Hygoclave 90

СТОМАРТ
DENTAL SOLUTIONS

EN

Installation and Operating Instructions

CE 0297

6046100064L02

DÜRR DENTAL

1702V002SE

Contents

EN

Important information

Product description

Installation

Operation

EN

Troubleshooting

Appendix

1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Warning – dangerous high voltage


Warning – hot surfaces

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
  Immediate danger of severe injury or death
– **WARNING**
  Possible danger of severe injury or death
– **CAUTION**
  Risk of minor injuries
– **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.


Take note of the accompanying documents.


CE labelling with the number of the notified body


Manufacturer


Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).


Serial number


Order number


On/off switch


Monitor ambient conditions


Steam sterilise at 134 °C


Fresh water


Waste water


Wear hand protection.


Switch off and de-energise the device (e. g. unplug from mains).

1.2 Copyright information

EN

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The Hygoclave is a small steam steriliser in accordance with DIN EN 13060 and is designed for medical use.

2.2 Intended use

The programs offered by the steam steriliser enable the selection of 'type B' sterilisation cycles. This means that it can be used to sterilise bulky products, porous products and products with a narrow lumen, packaged (single or multi-layer) or unpackaged.

Before sterilising any medical devices, also refer to the information provided by the manufacturers of these medical devices (refer also to EN ISO 17664).

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

WARNING
The sterilisation of liquids can cause a risk of explosion, risk of burns, boiling retardation and vapours that are hazardous to health.
› Do not sterilise liquids in the unit.

WARNING
Risk of explosion due to ignition of combustible materials
› Do not operate the unit in any rooms in which inflammable mixtures may be present, e.g. in operating theatres.

NOTICE
Damage to the unit or to the items being sterilised due to unsuitable materials
› Only sterilise instruments, packaging and textiles that are suitable for steam sterilisation according to the manufacturer's information.

2.4 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.5 Applicable guidelines and standards

Guidelines

Medical Devices Directive

93/42/EEC Directive on Medical Devices. In its current version.

Standards

In their current version.

DIN EN 13060

Small steam sterilisers.

EN 61010-1

Safety requirements for electrical equipment for measurement, control and laboratory use.

EN 61010-2-040

Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilisers and washer-disinfectors used to treat medical materials.

EN 61326-1

Electrical equipment for measurement, control and laboratory use – EMC requirements

2.6 Qualified personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

› Regularly train all operators who are responsible for use and maintenance of the device. As part of this, the operators must also demonstrate that they have understood everything covered. Attendance lists of the training course participants must also be kept.

Installation and repairs

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.7 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.

› Immediately replace any damaged cables or plugs.

2.8 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.

› Only use only genuine working parts and spare parts.

2.9 Transport and packaging

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the device in its original packaging.

› Keep the packing materials out of the reach of children.

2.10 Disposal

Unit

The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions in this case.

› Decontaminate potentially contaminated parts before disposing of them.

› Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.

› If you have any questions concerning the correct disposal of parts, please contact your dental trade supplier.

Decontamination of potentially contaminated parts

The following parts of the device may be contaminated.

– Sterilisation chamber

– Water container

– Water-carrying lines

In order to properly dispose of the potentially contaminated parts, they must first be decontaminated. To do this, carry out the following steps:

› Empty the water containers.

› Remove all fixed connections for fresh water and waste water.

› Wipe-disinfect the inner surfaces of the water containers with a surface disinfectant, e.g. FD 322 or FD 333 from Dürr Dental.

