autoclave to ensure that they function and interact correctly.
If one or more parameters exceed the defined thresholds, the autoclave provides warnings or error messages and, if necessary, interrupts the program. After a program termination, please follow the instructions on the display.

Additional functional check
With the help of test programs, you can conduct an additional function control at any time.
With the vacuum test, you check the autoclave for leaks in the steam system.
With the → Bowie & Dick test, you check for sufficient steam penetration of porous items to be sterilized (e.g., textiles).

Effective batch documentation
The autoclave has an internal log memory. In this memory, all data of the completed sterilization programs are always stored automatically.
You can read the internal log memory immediately after the program ends or later. In doing so, you determine whether the log data will be output to one or more output media (e.g., log printer NITRAprint, NITRAflash CF Card, computer).

Overview of the sterilization program

Type check	*Universal program*	*Quick program B*	*Quick program S*	*Gentle program*	*Prion program*
Program type according to →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 leakage	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	X	X	X	X
→hollow body A	X	X		X	X
→simple 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 temperature	2.1 bar	2.1 bar	2.1 bar	1.1 bar	2.1 bar
Sterilization time	5.5 min	5.5 min	3.5 min	20.5 min	20.5 min
X = compliance with all applicable sections of the standard →DIN EN 13060					

Table 4: Overview of the sterilization program

Chapter 2 – Device description

In this chapter, you will see

- **which components are included in the standard package**
- **the components of the autoclave**
- **the safety devices of the autoclave**
- **how the controls are constructed and how to use them**
- **how the user interface menus are structured**
- **which water supply the autoclave requires**

Scope of delivery

Standard scope of delivery

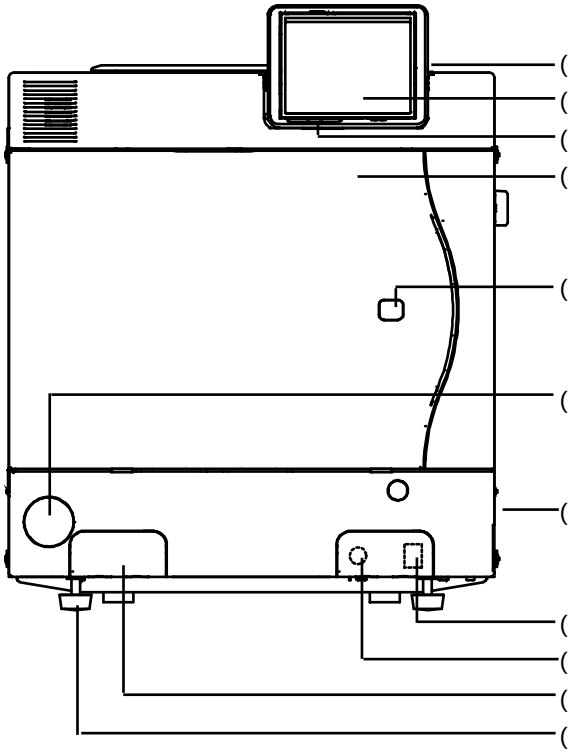
- DAC PREMIUM/DAC PREMIUM^{+}
- NITRAflash CF Card
- Information about downloading the technical data
- Factory test
- Declaration of conformity
- Holder for trays or cassettes
- Tray lifter
- 1 hose to drain the internal storage tanks
- Allen key for emergency opening of the door
- TORX wrench to remove the carrying straps

Optional

- Trays
- Standard tray cassettes
- Additional holder
- NITRAflash CF Card reader

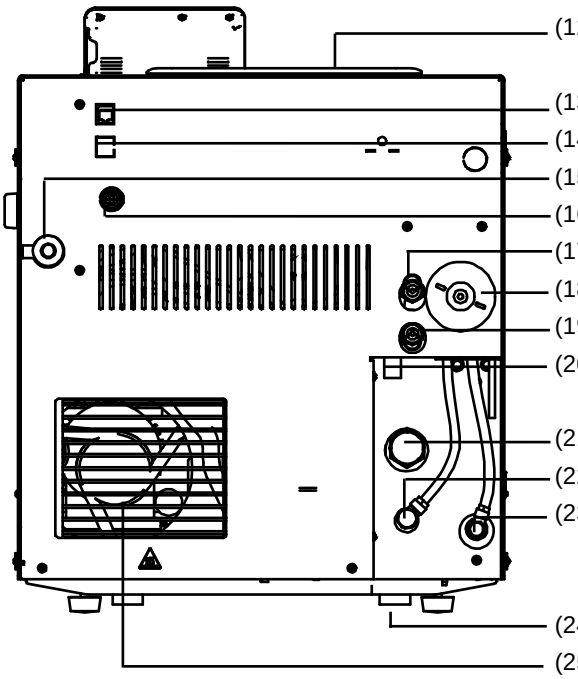
Views of the device

Front view



(1) Card slot for the →CF Card
(2) Touch display
(3) LED Status bar
(4) Door (open to the left)
(5) Cap for emergency opening of the door
(6) Cover cap for pressure gauge to indicate the pressure of the →double-jacket steam generator
(7) Power switch (hidden, accessible on side)
(8) Ethernet data connection 1*
(9) Reset button overheating protection*
(10) Quick couplings for draining the storage tank*
(11) Front equipment foot (adjustable)
* rear cover

Rear view



(12) Tank cap
(13) Ethernet data connection 2
(14) Ethernet data connection 3 (retrofittable)
(15) Power cable
(16) option of connecting a Flex Display
(17) Spring-operated safety valve boiler
(18) Sterile filter
(19) Spring-operated safety valve double-jacket
(20) Emergency overflow
(21) one-way outlet
(22) Pressure release connection
(23) Feed water flow (for NitraDem Direct Connect, swiveling screw fitting for hose ∅8x1, or straight)
(24) Rear equipment foot (attached)
(25) Cooler

Figure 1: Front and read view

Interior view

Figure 2: interior view

Useable space

The autoclave DAC PREMIUM/DAC PREMIUM^{+} differ only in their unit depth. As a result, their useable space varies in size.

	Diameter	***Depth***	***Volume***
DAC PREMIUM	25 cm	35 cm	18 liter
DAC PREMIUM^{+}	25 cm	45 cm	22 liter

Table 5: Dimensions of the useable space

Holder for the load

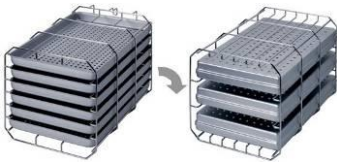
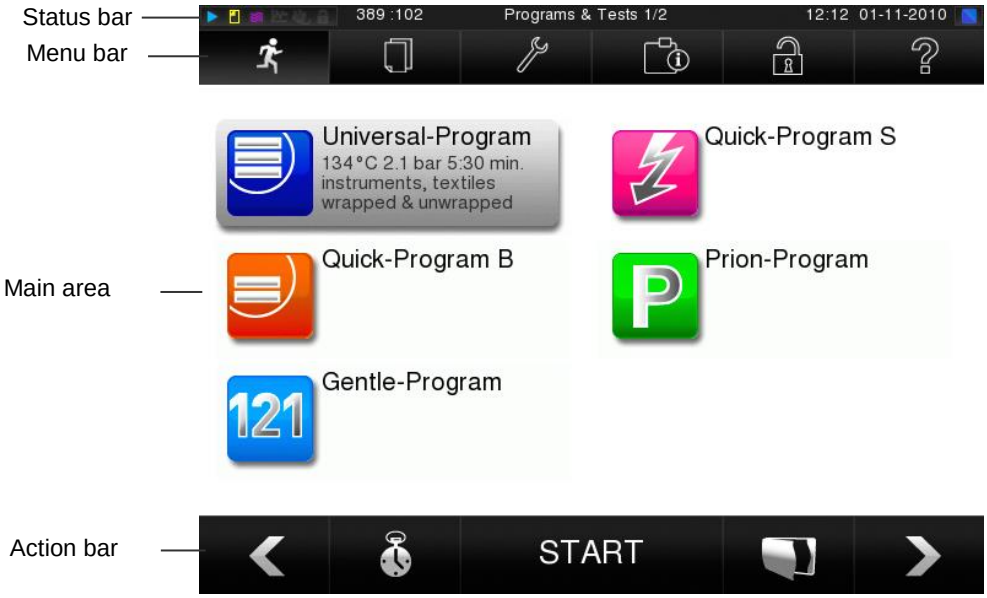


Figure 3: Holder C

The autoclave is always delivered with a holder for receiving trays or cassettes.
The holder (C) is standard and can receive either six trays or
– rotated by 90° – three standard tray cassettes.

Control panel

The control panel consists of a 5-inch color touch display.



Symbols in the status bar	*Meaning*
Programs/Tests	indicate whether a program/test is running
Immediate printout	indicates whether the immediate printout is activated/deactivated
Supplent drying	indicates whether the immediate supplent drying is activated/deactivated
Image logs	indicates whether the image logs are activated/deactivated
Power save mode	indicates whether the autoclave is currently in the energy save mode.
Service domain	indicates whether a service technician is logged into the service area
CF Card status	indicated whether a CF Card is inserted or whether a reading or writing access is occurring

Symbols in the menu bar	*Meaning*
Programs/Tests	Here, you can find all the sterilization programs and tests, such as the vacuum test, Bowie & Dick test, etc.
Output of records	Here, you can view the entire log list, logs of a demarcated time window, such as the day, the month, etc., or delete specific log types and logs.
Settings	Here, you can configure various settings, such as date and time, brightness, etc. In addition, you determine the "standard" log settings for the log output.
Information/ status window	Displays information about the software version and device data, such as total loads, maintenance counters, log settings, log storage and other technical data.
Service domain	Only for technicians
Help Menu	Depending on the selected window and the operating situation, provides intormation about the operation or function of the currently selected window.

Symbols in the action bar	*Meaning*
 ***Door open***	opens the door of the autoclave
 ***back***	changes from the previous window
 ***OK***	changes to the next window
 ***Cancel/ back without saving***	changes to the parent menu, leaves the window without saving
 ***Zoom (+)***	shows further details, such as further values at the end of a finished program
 ***Time delay***	changes to the "Time Delay" menu
 ***Clear***	deletes logs from the internal log memory/deletes the log printer or label printer stored as a standard
 ***Search***	Searches according to label printer(s)/log printer(s)

LED Status bar

The status bar, located at the edge of the display, displays a different color, such as in standby mode, when a program is running when warning and error messages appear.
blue - Standby, program is running, drying has not yet begun
green - drying is in progress, program successfully concluded
yellow- upon warning messages during a software update.
red - when error messages appear, program not yet completed

Feed water supply

For the steam generation, the autoclave requires → demineralized or →distilled →feed water. The supply of feed water occurs either via the internal storage tank or a water treatment system (e.g., NitraDem Direct Connect, SIRODEM). In this process, the autoclave sucks in the feed water automatically.

Feed water via the internal storage tank

If you use the internal storage tank for the feed water supply, you have to fill it manually from time to time. Use only commercially available water according to → DIN EN 13060, Annex C as → feed water.

Internal storage tank

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

Feed water via water treatment system

A water treatment system is connected to the drinking water network. It produces the →feed water required for the steam production of the autoclave. The feed water connection of the autoclave is directly connected to the water treatment system.

If you use a water treatment system, there is always enough feed water available. It is not necessary to fill the storage tank.

Water treatment systems
NitraDem Direct Connect
and
SIRODEM

The water treatment systems NitraDem Direct Connect and SIRODEM produce the optimum feed water quality for the autoclave. The selection of the respective system depends on the number of sterilizations per day as well as the load. Each Sirona autoclave can be supplemented with a water-treatment system.

NOTICE!

Please consult Sirona if you want to use water treatment systems of other manufacturers.

Switching on the autoclave

Danger

Please observe the following safety precautions when working with power cords and plugs:

- Never splice or alter the power cord.
- Never bend or twist the power cord.
- Never pull on the power cord to remove the power plug from the electric outlet. Hold it directly at the plug.
- Do not place heavy objects on the power cord.
- Never lay the power cord at locations where the cord can be jammed (e.g., doors or windows).
- Do not run the power cable along a heat source.
- Do not use nails, staples or similar objects to attach a cable.
- If the power cord or plug is damaged, decommission the autoclave. The power cord or plug must be replaced by →authorized individuals.

Failure to do so can damage the cable or plug and/or cause fire or an electric shock. Serious injury may result.

Insert the plug into the electric outlet
Turn on the power switch

If the autoclave is not connected to the power supply, plug the power cord into the electric outlet.
Turn the autoclave on at the power switch.

Following power-on

Preparation time

On the display, you see the startup screen **`Welcome`**. The →software of the autoclave is →initialized and its equipment components are checked. The water level of the →feed water in the →double-jacketed steam generator is automatically checked and, if necessary, ensured through the feed operation (feed pump runs). The feed water is preheated for steam generation.

After the autoclave has been switched on at the power switch, it requires →heating time for the one-time preheating of the →double-jacketed steam generator. For normal operation, this is

- DAC PREMIUM: 9 minutes
- DAC PREMIUM^{+}: 13 minutes

The display will show the program menu after each time that it has been turned on. The **`universal program`** is selected by default.

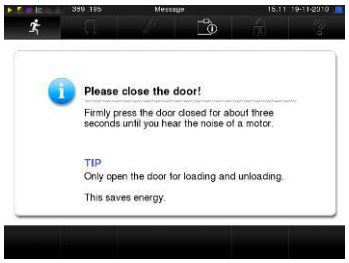
Closing the door

Caution

Observe the following information when closing the door of the autoclave:

- Do not push the door too lightly on the housing of the autoclave.
- Keep the door pressed for at least 3 seconds.
- Never slam the door.

Doing so may impair the functionality of the door lock mechanism.



The autoclave is equipped with a motor-driven automatic door lock with threaded spindle.
To close the door, press it securely.
With the start of a program, the door closes pressure-tight.

Closed door

Only when the door is closed is it possible to enter information on the →display of the autoclave.

NOTE!

Leave the door open only for loading and unloading the autoclave.

Chapter 3 – Commissioning

In this chapter, you will see

- **who may set up, install and commission the autoclave**
- **the requirements you need to set up, install and commission the autoclave**
- **where you can find further information**

Conditions for setting up, installing and commissioning

Danger

- Only have the autoclave set up, installed and commissioned by individuals who are →authorized by Sirona.
- According to the currently valid VDE regulations, the autoclave is not suitable for operation in areas subject to explosion hazards.

Failure to do so may result in damage to the autoclave and/or to injuries.

!

Attention

- The autoclave is intended for use outside the patient environment. The minimum distance from the treatment area must be at least 1.5 meters in radius.

Failure to do so may result in damage to the autoclave and/or to injuries.

Requirements of the installation location

Location

Set the autoclave in a dry and dust-protected location. The humidity should be 30 - 60 % and the ambient temperature 16 - 26 °C.

!

Attention

- Keep the predetermined distance from the surrounding surfaces on the sides and above the autoclave absolutely free.

Failure to observe this precaution may result in overheating. This could affect the function of the autoclave, shorten the lifespan of the vacuum pump and result in extended running times.

Distance from the surrounding surfaces

The distance to the surrounding surfaces has to amount to at least 5 centimeters on both sides and 10 centimeters at the back. The autoclave should be freely accessible from above so that the backup storage tank can be filled and good ventilation is provided.

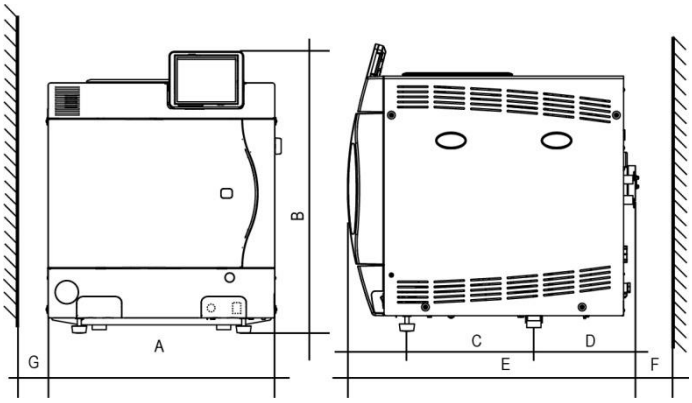
Space requirements		DAC PREMIUM	DAC PREMIUM+
	Width	A = 47 cm	A = 47 cm
	Height	B = 56.5 cm	B = 56.5 cm*
	Depth	C = 25 cm	C = 36 cm
		D = 18 cm	D = 18 cm
		E = 57.5 cm	E = 69 cm
		F = 10 cm	F = 10 cm
		G = 5 cm	G = 5 cm

Table 6: Space requirements of the autoclave

additional space for feed water supply
Space requirements for the water treatment system

Along with the autoclave, you may need space for a water treatment system for the feed water supply.

- Attachment next to the autoclave or above or below the autoclave (e.g., cabinet)

	Width	*Height*	*Depth*	*Diameter*
SIRODEM		60 cm		10 cm
NitraDem Direct Connect	32 cm	26.5 cm	12 cm	
NitraDem filter	29.5 cm	28.5 cm	28.5 cm	

Table 7: Space requirements for NitraDem / SIRODEM

Arrange connections

Danger

- Only have the electrical connections and connections for the water supply and drainage established by a professional.

Failure to do so can cause a short circuit and/or fire and/or water damage and/or electrical shock.
Serious injury may result.

Electrical connection

Provide the following electrical connections for the autoclave:

- Circuit with 220 - 240 V and 50/60 Hz
- 16 A separate fuse – at least Automatic Machine Type B
- RCCB 30 mA
- Power rating 3400 W

Waste water outlet

You can have the autoclave connected directly to the waste water either via the pressure release port (see page 8, Figure 1/(21)) or via the one-way outlet (see page 8, Figure 1/(22)).
Please refer to the installation instructions in the service manual regarding this process.

NOTICE!

The waste water hose must be able to be installed without sagging and with a steady incline.
For waste water paths that are longer than two meters, Sirona recommends the fixed installation of HT (high temperature) tubing by a professional installer.

Prerequisite for commissioning

For commissioning, the following prerequisites have to be met:

- The feed water supply must be ensured. For initial filling of the steam generating system, the autoclave requires about three liters →feed water.
- The power supply of the autoclave must be ensured.
- If available, the Nitra Flash →CF Card should be inserted in the card slot.

Chapter 4 - Sterilization

In this chapter, you will see

- **the requirements you need to create a problem-free sterilization**
- **what you should consider in the preparation of the items to be sterilized**
- **how to properly load the autoclave**
- **what programs you need for different purposes**
- **how to start a program**
- **which phases a program goes through**
- **how to interrupt a program**
- **how to recognize that the sterilization has been successfully completed**
- **what you can do to improve the drying results**
- **what to consider when you remove the sterilized items**

Creating conditions

You create the conditions for a smooth sterilization process as follows:

Provide feed water

- If you use the internal water tank for the feed water supply, check the level of the feed water tank (right side) and, if necessary, add fresh feed water up to MAX mark.
- If you use a water treatment system, such as NitraDem Direct Connect or SIRODEM, and the water inlet is closed, open it. If the water reservoir of the NitraDem Direct Connect is empty, turn the water tap off at least one hour prior to sterilization.

Switch-on

- If the autoclave is not already on, turn it on via the power switch. (see page 13, **Switching on the autoclave** and **Following power-on**.)

Insert CF Card

- If you want to use the CF Card as the output medium for logs and the NITRAflash CF Card is not inserted, insert it into the card slot (see page 30, **CF Card as output medium**).

Manufacturer's Recommendation for Daily Operation

Observe the manufacturer's recommendation by Sirona for the routine operation of Class B autoclaves.

Preparing the items to be sterilized

An essential prerequisite for the safe disinfection and sterilization of →the items to be sterilized is the proper cleaning and care of the items to be sterilized according to the manufacturer's instructions. In addition, the materials, cleaning agents and treatment processes which are used are of importance.

NOTE!

Sterilize textiles and instruments separately from each other in separate sterilization containers or sterilization wrapping, as far as this is possible.

Textiles

During the preparation of textiles and the introduction of the textiles into the sterilization container, observe the following:

Danger

- Observe the recommendations of the textile manufacturer regarding preparation and sterilization and comply with the relevant standards and guidelines, such as →RKI and →DGSV.
- Align the folds of the textiles parallel to each other.
- Stack the textiles as vertically as possible and not too tight in the sterilization containers, so that flow channels may be formed.
- If textile packages cannot be held together, wrap the textiles in sterilizing paper.
- Only sterilize dry textiles.
- The textiles may not have direct contact with the floor or walls of the sterilization chamber; otherwise, they will fill with absorbed →condensate.

Doing so may result in the steam penetration of the laundry package being impeded and/or poor drying results. As a result, the textiles would not be sterilized, which could endanger the health of your patients and dental team.

Instruments

Observe the following during the treatment of used and brand new instruments:

Danger

- It is imperative that you observe the recommendations of the instrument manufacturer regarding preparation and sterilization and that you comply with the relevant standards and guidelines, such as →BGV A1, →RKI and →DGSV.
- Clean the instruments very thoroughly: for example, by using a cleaning and disinfecting device.
- Rinse the instruments to complete the disinfection and cleaning process with →demineralized or distilled water and dry the instruments thoroughly afterwards with a clean, lint-free cloth.
- Only use care products which are suitable for steam sterilization. Ask the manufacturer about such care products.

Failure to do so could loosen up any present debris during the sterilization under steam pressure. Residues of disinfectants and cleaning agents lead to →corrosion. Increased maintenance and impaired function of the autoclave can result.

Unsuitable care products, such as water-repellent care products or oils which are impenetrable to steam can result in non-sterile instruments. This endangers your health and the health of your patients.
When using the following devices, it is imperative to observe the processing instructions of the instrument manufacturer.

- Ultrasound equipment
- maintenance equipment for handpieces and contra-angles
- cleaning and disinfecting devices

Loading the autoclave

The sterilization be only be effective and the drying can only provide good results when the autoclave is properly loaded.

NOTE!

Use the proper holder whenever placing trays or cassettes in the boiler. Use perforated trays, such as the trays from MELAG. Only in this way can →condensate run off. Using closed components or half shells for receiving the items to be sterilized will result in poor drying. Please note that the use of tray liners made of paper could also cause poor drying results.

Wrapping

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

Attention

Use only wrapping materials and systems which meet the standard DIN EN 868.

You can use reusable rigid wrapping (such as standard tray cassettes) or soft wrapping (such as clear sterilization wrapping, paper bags, sterilizing paper, textiles, or fleece).

Closed sterilization containers

Use sterilization containers made of aluminum. Aluminum conducts and retains heat well, thus speeding up the drying process.
Observe the following when using closed sterilization containers to accommodate →the items to be sterilized:

Attention

- Closed sterilization containers must be perforated or equipped with valves at least on one side (below, if possible).

Not doing so leads to insufficient steam penetration, and the sterilization could be unsuccessful. In addition, the condensate will not able to drain properly,resulting in poor drying results.This can ultimately lead to unsterile instruments and, thereby, endanger the health of patients and the dental team.

Stacking the sterilization containers

The sterilization containers (e.g.,from MELAG) meet all the requirements for successful sterilization and drying. They are perforated in the cover and on the bottom and are equipped with disposable paper filters.
If possible, only sterilization containers of the same size should be stacked one above the other so that the →condensate can drain laterally along the walls.

Attention

- Make sure that the stacking of the sterilization containers does not cause the perforation to be covered.

Failure to do so can cause the dripping →condensate to not be able to reach the bottom of the boiler. This would cause sensitive →items to be sterilized to be drenched below, in turn causing poor drying results. This can ultimately lead to unsterile instruments, thereby endangering the health of your patients and dental team.

Soft sterilization wrapping

→Soft sterilization wrapping can be sterilized in sterilization containers as well as on trays. Observe the following when using soft sterilization wrapping, such as MELA*fol*®:

! Attention

- Stand →soft sterilization wrapping upright and at a short distance from each other.
- Do not set several soft sterilization wrapping flat on top of each other on a tray or in a container.
- If the seal ruptures during sterilization, the cause may be that he package is too small. If this is not the case, rewrap the instruments and sterilize them again.
- If the seal tears during sterilization, extend the seal impulse on the foil sealer or create a seal with a double seam.

Failure to do so can ultimately lead to unsterile instruments, thereby endangering the health of your patients and dental team.

Multiple wrapping

The autoclave works with a →fractionated vacuum method. This allows the use of →multiple wrapping.