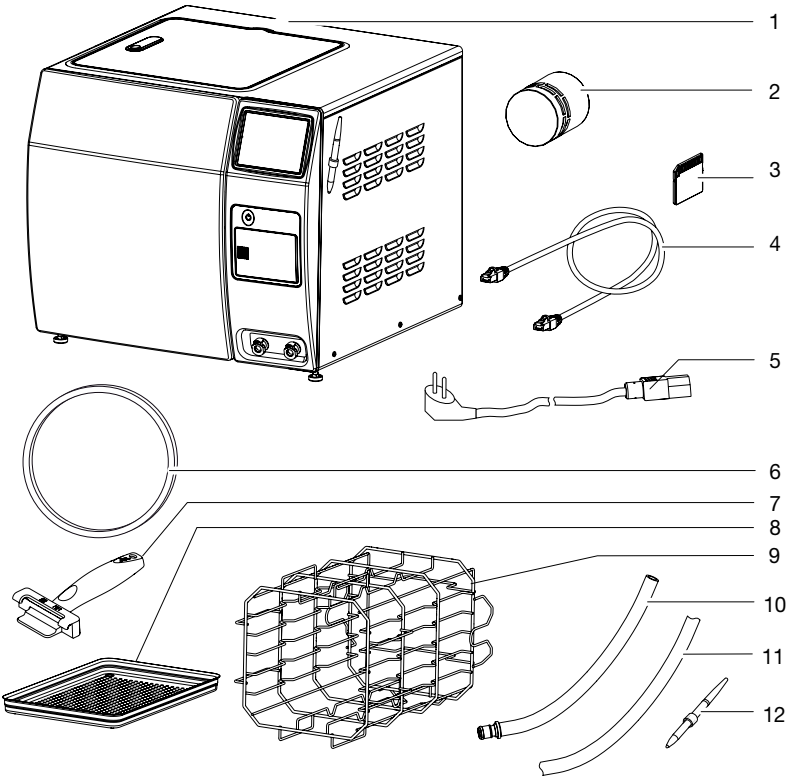
› Once the inner surfaces of the water containers have dried off, fill the fresh water container with demineralized fresh water (see "7.7 Connecting the unit").

› Run 2-3 cycles of the quick program.

› Empty the water containers and wipe-disinfect them.

EN

3 Overview



1 Steam steriliser Hygoclave 90
2 Sterile air filter
3 SD memory card
4 Network cable
5 Mains cable
6 Door seal
7 Tray handle
8 Tray
9 Carrier, rotatable, for 6 trays or 3 standard tray cassettes
10 Drain hose for waste water and fresh water
11 Water drain hose for "automatic water discharge"
12 Stylus with magnet bracket

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Hygoclave 90 6046-01

– Carrier for trays or standard tray cassettes
– Trays
– Tray handle
– SD memory card
– Stylus with magnet bracket
– Drain hose for manual emptying of fresh and waste water on the fore side of the device
– Water drain hose for "automatic water discharge" on the rear side of the device
– Water filter set
– Hexagon key for emergency unlocking
– Sterile air filter
– Hygotest, starter kit
– Network cable
– Mains cable
– Software "Tyscor Pulse"
– Installation and operating instructions
– Handover and installation record

3.2 Accessories

The following articles are necessary for the operation of the unit, depending on the application:

Tray (perforated) 6046100112

3.3 Special accessories

The following optional items can be used with the device:

Hygoprint Plus
(label printer, network capable) . . . 6046100035
Labelling set for
Hygoprint Plus 6046100130
Hygopure 90
(reverse osmosis system) 6046100017
Hygodem 90 (ion exchanger). 6046100114

3.4 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

Hygotest (Helix test bodies
with test strips) 6050-600-03

3.5 Wear parts and spare parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Sterile air filter 6046-000-14
Door seal 6046100080
Tray handle 6046100102
Stylus with magnet bracket 6046100129
Water filter set. 6046100132
Drain hose for manual emptying of
fresh and waste water on the fore side
of the device 6046100105
Water drain hose for "automatic water
discharge" on the rear side of the de-
vice. 6046100128
Lubricant 9000474001

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

Electrical data for the unit		
Nominal voltage	V AC	230
Electrical frequency	Hz	50
Rated power	W	2600
Standby consumption	W	1
Fuses		2 x T 12 AH / 250 V~ (IEC 60127)
Over-voltage category		II

General technical data of device		
Dimensions (H x W x D)	cm	48 x 57.5 x 54
Weight, empty	kg	65

Other technical data		
Heat output at 23 °C	MJ/h	6.5
Noise level *	dB(A)	<65
Operating mode		Continuous operation
Capacity of fresh water container	l	approx. 4
Capacity of waste water container	l	approx. 4
Operating pressure (absolute) max.	kPa	325
Operating pressure (absolute) min.	kPa	approx. 5
Response pressure (relative), safety valve	bar	2.55
Water and dust protection (in acc. with IEC 60529)		IP 20
Degree of soiling (in accordance with EN 61010-1)		2

* In accordance with EN ISO 1680 Airborne Noise Emissions; measured in a sound-insulated room.