Mixed loads

Observe the following for the sterilization of mixed loads:

- Textiles always toward the top
- Sterilizing container towards the bottom
- Transparent sterilization wrapping and paper wrapping towards the top – Exception: in combination with textiles, towards the bottom
- Clear sterilization wrapping as upright as possible; when this is not possible, with the paper side pointing downwards

	DAC PREMIUM		**DAC PREMIUM^{+}**	
	Instruments	Textiles	Instruments	Textiles
Maximum mass per item	2 kg	2 kg	2 kg	2 kg
Load variations Holder C *	max. 6 trays, 290 mm deep max. 3 sterilizing containers15 K Max. 3 sterilization containers 15M Max. 2 sterilization container 15G 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		max. 6 trays, 420 mm deep max. 6 sterilizing containers 15 K Max. 3 sterilization containers 15M Max. 2 sterilization container 15G Max. 6 sterilization containers 17K Max. 3 sterilization containers 17M Max. 1 sterilization container 17G Max. 3 swab drums 17R Max. 2 sterilization containers 23M Max. 1 sterilization container 23G Max. 2 swab drums 23R Max. 2 sterilization containers 28M Max. 1 sterilization container 28G Max. 3 standard tray cassettes	
Maximum total mass	6 kg	2 kg	7 kg	2.5 kg
* Holders, trays by Sirona see **Annex A**. Information relating to sterilization containers by MELAG				

Table 8:Loading variations, e.g., Holder C, and maximum load

Program selection

Select the sterilization program based on whether and how the →items to be sterilized are wrapped. You also need to observe the temperature resistance of the items to be sterilized.
All sterilization and additional programs are indicated in the **`Programs & Tests`** menu.
The following tables show you which program you need for which items to be sterilized, as well as which additional programs are also available to you.

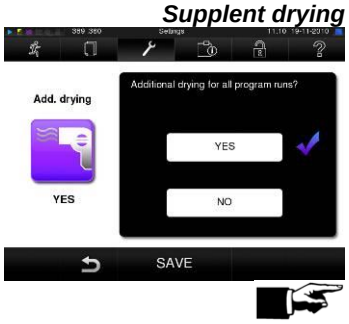
programs		*Wrapping*	*Particularly suited for*	*sterilization with*	*holding time of the sterilization time*	*operating time**	*drying*	*Loading 18.4l / 23.8l*
Universal program		→simple and →multiple wrapping	→mixed load; long, narrow-bore hollow body	134 ˚C	5:30 min	ca. 21 min	12 min	6kg/7kg
Prion program		→simple and →multiple wrapping	Instruments for which a risk of infection by pathologically altered proteins is suspected (e.g., Creutzfeld-Jacob, BSE)	134 ˚C	20:30 min	ca. 38 min	12 min	6kg/7kg
Gentle Program		→simple and →multiple wrapping	large quantities of textiles; Heat-sensitive items (e.g., plastic, rubber items)	121 ˚C	20:30 min	ca. 36 min	12 min	Textiles 2 kg (18.4l) 2.5 kg (23.8l) Heat-sensitive items 6 kg/7kg
Quick program B		→simply wrapped and unwrapped instruments (no textiles)	long, narrow-bore, hollow-body instruments	134 ˚C	5:30 min	ca. 14 min	6 min	simply wrapped max. 1.5 kg unwrapped. 6 kg/7kg
Quick program S		only unwrapped (no textiles)	simple →solid instruments; Transfer instruments; simple hollow body	134 ˚C	3:30 min	ca. 10 min	2 min	6 kg/7kg

*) without drying (at full load with DAC PREMIUM: 6 kg, DAC PREMIUM^{+}: 7 kg) and depending on the load and installation conditions (such as line voltage)

Additional programs		*Use/function*
Vacuum test		To measure the leakage rate, test with dry and cold equipment (test without load)
Bowie & Dick test		Steam penetration test with special test package (available in specialist stores)
Condcutivity measurement		For manual measurement of the quality of the feed water
Draining		For draining and pressure relief of the double-jacketed steam generator, e.g., during servicing, maintenance, or before transporting

Table 9: Overview of application areas of the sterilization programs

Supplent drying



The program-specific drying times ensure a very good drying of →the sterilized items in the case of a loading as described in this chapter (see page 20, **Loading the autoclave**).
For difficult drying tasks, you can extend the drying time of a program by 50% in the **`Settings`** menu via the option **`Supplent Drying`**.

NOTICE!
You can also activate the supplent drying subsequently during an ongoing program in the menu **`Settings`**.

Time delay

By using the Time Delay function, it is possible to select any program and to start it at a self-determined time.

- To do so, press the icon in the action bar, based upon the choice of program. The display returns to the "Time Delay" screen.
- To change the time, for example, type directly on the parameters Hour or Minute. The selected field is displayed as marked in light blue.
- You can now change the time by pressing the buttons and .
- Finally, press START. The display then remains in the display image "Time Delay".

NOTE!
Please note that the Time Delay function is not an option for the Quick Program S, due to the security query.

After the beginning of the time delay, except for the **`Info & Status`** menu, no other menu can be selected.
The time delay is only active for the one-time time and program selection, i.e., after the end of the program, the time delay is deleted.
You can turn off the autoclave while the time delay is running. However, the autoclave must be switched on again in a timely manner before the timer expires.

Attention

- The unattended operation of electrical devices, including of this autoclave, occurs at your own risk. The company Sirona assumes no liability for any possible damage caused by unattended operation.

Start program

If you have selected a program, it will be highlighted. You can start it now by pressing START.
With the start of the program the door closes pressure-tight. The autoclave checks the quantity of →feed water and its →conductivity.
When the Quick Program S starts, a warning appears and an acoustic signal is emitted. The Quick Program S may only be used to sterilize unwrapped instruments. If the load contains only unwrapped instruments, press YES to start the program.

Program is running

A program runs in three phases.
After the start of a program, you can follow the program sequence on the →display. The chamber temperature and pressure are displayed, along with the time remaining until the end of the sterilization or drying process.

Ventilation phase

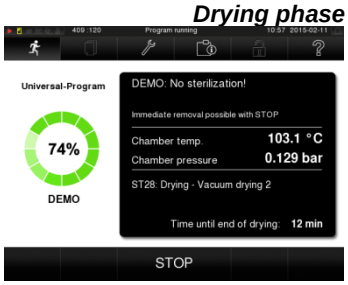
In the ventilation phase, air is repeatedly sucked out until a program-dependent pressure is reached. This occurs in alternation with the inflow of steam until a low pressure.

Sterilization phase

After reaching the sterilization parameters of pressure and temperature, the sterilization begins. The sterilization is shown on the →display. At the end of the sterilization phase, depressurization occurs.

Drying phase

After the pressure has been released, the drying phase begins.
The regular drying time lasts two minutes for the Quick Program S, seven minutes for the Quick Program B and 12 minutes for all other programs.

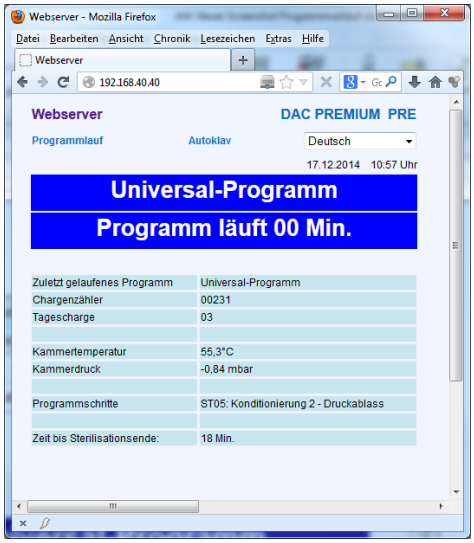


Follow program sequence on the computer

You can follow the current progress of a running sterilization program on any computer on the practice network over a web browser via the website integrated in the autoclave.
The prerequisite is that an IP address is assigned to the autoclave and that it is integrated in the practice network:

- Open a web browser window (Mozilla Firefox or Internet Explorer are recommended).
- Enter the IP address of the autoclave in the address bar of the web browser on the practice PC (e.g., 192.168.57.41) and confirm it by pressing “Enter”.

Now, you can see a display of the program sequence or information about your autoclave, such as the serial number, device software version and selected values.



Manual abort of the program

Danger

You can interrupt a running program in all phases.

- Be aware that when you open the door after a program interruption,depending on the time of the program interruption, hot water vapor may come out from the boiler.
- To remove the tray, use a tray lifter.
  Never touch the sterilized items, the boiler or the inside of the door →with your bare hands. The parts are hot.

Otherwise, burns may result.

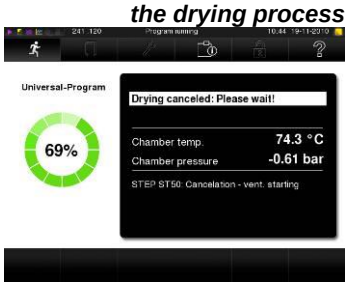
For a program interruption, press CANCEL and confirm with YES.
After a short time, you can open the door by touching the door symbol  , as shown on the → display.

Manual interruption before the beginning of the drying process

If you end a program before the beginning of the drying process, the →items to be sterilized will still be unsterile.

A warning message will appear on the display. A warning message will appear on the display. In the log, the sterilization will be marked as **`NOT successful`**.

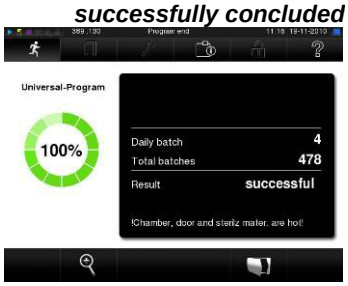
Manual interruption during the drying process



In the drying phase, you can interrupt the program via the STOP button without the autoclave reporting an error.
Especially for wrapped →sterilized items, you can then expect insufficient drying. Sufficient drying is necessary for sterile storage. Therefore, if possible, let programs with wrapped sterilized items run until the end of the drying process.
In a quick program, sterilized unwrapped instruments dry after removal, due to their own heat.

Sterilization phase is finished

Sterilization successfully concluded



From a distance, you can see on the display whether the sterilization has already been successfully completed.
Once the drying phase is initiated, the colored ring and the LED status bar both change from blue to green.

Sterilization not successfully concluded Interruption by the system

The sterilization is not successful if it is stopped by the operator or, when an error occurs, by the system.
During the interruption by the system, the double jacket is brought into an unpressurized state. Therefore, a system interruption takes longer than interruption by the operator.

Drying phase

The autoclave provides a very good drying of the items to be sterilized. If, for difficult drying tasks, it should be necessary, you can take the following measures to further improve the drying:

Improving the drying results

- Load the autoclave appropriately with regard to drying. For example, set up clear sterilization and paper wrapping like index cards. In doing so, observe section **Loading the autoclave** on page20. Use the optional film holder if necessary.
- Activate the supplent drying function. In doing so, observe the section **Supplent drying** on page23.

Program is completed

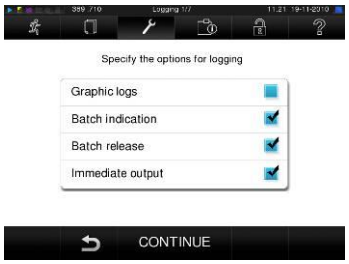
At the end of a program, the boiler pressure is equalized in relation to the ambient pressure. If the program is completed successfully, an appropriate message appears on the display.

See log header on the display

Before you open the door, you can see more values for the recently ended program on the display, such as the plateau time, the conductivity, etc. by pressing the magnifying glass icon.

automatic log output

If the **`Settings`** menu under **`Logging`** activates the automatic logging output at the end of the program, the log of the compelted program is output to the activated output media after the door is opened (see page 29, **Chapter 5 – Logging**).



Approval process

According to RKI - "Hygiene requirements in the preparation of medical devices", the preparation of instruments ends with the documented approval for storage and use of the sterilized items.
The approval process consists of the charge indication and the batch approvaland must be conducted by authorized and trained personnel.

Charge indication
includes the verification of the indicators carried along in the sterilization program, such as the testing set Helix test, proxy indicators, etc.
The approval of the indicators can only occur upon a complete color change of the indicator strip.

Batch approval
Includes the review of the process parameters based on the sterilization results on the autoclave and the sterilization log, as well as the verification of the individual packages for damage and residual moisture.
The approval of the batch and the indicators which might have been carried along are documented in the sterilization log.
Depending on the setting in the user administration, a user PIN of the person who approves the batch and the indicators is necessary for approval of the sterilized items.

Remove the sterilized items

After the end of a program, observe the following when removing the →sterilized items:

Danger

- Never open the door by force. The autoclave could be damaged and/or steam could escape.
- To remove the tray, use a tray lifter.
- Never touch the sterilized items, the boiler or the inside of the door with unprotected hands. The parts are hot.

Otherwise, burns may result.

Danger

- Check the wrapping of the sterilized items for damage when removing them from the autoclave.
- If a wrapping is damaged, rewrap the sterilized item and sterilize it once again.

Not doing so could result in non-sterile instruments. This endangers the health of your patients and dental team.

Condensate residues on the sterilized items

If the →sterilized items are removed from the autoclave immediately after the end of a program, small amounts of moisture on the sterilized items might result. According to the Arbeitskreis für Instrumentenaufbereitung (AKI; Rote Broschüre;10th edition; p. 57), the following applies:
"Tolerable residual moisture is considered – for all practical purposes – to be individual water droplets (no puddles) that have to be dried within 15 minutes."

Storage of sterilized items

Only use →standard-compliant packaging for the sterilized items. Do not store sterilized items in the treatment room. For the storage of sterilized items, observe →DIN 58953, Part 7 as well as the criteria below.

Storage conditions

- protected from dust, e.g., in a closed instrument cabinet
- protected from damage on smooth surfaces
- protected from excessive temperature fluctuations
- protected from moisture (e.g., alcohol, disinfectants, etc.)
- storage period in accordance with the type of wrapping

Storage period

The maximum storage capacity depends upon the wrapping and the storage conditions. For wrapped →sterilized items which conform to standards, this amounts to a maximum of six months – with dust-protected storage required.

Chapter 5 – Logging

In this chapter, you will see

- **why and how you document batches**
- **which output media can be used for the documentation of the batch results**
- **where you can find the logs for the documentation of the batch results**
- **how to read the logs correctly**
- **how to set the date and time on the autoclave**

Documentation of batch results

The documentation of batch results is essential as proof of the successful sterilization process and a mandatory measure of quality control.
The data, such as program type →batch and process parameters of all completed programs, are stored in the internal log memory of the autoclave.
For the documentation of batch results, you can read the internal log memoryand have the data transfered to various output media.

Output media

You have the option of outputting the logs of the completed programs to the following output media and to archive them accordingly.

- NITRAflash →CF Card
- Computer (over the network)
- Log printer NITRAprint

You can combine the output media as required. For example, it is possible to store logs on the NITRAflash →CF Card and to have they printed.
The output of the log to several activated media occurs sequentially. You select the desired output media by selecting this once in the **`Settings`** → **`Logging`** menu or in the **`Logs`** for Subsequent Log Output menu.
You can find detailed information about activating and setting the log output in **Chapter 6 – Settings**.

Factory setting

By default, the Nitra Flash →CF card as output medium for text and image logs and, therefore, the automatic log output (see p. 31) are automatically activated in the autoclave.

Capacity of the internal log memory

The internal memory capacity is sufficient for up to 100 logs.
If the internal log memory is almost full and at least one log has not yet been output to an activated output medium, the warning message **`Internal Log Memory Almost Full`** appears on the display. If this warning appears, you should use prepare the output media specified in the **`Settings`** → **`Logging`** menu and output the relevant logs (**`Logging`** menu).
Shortly afterwards, the message **`Internal Memory Full is`** displayed. Then, you have one last chance to archive the logs which have not yet been issued (confirm the message with YES) before the data in the log memory of the autoclave is automatically deleted up to the last 40 logs.

CF Card as output medium

Attention

Observe the following information for using a →CF Card:
Never force the CF Card into the card slot.

Never remove the CF Card from

the card slot during the reading and writing access. During writing access, a yellow square lights up in the upper right corner of the display.

Doing so may result in a loss of data, damage to the card and/or the autoclave and/or its software. As a result, the card may become unusable.

CF Card as output medium

If there is no →CF Card inserted in the card slot but it is activated, a warning message appears on the display.
Therefore, if you want to use the CF Card as the output medium, the card has to be inserted in the card slot, if this has not already been done.
If you do not have a CF Card on hand at the moment, you can output the log later via the **`Logs`** menu.

Insert CF card

The card slot for the →CF Card is located on the right side of the display housing.
To insert the CF Card, insert it into the card slot with the tactile grip edge to the rear right. If the CF Card is inserted correctly, a blue square lights up in the upper right corner of the display.

NOTE!

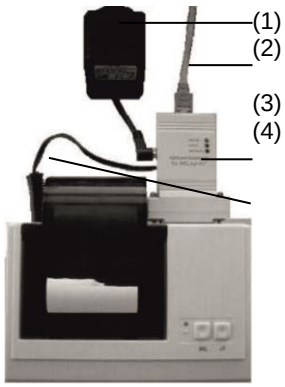
Because of the larger memory requirements when recording video logs in real time, it is recommended that only NITRAflash CF Cards with 1GB or more storage volume by Sirona be used. You receive these in a tested and formatted state. Some older CF Cards with up to 256 MB of storage volume are known to potentially cause file problem.

Using your PC as an output medium

You can connect a computer to the autoclave directly or via a (practice) network. It is necessary that the PC have a network card with RJ45 connector (LAN). Logging occurs either via an FTP or TCP connection. In the former case, an FTP server (communication program) or an FTP service is needed on the computer. For the log output via TCP, a suitable program is also needed, e.g., MELA*view3*.

Log printer as an output medium

Connecting a printer



If you want to use the log printer NITRAprint as an output medium, connect it to the autoclave as follows:

- Plug the power supply unit (1) into the socket.
- Connect the →network adapter (3) using the supplied cable (2) with an Ethernet data port of the autoclave.
- Plug the →network adapter (3) into the serial port of the log printer NITRAprint (screw-mountable).
- Plug the cable (4) of the adapter (3) into the power jack of the log printer.
- Switch on the autoclave.
- By plugging the power supply cord (1) into the power jack of the network adapter (3), the log printer is turned on.
- Set the log printer on the autoclave as an output medium (see p. 38, **Chapter 6 – Settings**).

Label printer as an output medium

The use of a label printer enables the traceability of the batch: By entering the sterilization date, the storage period, the batch number, the user ID of the person who has authorized the instruments for use, the deployed autoclave and the file name, the sterilized instruments can easily be assigned to the patient and the sterilization batch.
The flawless wrapping of the sterilized items is marked after sterilization by applying a label. As a result, the requirements for the proper "authorization" by the individual entrusted with the preparation are fulfilled.

As a result, all the information about the correct sterilization procedure of the deployed instruments can be assigned in the patient file.

Automatically output logs immediately

Output of the text log

If you want to automatically output the corresponding text log to an output medium immediately after the end of a program, use the automatic log output with immediate output. In the delivery state, the autoclave is set for automatic log output of both the text as well as the image logs via the CF Card immediately after the program ends.

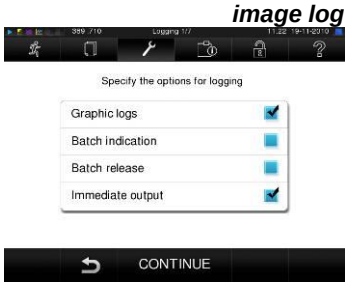
Requirements for the automatic output of the text logs immediately after the program ends

The following requirements must be met for the output of text logs immediately after the end of a program:

- Immediate output is activated in the **`Settings → Logging`** menu.
- At least one output medium is selected in the **`Settings → Logging`** menu.
- The activated output medium is connected (e.g., computer, log printer NITRAprint) or inserted (NITRAflash→CF Card).

In the **`Settings → Logging`** menu, you are guided step by step through the creation of the automatic log output.
If it is not possible for the automatic log output to issue a log, for example, because the activated output medium is not connected, a warning message appears. The autoclave registers as of yet unissued logs for each enabled output medium. It provides the output of these logs at the next opportunity.
Sirona recommends that you use the automatic log output with an immediate output of the logs (according to the delivery state).

Optional output of the image log



The following requirements must be fulfilled for the recording of image logs in real-time:

- The output of the **`image logs`** must be activated in the **`Settings`** → **`Logging`** menu.
- At least one of the selected output media agrees with an output medium for the text logs.
- The activated output medium is connected (computer) or inserted (NITRAflash→CF Card).

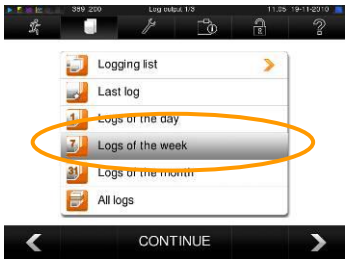
Explanation of the settings options for image recording:
CF Card (CFC) logging interval in sec. – indicates the time intervals at which the program profile is recorded on the CF Card. The smaller the time interval, the more accurate the profile. In the example, the time interval is set to 1 second.
PC logging interval in sec. – indicates the time intervals at which the program profile is recorded when the computer is selected as an output medium. The smaller the time interval, the more accurate the curve. In the example, the time interval is set to 1 second.
PC backup interval in sec. – Indicates the intervals at which the image data will be stored by the autoclave on the computer. In the example, the backup interval is set to 1 second.

NOTE!!
Image logs cannot be stored in the internal log memory. If you want to optionally record the image logs to the text logs, you always have to make sure that at least one common output medium is set for the output of text and image logs. In other words, at least the computer or the CF Card has to match as the output medium for both log types.

Outputting stored logs at a later time

Via the **`Logs`** menu, you have the option of outputting text logs subsequently and independently of the time of the end of a program.
In doing so, you can determine the output media yourself. By default, the output media which are selected under **`Settings`** → **`Logging`** are preselected, as long as automatic immediate output is activated.
Here is an example of how to deactivate the immediate output and, for example, to output all the text logs of the completed programs of an entire week:

Deactivating immediate output

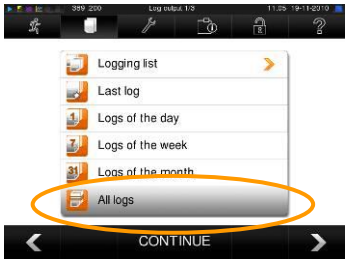


- Select the **`Settings`** → **`Logging`** menu.
- Remove the checkmark next to Immediate Output in order to disable it. Then, the system will be restarted.
- Select the **`Logs`** menu.
- Navigate to **`Logs of the Week.`**
- Press NEXT.
- Then, press OUTPUT to issue the log(s).

Output all saved logs on the CF Card

In the example below, you can read how to output all saved logs on →the CF Card. A prerequisite is that the CF card be inserted in the card slot.

- Select the **`Logs`** menu.
- Select **`All Logs`** and then select NEXT to determine an output medium.
- When finished, press OUTPUT to issue all the logs.



Log output options

In the selection list of the **`Logs`** menus (see example above), various options for log output are offered. Here are some examples:

"Logs" menu	*File extension*	*Explanation*
Log list		All program logs stored in the memory are shown on the display. You can sort the list by pressing the column headers according to No., date, time, program and results.
Last log	.PRO	The log of the last successfully completed program is issued.
Logs of the day	.PRO	The logs of the successfully completed programs of the current day are issued.
Logs of the week	.PRO	The logs of the successfully completed programs of the week – Monday to Sunday – are issued.
Logs of the month	.PRO	The logs of the successfully completed programs of the current month are issued.
All logs	.PRO	The logs of all the successfully completed programs are issued.
Last fault log	.STR	The last fault log is issued.
Fault log of the day	.STR	The fault logs of the current day are issued.
etc.		...
Key log	.LEG	Includes an explanation of all the abbreviations used in the log.
Status log	.STA	A summary of all the important settings and system states (counter, readings, etc.)
Error in standby	.STB	This log type is generated when errors occur without a program running.
System log	.LOG	A type of log which lists, in chronological order, all the errors and changes to the system which have occurred.
Delete all logs		Deletes all the logs stored in the internal log memory. !Attention! Logs which have not previously been issued to another output medium will also be deleted.