Technical data for the sterilisation chamber		
Internal dimensions, useable volume (∅ x D)	cm	26 x 35
Volume	l	19
Load capacity (unpackaged instruments)		
Bulky hollow instruments	kg	6
Porous materials	kg	2
Sterilisation temperature in acc. with DIN EN 13060	°C	134 + 3
Heat-up time, at room temperature	min	approx. 15
Sterilisation hold time, program-dependent	min	3.5 - 20.5
Drying time, program-dependent	min	10.5 - 16

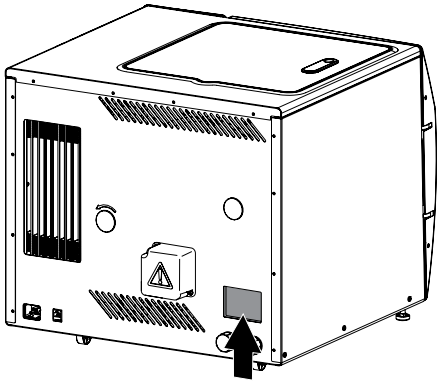
Classification	
Medical Devices Directive (93/42/EEC)	Class IIb
Manufacturer: Dürr Dental	(based on rule 15)

Electromagnetic compatibility (EMC)		
High-frequency emissions in accordance with CISPR 11		Group 1 Class B
Mains impedance, in accordance with IEC 61000-3-11	Ω	< 0.1
Harmonics in acc. with IEC 61000-3-2		Not applicable
Voltage fluctuations/flickers in acc. with IEC 61000-3-3		Not applicable
Conducted high-frequency disturbance variable V_1 in acc. with IEC 61000-4-6	V_{eff}	3
Emitted high-frequency disturbance variable E_1 in accordance with IEC 61000-4-3	V/m	4
Internal memory		
Memory capacity		10,000 cycles
Network connection		
LAN technology		Ethernet
Default		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5
Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	85
Ambient conditions during operation		
Temperature	°C	+15 to +35
Relative humidity	%	< 85
Air pressure	hPa	750 to 1060
Altitude above mean sea level	m	< 2000
Connection for "automatic fresh water supply connection"		
Union nut	"	3/4
Screw-in connector	"	3/8
Running water pressure	bar (kPa)	1.5 - 5.5 (150 - 550)
Drain hose		
Hose length	m	1.50

EN

4.1 Type plate

The type plate is located on the rear of the unit.

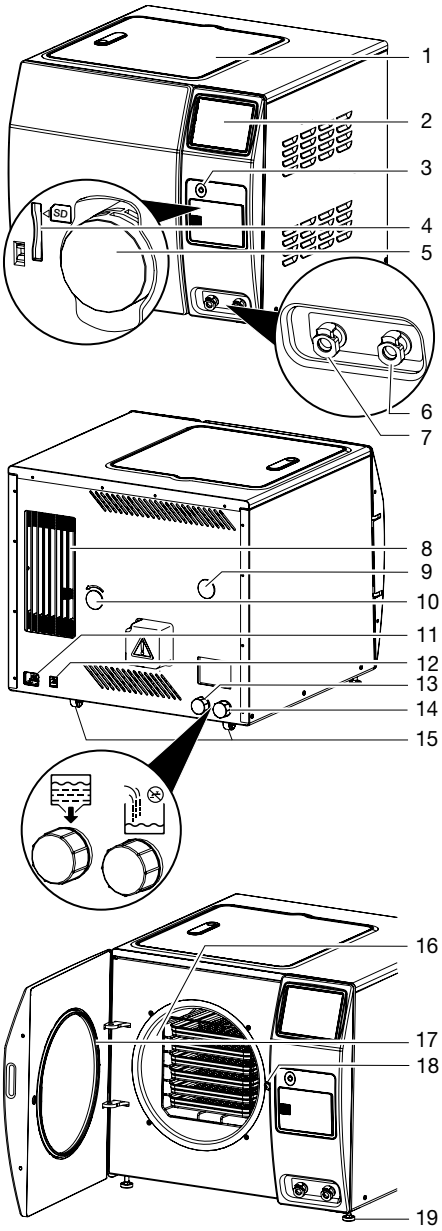


4.2 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation

5.1 Hygoclave 90



1 Cover for waste water container and fresh water container
2 Touch screen
3 On/off switch
4 SD memory card slot
5 Sterile air filter
6 Connection (quick release coupling) for "manual waste water emptying"
7 Connection (quick release coupling) for "manual fresh water emptying"
8 Condenser
9 Pressure gauge cover
10 Motor shaft cover
11 Electrical connections
12 Network connection
13 Connection for "automatic water drain"
14 Connection for "automatic fresh water supply connection"
15 Roller feet, for positioning of the unit
16 Sterilisation chamber
17 Door seal
18 Door spindle
19 Adjustable feet, for height adjustment of the unit

The Hygoclave 90 small steam steriliser is used to sterilise objects with steam at temperatures of 121 °C or 134 °C under pressure.

The unit sterilises on the basis of the fractionated vacuum method. This ensures that the objects being sterilised are wetted or penetrated with saturated steam. This method is suitable for steam sterilisation of all loads that will be encountered in a medical practice.

The sterilisation chamber is protected against overheating.

Use fresh distilled or demineralised water for every sterilisation process.

Vacuum phase

A vacuum is generated in several phases depending on the program.

Sterilisation phase

Saturated steam is generated inside the steriliser chamber until the specified values are reached. The actual sterilisation takes place during the predefined hold time.

EN

Drying phase

The parts for sterilisation in the sterilisation chamber are dried under vacuum. Afterwards the sterilisation chamber is vented via the sterile air filter and the door can be opened.

Vacuum drying ensures optimum drying results even when the parts for sterilisation are packaged.

Sterilisation chamber

The capacity of the sterilisation chamber is 19 litres. It can be filled with a load according to demand.

The maximum load depends on the load type and the selected program.

Steam generator and heating system

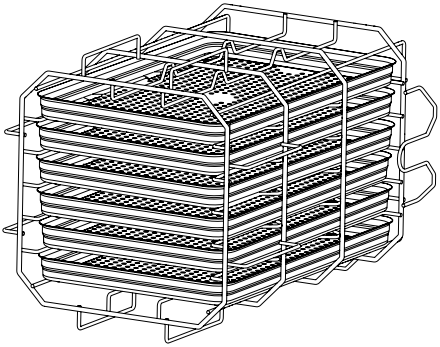
The device has a high-performance steam generator. This is coupled to an insulated heating system (heat pipe), which fully encloses the sterilisation chamber. This unique combination ensures fast process times and very good drying results.

Steam condenser and vacuum pump

The combination of steam condenser and vacuum pump, which has been specially developed for steam sterilisation, enables reliable and fast generation of a deep vacuum in all phases of the process.

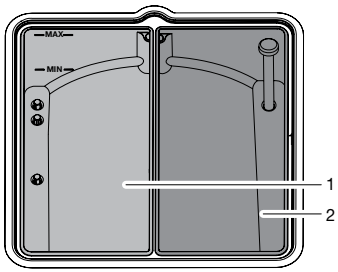
The resulting high venting capacity ensures the very good sterilisation and drying results.

Carrier, trays, standard tray cassettes



The carrier can be loaded with up to 6 trays or – rotated through 90° – 3 standard tray cassettes.

Water container



1 Fresh water container
2 Waste water container

The unit is equipped with a fresh water container (left-hand side) and a waste water container (right-hand side). The maximum capacity of each container is 4 litres.

Depending on the selected program and the load, an average of approx. 7 sterilisation cycles is possible.

The minimum and maximum fill levels are detected via a water level sensor.

Fresh water supply

The supply with fresh water is provided either via the internal fresh water container or via an external water treatment system, which is connected to the in-house water supply.

Only use high-quality distilled or demineralised water. Guideline values for water quality in accordance with DINEN 13060 Appendix C.

If a water treatment system is connected there is no need to fill up the fresh water container.

Waste water emptying

The waste water is collected in the waste water container at the end of each cycle.

The waste water can be manually emptied or, when connected to the central sewerage system, drain off automatically.

Water treatment system

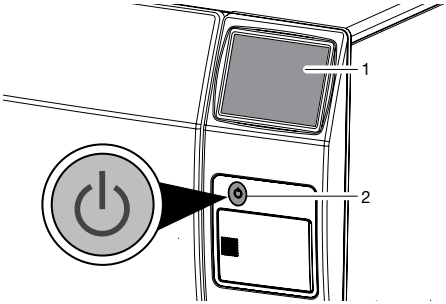
With the aid of a water treatment system it is possible to produce water with optimum fresh water quality for steam generation in the unit.

The water treatment system is connected to the fresh water connection of the unit and to the in-house water supply.

Altitude

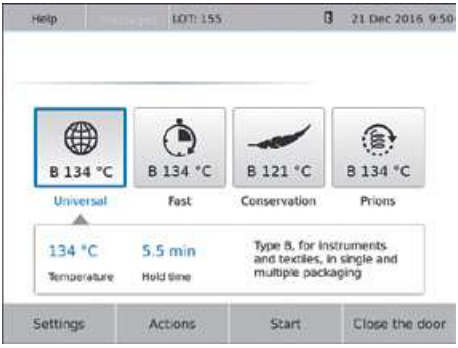
Adjustments for altitude (above mean sea level) and therefore to the ambient pressure are performed automatically.