Specify format for program logs

For each completed program, a log is stored in the internal log memory. Via the log format, you can specify which of the stored data should be output. You can choose between a short (0), medium (1) and long form (2).
The default format is the long form 2.
You can specify the output format for the program logs under **`Settings`** → **`Logging.`**

```
10 01100ED0E002
11 E10SD15L.PRO
10 Sirona DAC PREMIUM
15 Program:       Quick-Program B
20 Program type: 134 °C 1x wrapped
25 Date:          02.12.2014
30 Daily batch:   02 Total: 01497
35 User:          deactivated
36 Indicators changed: Yes
37 Batch released:     Yes
40 Quick-Program B Ended successfully
45 Temperature:  135.5  +0.07/-0.12 °C
50 Pressure:     2.17  +0.01/-0.01 bar
55 Plateau time: 03 min 30 s
60 Conductivity: 17 µS/cm (341:0.0)
65 Start time:   13:12:53
70 End time:     13:30:23 (17:30 min)
80 SN:2014PRE1021
81 MR   V3.096 25.11.2014
82 Para V3.115 31.10.2014
83 BO   V3.201 25.11.2014
Step time t[m:s] P[mbar] T[°C]
SP-S  0:00   0:00   1011   80.0
SK11  0:13   0:13   1651   90.5
SK12  0:37   0:24   1295  104.6
SK11  0:44   0:07   1627  106.9
SK12  1:06   0:22   1294  108.1
SK21  1:13   0:07   1645  110.4
SK22  1:36   0:23   1294  108.7
SK21  1:42   0:06   1633  111.2
SK22  2:06   0:24   1287  109.6
SF12  2:48   0:42    500  102.3
SF13  3:17   0:29   1615  111.5
SF21  3:23   0:06   1292  109.3
SF22  4:30   1:07    180  102.1
SF23  5:12   0:42   1806  115.1
SF31  5:21   0:09   1292  109.9
SF32  6:30   1:09    200  102.3
SF33  7:01   0:31   1930  117.7
SH01  7:34   0:33   2718  129.9
SH02  7:55   0:21   2856  132.0
SS01  8:26   0:31   3078  134.2
SS02 11:57   3:31   3176  135.6
SA00 12:26   0:29   1291  110.3
ST01 14:47   2:21    101  101.2
ST02 14:52   0:05    392  102.0
ST03 17:12   2:20     84   96.9
SB10 17:25   0:13    803   99.8
SB20 17:28   0:03    921  100.5
SP-E 17:29   0:01    927  100.6
>> Never change code on follow. line <<
0100419EB7141B547655772A1FA20ED9437E9332
8C9872432B2F090AE30C0E3F771932127F71C7144
1CDA0E636BCF7962766901868F7DCDDCC3FD9064F
CFC16399500FE22FAFDF782541AD2C2D5F424A2A
9D5178193EC016D41C5256546DE7B2072167C6E46
Program start
Conditioning type 1 (steam intake)
Conditioning type 1 (pressure release)
Conditioning type 1 (steam intake)
Conditioning type 1 (pressure release)
Conditioning type 2 (steam intake)
Conditioning type 2 (pressure release)
Conditioning type 2 (steam intake)
Conditioning type 2 (pressure release)
1st Fractioning evacuation
1st Fractioning steam intake
2nd Fractioning pressure release
2nd Fractioning evacuation
2nd Fractioning steam intake
3rd Fractioning pressure release
3rd Fractioning evacuation
3rd Fractioning steam intake
Hold Steam intake
Hold Regulation
Sterilization begin
Sterilization
Pressure release
Drying: 1st vacuum drying
Drying: ventilation drying
Drying: 2nd vacuum drying
Ventilation 1
Ventilation 2
End
```

	Log format		
Component	***0***	***1***	***2***
Head	X	X	X
Values regarding the program steps		X	X
Key			X

Standard format

Table 10: Log format and other components

Reading logs correctly

Head

The head is output in all three selectable log formats. The Format 0 contains only the head of a log.
The head of the program log comprises the lines 10 to 83 and includes the most important information about the completed program, such as whether the program has been successfully completed.

Values of the program steps

During the program, the time, pressure and temperature will be recorded, among other data.

Key

The key is part of the most comprehensive log format 2. It is used to identify the program steps to which the specified values refer.
In digitally output logs (→CF Card, PC), the key is directly next to the values of the respective program step. Every key line refers to the line on its left.
For logs which are output from the log printer NITRAprint, the corresponding key line is always below the line to which it refers.

	Head

`----------`
`!0 01100ED0E001`
`!1 E10SD15K.PRO`
`----------`
	!0 Ident number
	!1 File name

`10 Sirona DAC PREMIUM` `----------`	10 Type of autoclaves

`15 Program: Universal-Program`
`20 Program type: 134 °C wrapped`
`25 Date: 02 Dec 2014`
`30 Daily batch: 01 Total: 01496`
`35 User: deactivated`
`36 Indicators converted: Yes`
`37 Batch approved: Yes`
`======`
	15 Program name
	20 Sterilization parameters of the program
	25 Date
	30 Daily and total batch number
	35 User ID
	36 Batch indication } Approval process
	37 Batch approval

`40 Universal program successfully con-`
`cluded`
`42 = =`
`======`
	40 Control message
	42 Warning or error message upon program interruption

`45 Temperature: 135.5 +0.13/-0.12 °C`
`50 Pressure: 2.17 +0.01/-0.01 bar`
`55 Plateau time: 05 min 30 s`
`60 Conductivity: 19 µS/cm (242:0.0)`
`65 Start time: 11:31:21`
`70 End time: 12:00:25 (29:04 min)`
`======`
	45 Sterilization temperature with max. deviations
	50 Sterilization pressure with max. deviations
	55 Sterilization time
	60 →Conductivity of the →feed water
	65 Time at the start of the program
	70 Time at the end of the program

`80 SN:2014PRE1021` `======`	80 Serial number of the autoclave

`81 MR V3.096 25 Nov 2014`
`82 Para V3.115 31 Oct 2014`
`83 BO V3.201 25 Nov 2014`
`----------`
	81 current version of the device firmware
	82 current version of the device parameters
	83 Current version of the user infertace

`Step Time t[m:s] P[mbar] T[°C]`	***Values of the program steps and keys***

`SP-S 0:00 0:00 1011 91.6`
`SK11 0:12 0:12 1612 94.4`
`SK12 0:35 0:23 1288 104.0`
`SK11 0:43 0:08 1636 108.8`
`SK12 1:07 0:24 1293 107.8`
`.`
`.`
`SF32 7:14 1:11 200 101.9`
`SF33 7:58 0:44 1956 117.9`
`SF41 8:11 0:13 1287 109.8`
`SF42 9:00 0:49 398 105.3`
`SF43 9:25 0:25 1748 114.2`
`SH01 10:04 0:39 2695 129.7`
`SH02 10:25 0:21 2850 132.0`
`SS01 10:56 0:31 3077 134.1`
`SS02 16:26 5:30 3177 135.4`
`SA00 16:57 0:31 1296 111.7`
`ST01 19:52 2:55 90 98.3`
`ST02 19:55 0:03 186 98.3`
`ST03 22:50 2:55 78 92.5`
`ST02 22:52 0:02 169 92.6`
`ST03 25:47 2:55 79 90.6`
`ST02 25:50 0:03 169 90.8`
`ST03 28:45 2:55 78 91.4`
`SB10 28:57 0:12 801 94.9`
`SB20 29:00 0:03 914 95.7`
`SP-E 29:00 0:00 922 95.8`
	Time Time (minutes:seconds) since the start of the program
	t [m:s] Duration (minutes: seconds) that a program step takes to complete
	P [mbar] Pressure in the chamber in millibars
	T[°C] Temperature in the chamber in degrees Celsius
	At the beginning of each line are shortcuts that refer to the type of each program step. You get a list of all the step shortcuts when you output a key log via the **Logs** menu.

	Program steps: SK Conditioning SF Fractioning SH Retain SS Sterilization SA Pressure release ST Dry SB Ventilate SP-E End

`>> Never change the code in the following line <<`
`C200000500F8020D82E9280A03F2034031943490`
`>> Proof of authenticity batch record <<-`
`----------`
	Proof of authenticity (electronic signature)
	Should never be changed; the entcyphering of the code by Sirona allows a conclusion as to whether the data have been created and changed in a Siro-na autoclave.

`0.00 0.0 0.0 0.0 0.0 0.0` `-edk----etm---etd---etp---etv--ett-ENDE-`	Sensor readings are displayed here in case of malfunction. The values are helpful for the technician.

Table 11: Example of a program log for a successfully ended universal program

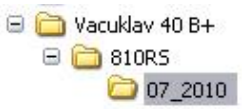
Find a log

After a log output, you can find a directory on the storage media → CF Card or computer.

Directory names, log names

The name of this directory consists of five characters, e.g., 810RS. These characters encrypt the serial number of your autoclave.
Therefore, the directory is also called the device directory.

Subdirectories



A device directory has subdirectories that are identified by the months of the log production, e.g., 07_2010.
In the subdirectories, you will find all the logs produced during the respective month. Each log name begins, as with the device directory, with the five characters of the encrypted serial number (e.g., 810RS).

Output of records

The autoclave checks the output medium with every log output. If not yet available, the autoclave automatically creates a device directory with the encrypted serial number and a subordinate monthly directory.

Log output on the CF Card

On the →CF Card, the device directory is created directly, i.e., without a parent directory.

Log output on a computer

If you output the logs on a computer, the device directory is created in the directory which is specified in the FTP server Program. With very simple FTP servers, that is the folder where the FTP server program itself is located.
In the case of the output via TCP and, for example, MELA*view*3, you determine the storage folder directly in the program.

NOTE!

Do not rename the directories. The autoclave will re-create a directory, because it will not recognize the existing one anymore. It will create logs both in the renamed directory as well as in the directory which will be regenerated by the autoclave.

Multiple output of logs

If you output logs several times on the same output medium, a subdirectory with the name **`doubled`** will be created in the device directory.

Chapter 6 – Settings

In this chapter, you will see

- **which settings you can create**
- **how to change default settings**

Note the time change

Setting the date and time

For the proper documentation of the batch results, the date and time of the autoclave must be set correctly. Note the time change in the autumn and spring, since this does not occur automatically. Once set, the clock of the autoclave is very accurate. Set the date and time as described below:

- Select the **`Settings`** menu.
- Navigate to **`Date and Time`**.
- The display switches to the **`Date and Time`** window.
- Directly select the parameter that you want to change (day, month, year or hour, minute, second). The selected parameter is shown in light blue.
- Change the respective parameter values via the buttons  and  .
- Repeat these steps for all the parameters which you want to change.
- Confirm the changes with SAVE.
- The display will reboot after saving and will switch automatically to the **`Programs & Tests`** menu.

Add/edit a new user

User management

For reliable traceability throughout the approval process after the end of a sterilization program, an individual ID and PIN can be assigned for each user, with which the user can authenticate himself before he releases the batch.
You can determine whether user authentication is required by the PIN entry in the **`Manage Users`** window by checking the box next to **`Approval Process with PIN`**.
If this option is activated, the user ID and the result of the approval process is documented in the log header.
To create a new user, please read the following:

- Select the **`Settings`** menu.
- Navigate to **`User Management`**.
- To access the **`User Management`** menu, and to determine settings there, the entry of the Admin PIN is necessary. Enter the Admin PIN (default: 1000) and confirm with LOGIN.
- The display switches to the **`User Management`** window.
- Press the button **`Go to User List`** in order to view the list of users.

- To now create a new user, choose an unused ID and select EDIT. Note that the first ID is reserved for the Admin PIN.
- Enter a 4-digit PIN for the selected User ID in the field to the right and confirm with SAVE.
- With SAVE, you accept all the settings and exit the menu.
- By pressing the symbol , you will leave the menu.

Changing the Admin-PIN

The Admin PIN (default: 1000) can be edited like any other user PIN in the same way and should be changed upon delivery.

NOTE!

If you forget the Admin PIN, contact your dealer.

Deleting a user from the list

To delete a user from the list, please read the following:

- Select the **`User Management`** menu as described above and open the list of users.
- Select the user ID that you want to delete.
- Select the symbol , to delete that user. A warning will follow. If you confirm the warning message with YES, the PIN number of this ID will be set to "0".

A new PIN can be assigned again for this user ID at any time.

Select the log printer as the standard printer

If you want to output the sterilization log via the log printer, you need to set this once on the autoclave.
To establish a log printer, please read the following:

- Select the **`Settings`** menu.
- Navigate to **`Log Printer`**. The display switches to the **`Log Pri`**nter window.

If a previous log printer has not been determined, the field "IP Address" and "MAC address" is blank.