Operating elements



1 Touch screen
2 On/off switch

The touch screen can be used to adjust settings on the device and select programs. Instructions can be entered on the touch screen either with the tip of a finger or with a stylus.



Start screen on the touch screen

Batch documentation

The device has an internal memory in which all data for completed cycles (> 10,000 cycles) is saved.

In order to enable effective batch documentation and subsequent checking of completed programs, the record can be saved immediately after the end of the cycle and output at a later time.

The record data can be further processed in various ways:

– saved to an SD memory card
– saved to a network storage location
– printed out via a network printer
– forwarded to document creation software

5.2 Safety devices

The unit has several safety devices for protecting the operator, patient and unit:

– Safety door latch
– Fresh water check
– Electronic parameter control
– Process evaluation system
– Safety valve
– Additional function check

If one or more of the parameter(s) exceed the specified limit values, the unit outputs warnings or fault messages and cancels the program if necessary.

If the program is cancelled a message will be displayed on the touch screen.

Safety door latch

The device continuously monitors the pressure and temperature and will not allow the door to be opened if overpressure is present in the sterilisation chamber. The automatic door latch ensures that the door only opens slowly (by rotating the door spindle). Even in the case of pressure differences, pressure equalisation takes place until the door is fully opened.

Fresh water check

Each time the program is started an automatic check of the fresh water is performed via an integrated conductivity measurement. This ensures that specified values are not exceeded. Stains on instruments and contamination of the unit are prevented (assuming careful instrument preparation).

Electronic parameter control

The device operates with electronic parameter control. Values for pressure, temperature and time are automatically monitored in the programs. This ensures that the total running time of a program is optimised depending on the load.

Process evaluation system

The process evaluation system monitors and compares ACTUAL process parameters with TARGET process parameters. In this way, faults in the program sequence can be detected and correct sterilisation results can be ensured.

Safety valve

A safety valve ensures pressure is released if the pressure is higher than 2.6 bar.

Additional function check

With the aid of test programs, it is possible to perform additional function checks at any time:

– Check the device for leakages in the steam system with the vacuum test
– Use the Bowie-Dick test to check that the steam penetration of porous items for sterilisation (e.g. textiles) is sufficient.

5.3 Overview of programs

Type tests	Universal program B 134 °C	Quick program B 134 °C	Gentle program B 121 °C	Prions program B 134 °C
Programme type in accordance with EN 13060	Type B	Type B	Type B	Type B
Dynamic pressure testing of the sterilisation chamber	X	X	X	X
Air leakage	X	X	X	X
Empty chamber test	X	X	X	X
Bulky load	X	X	X	X
Porous partial load	X		X	X
Porous full load	X		X	X
Hollow body B	X	X	X	X
Hollow body A	X	X	X	X
Single packaging	X	X	X	X
Multiple packaging	X		X	X
Drying, bulky load	X	X	X	X
Drying, porous load	X		X	X
Sterilising temperature	134°C	134°C	121°C	134°C
Steriliser pressure (absolute)	312.0 kPa	312.0 kPa	210.7 kPa	312.0 kPa
Hold time	5.5 min	5.5 min	20.5 min	20 min
Max. bulky load	10 kg	6 kg	6 kg	10 kg
Max. single weight (e.g. load on tray, standard tray cassettes)	3.3 kg	2 kg	2 kg	3.3 kg
Max. massive load in containers	10 kg		6 kg	10 kg
Max. single-packed, bulky load	6 kg	1.5 kg	6 kg	6 kg
Max. double-packed, bulky load	6 kg		6 kg	6 kg
Max. porous load	2 kg		2 kg	2 kg
Max. single-packed, porous load	2 kg		2 kg	2 kg
Max. double packed, porous load	2 kg		2 kg	2 kg

X = compliance with all applicable sections of standard DIN EN 13060

5.4 Tyscor Pulse (optional)

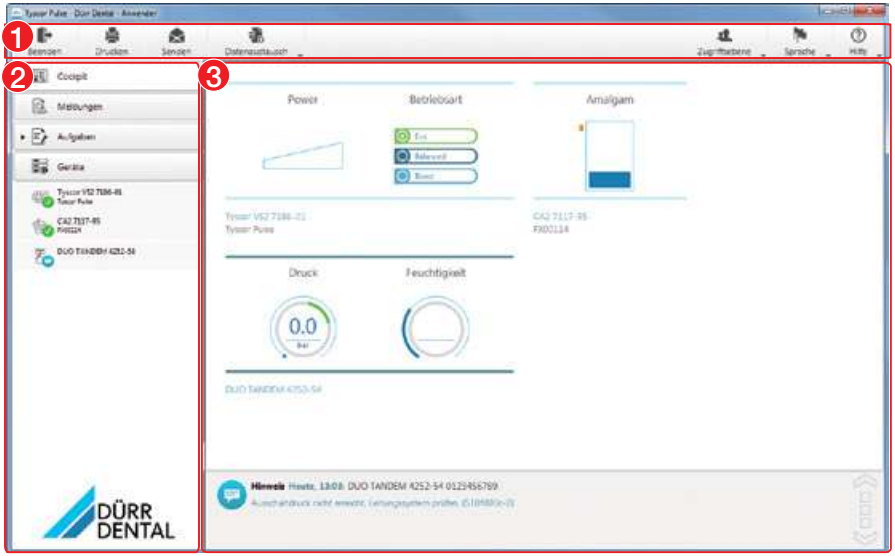
The software is connected via the network to the units from Dürr Dental and displays the current status as well as messages and errors.

All messages are logged and can be printed or sent.

Regular maintenance and upkeep is implemented in the tasks. Reminders signal when a task is due.

The *cockpit* shows the devices with the current characteristic data and provides a quick overview of the functional status of the devices.

The software interface consists of the menu bar, the side bar and the contents area.



1 Menu bar
2 Side bar
3 Contents area

The contents area depends on the tab selected on the side bar. The current messages are always displayed in the lower part of the contents area.

If there are several current messages, then the mouse wheel or the  or  buttons can be used to scroll through the messages.

The views and rights depend on the selected access level (Operator, Administrator or Service Technician).

While the software is running (even if the software window is closed), the access level is visible in the task bar (or Mac OS menu bar). The symbol shows the current status of the devices (see "13.4 Monitoring the device with Tyscor Pulse"). If a new message appears, a speech bubble tip also appears.

EN

6 Requirements

6.1 Installation/setup room

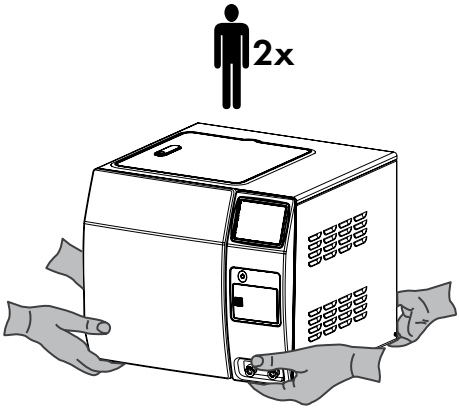
The room chosen for set up must fulfil the following requirements:

– Solid, horizontal ground/floor
– Closed, dry, dust-protected interior room. Should not be a room made for another purpose (e.g. boiler room or wet cell)
– Required distances between the unit and the wall and to the side must be complied with (see "7.3 Setting up the unit").
– Room chosen for set-up must be well ventilated
– No flammable gases in the proximity of the unit
– Observe the required ambient conditions (see "4 Technical data").
– Mains cable plug connections must be freely accessible so they can be quickly disconnected if there is any danger.

7 Installation

7.1 Carrying the unit

› The unit must only be carried by two persons.
› Use suitable carrying aids if necessary.



7.2 Remove the transport locks

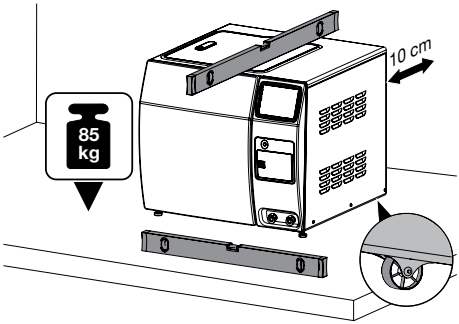
› Remove the internal and external packaging materials and transport protection.

7.3 Setting up the unit

The unit is intended for operation outside the patient environment.

The following gaps/distances must be maintained:

– To the treatment chair: min. radius of 1.5 m
– To the rear wall: at least 10 cm
– To the sides: at least 5 cm
– The unit should be freely accessible at the top so that the installed fresh water container can be filled and to ensure good ventilation.



EN

NOTICE
A build-up of heat can impair correct operation of the unit.
This may result in a shortened service life and extended cycle times.
› Comply with the specified minimum gaps/distances.
› Do not exceed the maximum permitted ambient temperature.