- Select Search to have all the log printers which are available and connected in the practice network to be displayed in the list. The window switches to the list of printers.
- If one or more log printers in the practice network are available, they are displayed in the list of printers.
- Select the desired log printer from the list and confirm by pressing SAVE.

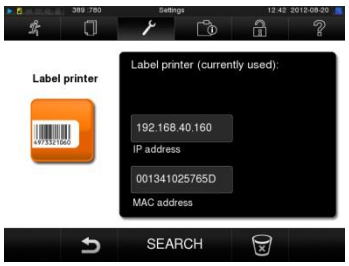
The display switches again to the "Log Printer" window.

- Press in order to leave the menu
- Finally, in the **`Settings`** → **`Logging`** menu, select the log printer for the log output.

NOTICE!

If the desired log printer does not appear in the printer list, you can repeat the search by pressing the printer icon.

Setting up the label printer as the default printer

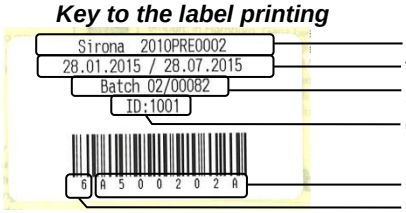


When you set up a label printer, please read the following:

- Select the **Settings** menu.
- Navigate to **Label Printer**. The display switches to the **Label Printer** window.
- In the next steps, proceed as described in the previous section **Log Printer**.
- Finally, in the **Settings** → **Logging** menu, select the label printer for the log output.

NOTE!
So that a wrapping marked with a label can easily be assigned later to a specific batch, the file names of the sterilization log must not be renamed under any circumstances.

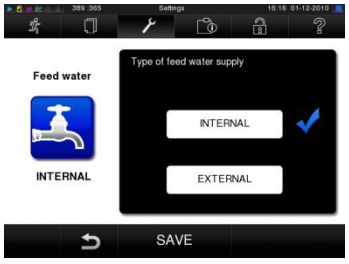
Key to the label printing



Type, serial number
Sterilization date / expiry date
daily batch / total batches
User ID (see page 38, **User** management)

File name
storage period

Water supply



Depending on whether the feed water supply should come from the internal storage tank or you have connected a water-treatment system, select the appropriate setting on the display:

- Select the **Settings** menu.
- Navigate to **Device Settings** → **Water Supply**. The display switches to the **Water Supply** window.
- Select **INTERNAL** if the water supply comes via the internal storage tank or **EXTERNAL** if you have connected a water-treatment system.
- Confirm by pressing SAVE.

Power save mode

If the autoclave is not turned off in the case of longer stoppages, it can be operated in power save mode. As a result, the time required for the autoclave to preheat the →double-jacketed steam generator to the necessary starting temperature after being turned off is reduced.
Two waiting times can be set in the power save mode:

Waiting Time 1 (W1): After a preset waiting time of 15 minutes, the temperature of the double- jacketed steam generator is lowered to 103 °C. The program running time is extended by about 2 minutes upon the next start-up.
Waiting Time (W2): After a preset waiting time of 60 minutes, the double-jacketed steam generator is no longer heated. Accordingly, the program running time is automatically extended upon the next start-up by about 5 minutes, depending upon the length of the stoppage, because the double jacketed steam generator is first preheated to the required starting temperature.

When you set up the power save mode, please read the following:

- Select the **`Settings`** menu.
- Navigate to the **`Energy Save Mode`**. The display switches to the **`Energy Save Mode`** window.
- In the next steps, proceed as described in the section **Setting the date and** time.

Screensaver

To protect the display in the standby mode, a screen saver can be activated which presents a continuous slide show with any desired selection of images.

To activate the screen saver and to select images for the slide show, proceed as follows:

- Select the **`Settings`** menu.
- Navigate to **`Screen Saver`**. The display switches to the **`Screen Saver`** window.
- To select an image, press on the corresponding image. The white border around the image indicates which image is currently selected.
- Pressing on the image again will select it for the slide show.

You can recognize whether the image has been selected for the slide show by the checkmark in the bottom right corner ☑.

- To determine further settings, press NEXT. The display switches to the accompanying window.

Here, you have the option of changing the following parameters:
Image change in slide show: Specifies how many seconds an image is displayed on the screen before the slide show moves to the next image.

Waiting time: Specifies how long the display remains in normal mode before the slide show starts.

Activated: The screen saver is activated by placing a checkmark, and deactivated by removing one.

You can change the parameters as follows:

- Directly select the parameter that you want to change.

The selected parameter is shown in light blue.

- Change the respective parameter values via the buttons  and  .
- Confirm the change by pressing SAVE.

Switching off the display

You can switch off the display completely after a certain time.

Chapter 7 – Maintenance

In this chapter, you will see

- **how to clean the autoclave and which cleaning agents are suitable to do so**
- **how to avoid spotting**
- **which feed water you can use**
- **how to oil the door spindle**
- **what you have to consider regarding the maintenance of the autoclave**

Cleaning

Weekly monitoring of the boiler, door seal, mounting, boiler sealing surface
In the case of contamination:

Inspect the boiler, including door seal and boiler sealing surface and the holder for load (page 9, Figure 2) once weekly for contamination, debris or damage.
If you notice contamination, take the existing trays or cassettes and the associated holder out of the boiler. Clean the contaminated parts.

!
Attention

When cleaning the boiler, the holder of the load, the boiler sealing surface and the door seal, observe the following:

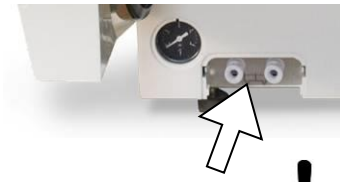
- Switch off the autoclave before cleaning and pull the power plug from the electric outlet.
- Make sure that the boiler is not hot.
- Use a soft, lint-free cloth.
- Use detergent which is free of chlorine and vinegar.
- Soak the cloth with rubbing alcohol or spirits first and try to wipe the contamination away with this.
- Use a mild stainless steel cleaning agent with a pH-value between 5 and 8 only for stubborn dirt →on the boiler, holder or boiler sealing surface.
- Use neutral liquid detergent for cleaning the door seal.
- Do not use detergent in the piping which exits the autoclave.
- Do not use hard objects such as metal scouring pads or steel brushes.

Otherwise, the cleaned surfaces could be scratched and damaged and the sealing surfaces might leak. Dirt and →corrosion in the sterilization chamber would be preferable.

Housing parts
Internal storage tank for feed water

Clean the housing parts with neutral liquid cleaners or spirits.
If you supply the →feed water manually via the internal storage tank, you should check for impurities upon each refill. When appropriate, clean the storage tank before refilling with fresh feed water.
Clean the left chamber of the storage tank (waste water) every two weeks.

Draining the internal storage tank



Drain the chambers of the storage tank as follows:

- Pull off the cover for the tank drainage at the bottom front panel.
- 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.
- Drain the water into a container with a capacity of at least 5 liters.
- To remove the drain hose, press the gray release button on the quick coupling. The hose releases automatically from the coupling.

Warning

Observe the following when removing the quick coupling:

- When draining the supply chambers, stand to one side in front of the connection.
- When pushing the release button of the quick coupling, be sure to hold the hose securely in place with your other hand in order to stave off the spring force of the catch.

Failure to observe this precaution may result in injury.

To avoid spotting

Staining due to improperly cleaned instruments

Only by properly cleaning the instruments before sterilization can you avoid that residues from loading or instrument preparation are loosened during the sterilization process. Loosened dirt can clog the filter, nozzles and valves of the autoclave and result in stains and deposits on the instruments as well as in the boiler (see page 20, **Preparing the** items to be sterilized).

Spotting due to external rust

All steam-conducting parts of the autoclave are made of rust-proof materials. This excludes the possibility of rust being caused by the autoclave. Should rust stains occur, it is a case of external rust.
As a result of incorrect instrument preparation, rust can develop even on stainless steel instruments of respected manufactures. It often only takes one instrument separated due to rust to cause rust to develop on the other instruments or in the autoclave. Remove rust from the instruments with a chlorine-free →stainless steel cleaning agent (see page 43, **Cleaning**) or send the damaged instruments to the manufacturer for processing.

Staining due to poor quality of the feed water

The extent to which spots form on instruments will also depend on the quality of the →feed water used for steam generation.

Use high-quality feed water

Observe the following when using →feed water for steam sterilization:

Attention

- Use only →demineralized or distilled water pursuant to →DIN EN 13060, Annex C.

Otherwise, stains can occur on the instruments, and the operability of the autoclave may be impaired.

NOTICE!

→Feed water that you can produce affordably with NitraDem Direct Connect or SIRODEM meets the requirements of the feed water.

Oiling the door spindle

Oil the door spindle every two months as follows:

- Clean the spindle with a lint-free cloth.
- In the threaded bushing (page 9, **Figure 2/(4)**) in the autoclave door, add two drops of oil from the supplied oil bottle (Item-No. 27515).

Please notice

You will find a guide oiling the door spindle on the inside of autoclave door.

Maintenance

Danger

- Maintenance should only be performed by trained customer services technicians, or stockist technicians. For this purpose, consult your stockist.
- Maintain the specified servicing intervals.

Failure to comply can cause damage to the autoclave as well as severe health damage.

For maintaining value and functionality

To maintain value and the reliable practice operation of the autoclave, regular maintenance is essential.
During maintenance, all functional and safety components and electrical equipment must be checked and, if necessary, replaced. Maintenance must be performed according to the maintenance instructions which are relevant for this autoclave.

Maintenance intervals

Have maintenance performed regularly every two years or after every 2000 program cycles. The autoclave will display a maintenance message at the appropriate time.

Regarding industrial safety regulations

According to BetrSichV Section 15, operators of pressure equipment (such as autoclaves) are obliged to have their device checked for a proper condition. For this purpose, a corresponding guide can be downloaded from our website. This shows our recommendation regarding which components are to be checked as which intervals.

Chapter 8 – Stoppages

In this chapter, you will see

- **how quickly you can start sterilization programs in succession**
- **what you should watch for during short and longer stoppages**
- **how to decommission, transport and recommission the autoclave**

Sterilization frequency

No pause times necessary

Pauses between each program are not required because the →sterilization chamber is kept permanently at a constant temperature. After completing or interrupting the drying time and removing the →sterilized items, you can immediately reload the autoclave and start a new program.

Pause times

Short pauses between sterilization

Keep the door closed in the pauses between the sterilization processes when the autoclave is turned on. This requires less energy for the →double-jacketed steam generator to maintain a constant temperature.

Pauses which are longer than one hour

If the pauses between two sterilization procedures lasts longer than one hour, Sirona recommends turning off the autoclave. As a result, you can save energy. If the autoclave has been turned off for one hour, it will need about four minutes to preheat the →double-jacketed steam generator to be ready to start.
If the autoclave is not turned off during extended periods of operation, the energy saving mode can be set (see **Chapter 6 – Settings, Power** save mode).

Longer stoppages

Switch off the autoclave upon longer stoppages, such as overnight or on the weekend, and just leave the door ajar. In this way, you will relieve the door seal and protect it from premature fatigue. In addition, guard against the door seal sticking.

Stoppages lasting longer than two weeks

After stoppages lasting longer than two weeks, conduct a vacuum test and, thereafter, an empty sterilization with the rapid S program (see page 49, **Chapter 9 – Function** test). The following situations can occur after long pauses:

Event	*Possible cause*	*What you can do*
→Conductivity too high	Poor feed water	Change the →feed water
Door will not open, despite the motor running	Sticking of the door seal at the sealing surface	Turn off the autoclave and pull hard on the door to open it.

Table 12: Possible situations after stoppages lasting more than two weeks

Functional check after pauses

After pauses, and depending on the duration of the pause, perform the functional testing checks described in **Chapter 9 – Function** test.

Decommissioning

If you want to decommission the autoclave for a longer break, such as by reason of holidays, proceed as follows:

- Turn the autoclave off at the power switch.
- Disconnect the cord from the power source.
- Drain the internal storage container.
- If present, turn off the water supply of the water treatment system.

Transport

Moving the autoclave

When moving the autoclave, observe the following:

Danger

- Only carry the autoclave with two people.
- Use suitable carrying straps for moving the autoclave.
- Note that the distance between the bottom plate of the autoclave housing and the installation surface is small.

Failure to do so may result in bruises as well as damage to your spine.