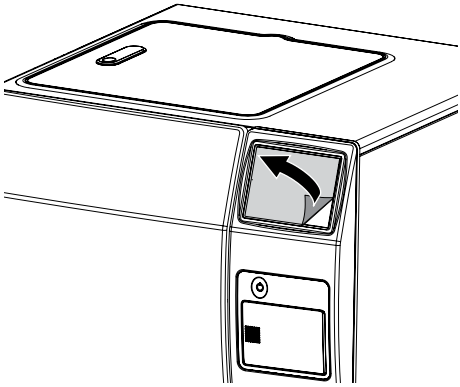
CAUTION
Danger of burns from hot steam
In the event of a fault, the safety valve on the rear of the unit is triggered by overpressure, i.e. if the pressure is above the normal operating pressure, and hot steam is given off.
› Install the unit in such a way that operators are not put in any danger.

› Place the unit on a horizontal table. The load-bearing capacity of the table must be suitable for the weight of the unit including operating media and load (see "4 Technical data").
› Align the unit in both planes so that it is horizontal using the two front adjustable feet.
On the underside of the unit there are 2 adjustable feet at the front and 2 roller feet at the rear, which are used for easier positioning of the unit.
When adjusting the unit, make sure that it is secured at all times so that it cannot fall down, e.g. by getting somebody else to help.

The design of the internal sterilisation chamber has a slope so that full condensate draining is ensured. For this reason it is not necessary to set up the unit with a tilt towards the rear.

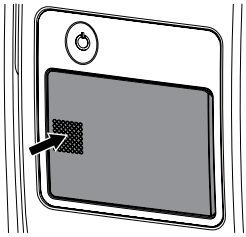
7.4 Removing the protective film from the touch screen

› Grasp one corner of the protective touch screen film and peel it off carefully.

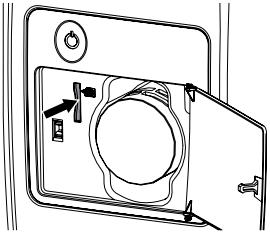


7.5 Checking the SD memory card

After transport it is possible that the SD memory card is no longer in the correct position.
› To open the cover: briefly press on the marked area.



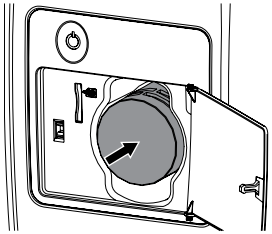
› Take out the SD memory card and reinsert it: press it in slightly, carefully pull it out and then slide it back in until it clicks.



7.6 Checking the sterile air filter

› Open the cover.

› Check to make sure that the sterile air filter is pushed in as far as it will go.

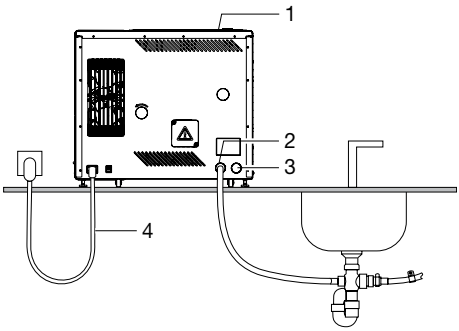


› Close the cover.

7.7 Connecting the unit

Installation examples

Example of a standard installation



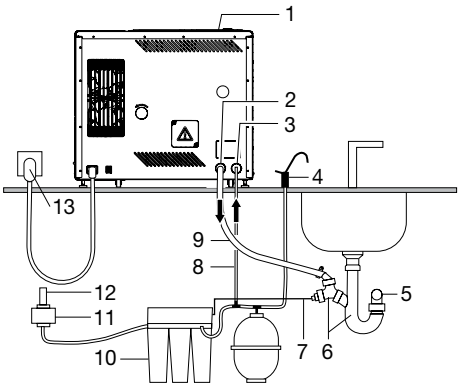
Installation example – standard delivery state

1 Cover for waste water container and fresh water container
2 Connection for "automatic water drain"
3 Connection for "automatic fresh water supply connection"
4 Electrical connections

The unit is supplied with fresh water directly via a hose from the internal fresh water container. No additional water connection is required.

The waste water either collects in the internal waste water container, or (if a hose for "automatic water discharge" is connected) it flows away directly. A message is displayed when the waste water container is full. The waste water then needs to be manually drained.