Transport over larger distances, delivery

Observe the following during transport (such as moving or shippment) of the autoclave:

Attention

- For transport over longer distances and/or a risk of frost and/or for shipment, an →authorized person must prepare the autoclave as directed and completely drain the →double-jacketed steam generator (see **Draining the** double-jacket).

Otherwise, damage to the autoclave and malfunction can result.

Transport within the practice

Observe the following for the transport of the autoclave within a room or within the practice:

Attention

- After switching off the autoclave, wait until the manometer for the pressure indicator of the →double-jacketed steam generator displays zero bar before moving the autoclave.
- Drain the internal storage container.
- When using a water-treatment system, close the water supply and remove the hose connections on the rear panel of the housing.
- If you want to keep the holder and the trays or cassettes in the boiler during transport, protect the surface the door plate. To do so, lay (for example) a piece of foam or bubble foil between the door plate and the holder.
- Close the door of the autoclave before you move it.

Otherwise, damage to the autoclave and malfunction can result.

Draining the double-jacket

You have the option of completely draining the water in the →double jacketed steam generator simply via the **`draining`** program.

To do so, the autoclave is heated once and pressure in the double jacket is released so that the water can be completely removed from the double jacketed steam generator.
Then, switch off the autoclave in the Program Complete Image **`Draining Complete`**, so that the autoclave does not feed water back into the double jacket.

Recommissioning after a change in location

Proceed as in the first commissioning process

When recommissioning after a change of location of the autoclave, proceed as during an initial startup (see page 15, **Chapter 3 – Commissioning**).

Chapter 9 – Function test

In this chapter, you will see

- **how the autoclave automatically performs the function test**
- **the possibilities of manual functional testing**
- **which function tests should be performed in daily operation**
- **why and how to perform a vacuum test**
- **why and how to perform a Bowie & Dick test**

Automatic function check

Process assessment and monitoring system

Via the electronic parameter control, the interaction of the sterilization-relevant parameters of pressure, temperature and time are continually and automatically monitored.
The →process evaluation system of the autoclave compares the process parameters during the program with each other and monitors them with respect to their limits.
The monitoring system of the autoclave checks the device components regarding their functionality and their plausible interaction. If the parameters exceed defined thresholds, the autoclave displays warnings or error messages. If needed, it interrupts the program with a corresponding notice.
If the program has successfully been completed, a corresponding message is issued on the →display.

Manual function check

On the display and as a result of the log

Based on the displayed values on the →display, you have the option of following the program execution.
On the basis of each program recorded in the log, you can also verify whether a program has been successful (see page 29, **Chapter 5 – Logging**).

Tests in daily operation

Notice!
In this case, please refer to the manufacturer's recommendation from Sirona for the routine operation of Class B autoclaves according to the recommendations of the Robert Koch Institute.

Vacuum test

Weekly in routine operation, upon initial start-up, after pauses longer than two weeks and in the case of malfunction

Perform a vacuum test in the following situations:

- in routine operation, once a week
- upon initial startup
- after longer stoppages

- in the event of such a malfunction (e.g., in the vacuum system)

The test is used to detect leaks in the autoclave. As a result, the leakage rate is determined.
Perform the vacuum test with a cold and dry autoclave as follows:

- Turn the autoclave on at the power switch.
- In the **`Programs & Tests`** menu, select the vacuum test.
- Press START.

The boiler is →evacuated until the pressure for the vacuum test is achieved. This is followed by a compensation period of five minutes and a measurement period of ten minutes. During the measuring period, the pressure increase in the boiler is measured. At the end of the measurement period, you will see a message indicating the leakage rate on the →display. If the leak rate is too high, a corresponding message is provided on the display (if this occurs repeatedly, notify your stockist).

Bowie & Dick test

The →Bowie & Dick test is used for the detection of steam penetration of porous materials, such as textiles. For function control, you can routinely perform a verification of the steam penetration. To do so, use the test program Bowie & Dick test.
For the →Bowie & Dick test, different test systems are offered by specialist suppliers. Perform the test according to the instructions of the test system manufacturer.

Chapter 10 – Malfunctions

In this chapter, you will see

- **what kind of messages there**
- **what to do in the event of malafunctions**
- **what you can do before calling the hotline**
- **what you can do when experiencing poor drying results**

A warning is not a malfunction

Not all messages that appear on the →display are error messages. Warnings and error messages are shown with an event number on the display. This number is used for identification.

NOTICES

Many messages are notices that are for your information. Notices are not error messages or warnings.

Warnings

If necessary, warning notices are displayed. These include instructions for you. Warning notices are not error messages. They help you to ensure trouble-free operation and to recognize undesirable states. Observe these warning notices in a timely fashion so as to avoid interference.

Error messages

If safe operation or safe sterilization cannot be guaranteed, error messages are displayed.
This can appear on the →display shortly after switching on the autoclave or during a program run.
If an error occurs during a program run, the program will be interrupted.

Danger

- If a program is interrupted prior to drying, the load will not be sterile. Repeat the wrapping process if necessary and repeat the sterilization for the respective →items to be sterilized.

Otherwise, the health of your patients and dental team can be endangered.

Before you call

Follow the instructions which are shown in connection with a warning notice or an error message on the →display of the autoclave. Moreover, you can find the most important results in the table below. For the events, possible causes and corresponding operating instructions are listed.
If you cannot find the relevant event listed in the table below or if your efforts are not successful, contact the stockist in your area. In order for you to be helped, have the serial number of your autoclave and a detailed error description ready.

Event	*Possible causes*	*What you can do*
61	For the internal storage tank for →feed water: no water in the storage tank, For the water treatment system: Does not produce any water, because the faucet is not open.	Fill the internal storage tank, Open the water intake for the water treatment system
63 **64** **65**	For the internal storage tank for →feed water: water of inadequate quality will be poured into the storage tank (> 60µS/cm) For the water treatment system: Mixed bed resin in the water treatment system is exhausted	Drain and clean the supply tank and fill feed water of the quality → DIN EN 13060, Annex C Replace the mixed bed resin in the water treatment system
67 **68**	Water flow is not guaranteed; the measures in the announcement of the rinsing process were not followed	Enable water draining, monitor the siphon
72 **73** **74** **75**	The feed water quality is decreasing (> 40 ĩS/cm) Mixed bed resin is nearly exhausted	You can still continue with all the work with the autoclave, but you should add new feed water or replace the mixed bed resin as soon as possible
76	see Event 67	
78 **79** **80**	Drain tank has not been (completely) drained	Drain the drain tank completely
102	Waste water hoses which are kinked or have large sags	Check the waste water hose: They have to be laid without sagging and with a steady incline
113	The autoclave was turned off during a running program, Plug connection not fully established, machine has been unplugged, Power failure in the building supply	Do not switch off the autoclave at the power switch when the program is running on, Check the building installation, operate the autoclave on a separate circuit
116	The maximum permitted difference between the theoretical temperature and the temperature measured on Temperature Sensor 1 (AIN01) is too large.	If this error occurs repeatedly, please notify your specialized dealer.
117	Temperature Sensor 1 or 2 is defective, temperature difference too large	If this error occurs repeatedly, please notify your specialized dealer.
118	Exceeding of the maximum permissible sterilization temperature at Temp. Sensor 1 (AIN01)	If this error occurs repeatedly, please notify your specialized dealer.
119	The temperature at Temp. Sensor 1 (AIN01) has fallen below the minimum permissible sterilization temperature	If this error occurs repeatedly, please notify your specialized dealer.
123	Ambient temperature too high,	Observe set-up directions (see page 15, **Requi-**

Event	*Possible causes*	*What you can do*
124 **125** **126**	built-in autoclave is receiving no or too little cool air, autoclave is overloaded, Autoclave was operated without holder, so, for example, the laundry package had direct contact with the chamber and is absorbing large amounts of →condensate; Cooling air intake holes in the bottom panel are, for example, obscured by vacuumed up paper	**rements of the installation** location), Monitor the load, observe the loading instructions (see page20, **Loading the** autoclave) Remove objects (e.g., paper) from beneath the autoclave
128	see Event 102	
129	autoclave is overloaded Poor power supply (undersized house wiring to the plug, damaged power outlet, multiple devices into a power outlet or fuse)	Check load, (see page 20, **Loading the** autoclave) Check power supply
134	see Event 123	
136	Ambient temperature too high, Vents concealed, minimum lateral distance not complied with, door is permanently open,	Check set-up conditions (see page 15, **Requirements of the installation** location), Closing the door
183	see Event 123	
175 **176**	ACOUT1 main heating or ACOUT2 controlled heating, electrical supply interrupted; FOY1 + FOY2 can occur alternately.	1. Turn off device and press reset button Overheating Protection **(page 8, Fig.1 / (9))** again. 2. Acknowledge error messages, 3. Switch autoclave off and back on again 4. Continue with sterilization or conduct empty sterilization.
192	Notice on subsequent rinsing process, rinsing condition in the feed water tank should be established	Fill the tank with feed water fully or ensure the water supply to the water treatment system
193	Notice on subsequent rinsing process, rinsing condition in the drain tank should be established	Drain the drain tank completely
231	No →CF Cards are inserted in the following situations: CF Card is selected in the **`Settings`** → **`Logging`** menu as the output medium and instant output is activated or log output is started from the **`Logs`** menu and the CF Card is determined as the output medium or the CF Card should be formatted	Insert CF Card in the card slot (see page 30, **CF Card as** output medium) switch to the **`Logs`** menu and, from there, save the desired logs to the CF Card (see page 32, **Outputting stored logs at** a later time), Repeat the formatting of the CF Card
248	Vacuum test for residual moisture in the boiler or with a load	Repeat vacuum test if autoclave is cold, dry and empty
351	It has been two years since the initial start-up or since the last maintenance, or 2000 sterilization programs have been completed	Contact stockist and agree upon a maintenance appointment; Autoclave can be started again
377	Attempt to output the log to the log printer, but no log printer is connected	Connect printer (see page 31, **Log printer as** an output medium)
386	Internal memory of the autoclave for the logs of the completed programs is almost full	Select the internal log memory on a storage medium of your choice from the **`Logs`** menu (see page 32, **Outputting stored logs at** a later time)
387	Internal memory of the autoclave for the error logs	Error logs are needed, for example, by the tech-

Event	*Possible causes*	*What you can do*
	is almost full	nicians during maintenance and troubleshooting. Select the internal error log memory on a storage medium of your choice via the **Logs** menu.
394	In the **Settings** → **Logs** menu, **immediate output** is activated, and the →CF Card has been selected as the output medium, but has not yet been inserted.	Press YES if you want to output the as-of-yet unissued logs on the CF Card now.
395	In the **Settings** → **Logs** menu, **immediate output** is activated, and the log printer has been selected as the output medium but has not yet been connected.	Press YES if you want to print the as-of-yet unissued logs.
396	In the **Settings** menu, **immediate output** is activated, and the computer has been selected as the output medium but has not yet been connected or switched on.	Press YES if you want to output the logs now which have not yet been transferred to the computer.
408	see Event 135	
414	For direct waste water connection: kinked waste water pipe Autoclave is overloaded Autoclave is in too high an ambient temperature, Autoclave is installed and is receiving no or insufficient cooling air Autoclave was operated without shelf rack, so, for example, the laundry package had direct contact with the chamber and is absorbing large amounts of →condensate. This condensate evaporates during evacuation and forms large amounts of steam; Cooling air intake holes in the bottom panel are, for example, obscured by vacuumed up paper	Check drain hose for kinks or crushing Note the maximum loading amounts; Ensure proper air supply to the back of the autoclave Use shelf rack; Look out for wrapping residues in the boiler;
428 **439**	For direct waste water connection: kinked waste water pipe, Poor installation (several devices on one siphon, drain hose has large sags) Wrapping remains are clogging the pressure relief port	Check drain hose for kinks or crushing, check for wrapping remains in the boiler

Event	*Possible causes*	*What you can do*
433	The maximum permitted difference between the theoretical temperature and the temperature measured on Temperature Sensor 2 (AIN02=display) is too large.	If this error occurs repeatedly, please notify your specialized dealer.
434	Exceeding of the maximum permissible sterilization temperature at Temp. Sensor 2 (AIN02=display)	If this error occurs repeatedly, please notify your specialized dealer.
435	The temperature at Temp. Sensor 2 (AIN02=display) has fallen below the minimum permissible sterilization temperature	If this error occurs repeatedly, please notify your specialized dealer.

Table 13: Important warning notices and error messages

Poor drying results

In addition to proper functioning of the autoclave itself, satisfactory drying will essentially depend on proper installation and loading of the autoclave.

What you can do

- Check the correct installation of the autoclave. If necessary, enlarge the sloping position by extending the front feet by a maximum of 2 turns.
- The bottom of the boiler must be free. Remove any fallen instruments, filter paper, etc.
- Ensure the correct loading of the autoclave. Do not overload the autoclave. Make sure that the textiles do not have contact with the boiler wall and floor.
- Use the supplent drying function.

Technical Data

Model name	**DAC PREMIUM**	**DAC PREMIUM^{+}**
Device dimensions (HxWxD)	56.5 x 47 x 57.5 cm	56.5 x 47 x 69 cm
Sterilization chamber (Diameter x Depth)	Ø 25 cm x 35 cm	Ø 25 cm x 45 cm
Volume of the sterilization chamber	18.4 liter	23.8 liter
Weight (empty)	59 kg	66 kg
Electrical connection	220 - 240 V* 50/60 Hz, 16 A separate fuse, RCCB 30mA	
electric power	3400 W	
max. sound power	64 dB(A)	
Waste heat (at max. solid load)	1.6 kW/h	1. kW/h
Ambient temperature	16 - 26 °C	
relative humidity	30 - 60 %	
Feed water quality	distilled or demineralized water according to DIN EN 13060, Annex C	
Length of the power cable	1.35 m	
Protection type (according to IEC 60529)	IP20	
CE mark	CE 0123, CE 0035	

*Observe the maximum tension range of 207-253V

Glossary

1:1 Cable
(also called "straight through" cable) or "normal" network cable for the connection of a computer (by network card) with the →hub/→switch; also corresponds to the direct connection of a computer to the network interface of the autoclave. The cable runs in parallel paths between the plugs in contrast to the →crossover cable.

aqua dem
→demineralized water

aqua dest
→distilled water

Pre-heating time
Time needed, after switching on the autoclave or the start of a sterilization program, for heating the → double-jacketed steam generator before the sterilization process starts; the duration depends on the temperature at which the sterilization process occurs.

authorized individuals
Technicians from depots or employees of customer services identified by Sirona and who are trained by Sirona.

BGV A1
Professional association regulations – Principles of Prevention

Bowie & Dick-Test
Steam penetration test with standard test pack; described in →DIN EN 285; test in recognized in large-scale sterilization

CF-Card
Compact Flash Card;
Compact flash card; Memory card for digital data with a compact size;
CF is standard, i.e., these memory cards can be used in any device with a CF slot. The CF Card can by read and, if applicable, inscribed by any device that supports the standard.

Charge
Summary of the →sterilized items which have gone through one and the same sterilization program together.

Crossover Cable
A crossover cable connects two computers (through a network card)directly without using a →hub/→switch. This type of connection corresponds to the network connection of the autoclave in the (practice) network. The crossover cable does not run in parallel paths between the plugs; rather, certain cable cores are interchanged or "crossed".

Demineralized water
Water without minerals which appear in normal well or tap water; obtained from normal tap water as a result of ion exchange. It is used here as →feed water.

Distilled water
Also aqua dest from the Latin aqua destillata; is largely free of salts, organic matter and microorganisms, is obtained from ordinary tap water or pre-purified water through distillation (evaporation 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 " Anforderungen an das Personal" [Personnel Requirements].

DIN 58953
Standard – sterilization, sterile supply

DIN EN 867-5
Standard – Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and test pieces for performance testing of small Type B and Type S sterilizers

DIN EN 868
Standard – packaging materials and systems for medical products to be sterilized

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

DIN EN 13060
Standard – small steam sterilizers

DIN EN 285
Standard – sterilization – steam sterilizers – large sterilizers

Double-jacketed steam generator
used for fast steam production outside of the actual sterilization chamber, surrounds the sterilization chamber

Dynamic pressure testing of the sterilization chamber
Is used to demonstrate that the rate of the pressure changes occurring in the sterilization chamber during a sterilization cycle does not exceed a value which can cause damage to the wrapping material. [→DIN EN 13060]

Stainless steel cleaner
e.g., Sidol

Simple wrapping
Wrapped once; for example, instruments sealed in a foil – in contrast to: →multi-wrapping

Evacuation
Production of a →vacuum in a vessel

Firewall
Is a combination of hardware and software as a network security component. The purpose of a firewall is to secure the data traffic between network segments with different confidence levels. A typical application is to control the transition between a local area network (LAN) – high confidence – and the Internet – no confidence. You can prevent, for example, that an FTP server (program) receives data from another network participant (autoclave) or computer.

Fractionated vacuum process
Technical steam sterilization process;
is the repeated →evacuation of the sterilization chamber →alternating with steam inlet.

FTP
(**F**ile **T**ransfer **L**og) is a data transmission method which serves the transport of data from the Internet, subject to changes in the course of technical advancements**.** These data can include programs, files, or even information. Special FTP programs (FTPClients) are used to load the data to a server (upload).

Mixed load
Wrapped and unwrapped items to be sterilized within a load

Handshake
A handshake is a simple method of data-flow control by which two participants involved in a transfer of data are synchronized after each transmission by direct acknowledgment signals via control lines.

Hollow Body A
A body opened on one side and for which the following applies:
1 ≤ L/D ≤ 750 and L ≤ 1500 mm or
a body opened on both sides and for which the following applies:
2 ≤ L/D ≤ 1500 and L ≤ 3000 mm and which does not correspond to Hollow Body B
L…hollow body length
D…hollow body diameter
[→DIN EN 13060]

Hollow Body B
A body opened on one side and for which the following applies:
1 ≤ L/D ≤ 5 and D ≥ 5 mm or
a body opened on both sides and for which the following applies:
2 ≤ L/D ≤ 10 and D ≥ 5
L…hollow body length
D…hollow body diameter
[→DIN EN 13060]

Hub
Is used to connect several computers in a network, such as by an Ethernet star configuration, i.e., all the devices on the network are connected to the hub.

Initialization
Production of a given output state of the→software upon startup

Condensate
Liquid (e.g., water) which results from the vapor state upon cooling and is secreted as such

Corrosion
Chemical alteration or destruction of metal materials by water and chemicals

Contamination
Here: pollution of the sterilizer load with unwanted or harmful substances

LED (bar)
(Abbr.: Light Emitting Diode)
Semiconductor diode that lights up when power is supplied. LEDs areused mainly for status displays of equipment.

Empty chamber test
Test without a load; conducted to evaluate the performance of the sterilizer without the influence of a load; permits verification of the obtained temperatures and pressures with respect to the intended settings.
[→DIN EN 13060]

Conductivity
is the reciprocal value of the electrical resistance; The unit of measurement is microsiemens/cm (µS/cm); The more substances which are dissolved in the water, the more effectively it conducts electric power and, therefore, the higher its conductivity.
→ideally, distilled water has a conductivity of zero.

Air leakage – Testing of air leakage
Air leakage is an unsealed area via which air can enter and escape when this is not desired;
Examination of the air leakage is used to demonstrate that the volume of the air inlet in the sterilization chamber during the vacuum phases does not exceed a value which prevents the penetration of steam into the sterilizer load, and that the air leakage it not a possible cause of →recontamination of the sterilizer load during drying.

Solid
without hollow or intermediate spaces, tight, sealed, closed

Solid load – Test with a solid load
Serves to demonstrate that at the values according to which the control is set, the required sterilization conditions are achieved in the entire load. The load has to reflect the maximum mass of solid instruments for the sterilization of which a sterilizer is designed pursuant to →
DIN EN 13060.
[DIN EN 13060]

Multi-wrapping
For example, instruments double sealed in foil or wrapped in foil are also in a receptacle or a container wrapped in textiles.

Network adapter
Ethernet printer module for the
NITRAprint printer; On the one side is the printer port and on the other side is the connection socket for a network cable

Multi-thread capable
Refers to the simultaneous processing of multiple threads (execution threads within a process). Referring to an FTP server program, multiple users can store data there at the same time, i.e., multiple autoclaves can simultaneously send logs to the FTP server.

Standard compliant
Conforms to all relevant standards

Ping
Is a diagnostic program for testing the availability and reaction time of computers in networks.

Porous
permeable to liquids and air, such as textiles

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

Porous partial load – Testing of porous partial loads
Serves to demonstrate that at the values according to which the control is set, the steam quickly and evenly penetrates into the specified test package
[→DIN EN 13060]

Porous full load – Testing of porous full loads
Serves to demonstrate that at the values according to which the control is set, the required sterilization conditions can be achieved in porous loads with the maximum density for the sterilization of which a sterilizer is designed pursuant to →DIN EN 13060
[DIN EN 13060]

Process evaluation system
also Self-monitoring system – observes itself, compares sensors while a program is running

RKI
Robert Koch Institute

Lubricant
e.g., instrument oil

Self-Monitoring-System
→Process assessment system

Delay in boiling
Is the phenomenon that, under certain conditions, liquids can be heated to above their boiling point without their boiling; this condition is unstable; at low vibrations, a large gas bubble which expands explosively can quickly develop.

Software
Non-physical components of a computer system; e.g., computer program

Feed water
Is used to generate the steam needed for sterilization; Standard values for water quality according to →DIN EN 285 or →DIN EN 13060 – Annex C

Sterilized items
Are also referred to as the →batch, have already been successfully sterilized, i.e., sterile products

Sterilization chamber
Interior of a sterilizer
receives the →items to be sterilized

Items to be sterilized
Are non-sterile, sterilizable items which are yet to be sterilized

Switch
A switch is a network component to connect multiple computers or network segments in a local area network (LAN). Since switches analyze network traffic and make logical decisions, they are also called intelligent switches.

TCP
(Transmission Control Log) refers to a standard log for connecting computers and networks.

Vacuum
Colloquially: matter-free space
in the technical sense: volume with reduced gas pressure (usually air pressure)

Vacuum drying
Gentle drying; The dried material is a exposed to negative pressure, which reduces the boiling point and thus results in water evaporation, even at low temperatures.

VDE
Verband der Elektrotechnik, Elektronik und Informationstechnik e.V. [Association for Electrical, Electronic & Information Technologies]

Pre-heating time
→Warm-up time

Soft sterilization wrapping
For example, paper bags or clear plastic sterilization wrapping

Annex A – Accessories

Article	***Product group***	***REF.***	
		DAC PREMIUM	***DAC PREMIUM+***
Tray Holder C for 6 trays or 3 standard tray cassettes	94	65 39 790	65 39 808
Sterile filter		61 26 093	
NITRAprint	92	61 17 324	
NITRAprint printer paper	94	58 77 266	
NITRAprint printer ribbon	94	58 77 274	
NITRAflash	92	61 34 394	
NITRAflash CF Card	94	65 43 214	
Test set for Bowie&Dick test	92	58 92 034	
Test set for Helix test	92	58 92 042	
Replacement indicators	94	59 03 641	
Chemical indicator Class 5	92	58 92 059	
NITRAprint 60, label printer	92	65 43 172	
NITRAprint 60 labels white	94	65 43 180	
NITRAprint 60 labels, blue	94	65 43 198	
NitraDem Direct Connect	92	62 59 852	
NitraDem filter	94	61 98 431	
NitraDem Installation Kit	94	62 59 076	
Water pistol	94	62 59 084	
SIRODEM	92	58 86 168	
Cartridge for SIRODEM	92	58 92 026	
Main Fuse 16 A	92	61 26 572	
NITRAprint network adapter (in connection with DAC PREMIUM/DAC PREMIUM+)	92	65 46 266	

Annex B – Symbols on the Autoclave

With the adjacent unit sticker, the manufacturer of the device states that the medical device complies with the essential requirements of European standard EN1717 – Protection of Drinking Water from Contamination.

The symbol of the crossed-out garbage can indicates a device that must not be disposed of with household waste. It has to be handled via a proper and professional disposal point.

With the labeling of a device with this symbol, the manufacturer also explains that he fulfills all the requirements of the law regarding the sale, return and environmentally sound disposal of electrical and electronic equipment.

By labeling with this CE mark, the manufacturer declares that the medical device complies with the essential requirements of the Medical Devices Directive. The four-digit number signifies that an approved certification body supervises it.

By labeling with this CE mark, the manufacturer declares that the medical device complies with the essential requirements of the Printer Directive. The four-digit number signifies that an approved certification body supervises it.

Subject to changes in the course of technical advancements.

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