Installation example with a water treatment system



Installation example e.g. Hygopure 90 (schematic diagramme)

1 Cover for waste water container and fresh water container
2 Connection for "automatic water drain"
3 Connection for "automatic fresh water supply connection"
4 Removal of demineralized water
5 Wall drain (NW 40 – provided on-site)
6 Double chamber siphon with Y-piece
7 Concentrate drain from water treatment system
8 Automatic fresh water supply connection
9 Automatic water drain
10 Water treatment system
11 Aqua-Stop
12 Water tap (provided on-site)
13 Electrical connections

The device is supplied with demineralised water directly via a hose from the water treatment system.

Electrical connections

Electrical safety when making connections

› The device must only be connected to a correctly installed and earthed power outlet.

› Do not use movable multi-way power outlets.

› Make sure that none of the electrical cables leading to the unit are under any mechanical tension.

› Before start-up, check the mains voltage against the voltage indicated on the type plate (see also "4 Technical data").

EN

› Detachable mains cables must only be replaced with suitable, equivalent mains cables with the same performance data – refer to the inscription on the mains plug and mains cable.

Connecting the unit to the mains

The unit has no main power switch. For this reason it is important that the unit is be set up in such a way that the plug can be easily accessed and unplugged if required.

Requirements:

– Properly installed power outlet close to the unit (observe the max. mains cable length)
– Easily accessible power outlet
– Mains voltage must match the information shown on the type plate of the power supply unit

Fresh water supply

During commissioning, a volume of approx. 2 litres of water is automatically drawn from the fresh water container once in order to fill the empty steam generator.

The fresh water container can either be filled manually or filled via a water treatment system (if one is connected).

Manually filling the fresh water container

WARNING
Use of tap water compromises sterilisation

The use of tap water can lead to the following problems: Sterilisation cycles may be unsuccessful due to the introduction of incondensable gases. Formation of spots on sterilised objects. The unit may be damaged.

› Only use high-quality distilled or demineralised water. Guideline values for water quality in accordance with DIN EN 13060 Appendix C.

› Remove the lid.
› Fill up the fresh water container to the MAX mark with distilled or demineralised water (approx. 4 litres).
Make sure that the water does not overflow.

Connection of a water treatment system (optional)

› Connect a pressure hose to the "automatic fresh water supply" connection on the rear of the unit.
› Connect a pressure hose to the external water treatment system.

Result:

The fresh water container is filled as soon as the parameter ***Water supply*** is activated in the device configuration on the touch screen (see "8.6 Parameter selection").

Connection for automatic water drain (optional)

› Connect the supplied drain hose to the connection for the "automatic water drain" on the rear of the unit.
› Route the drain hose with a constant incline and no sagging.
For waste water lines longer than 2 metres we recommend getting a specialist installation firm to carry out a fixed installation of high-temperature pipes.
› Connect the waste water hose to the in-house waste water connection.

7.8 Connecting the unit to the network

The unit can be connected to the network with a network cable.

Purpose of the network connection

The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

– Display parameters
– Select operating modes
– Indicate messages and error situations
– Change unit settings
– Activate test functions
– Transmit data for archiving
– Provide documents concerning the units

Network protocols and ports

Port	Purpose	Service
9100 TCP	Record printer and label printer	
137 UDP, 137 TCP, 138 UDP, 139 UDP, 445 UDP	Network drive	SMB
123 UDP	Time server	NTP
67 UDP, 68 UDP		DHCP

If the device is monitored with the software Tyscor Pulse, see "9.2 Network protocols and ports".

Combining devices safely

- Safety and essential performance features are independent of the network. The device is designed for operation independent of a network. However, some of the functions are not available in this case.
- Incorrect manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
- The data connection utilizes part of the bandwidth of the network. Interactions with other medical devices cannot be completely excluded. Apply the IEC 80001-1 standard for risk assessment.
- The device is not suitable for direct connection to the public internet.
- When connecting the unit to other devices,-such as a PC system,comply with the requirements set out in section 16 of IEC 60601-1 (EN 60601-1).
- When setting up the PC system in the vicinity of the patients:

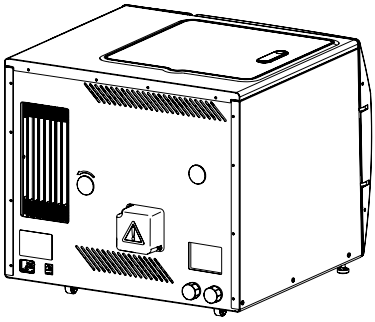
  Only connect components (e.g. computer, monitor, printer) that comply with the standard IEC 60601-1 (EN 60601-1).
- When setting up the PC system outside of the vicinity of the patients:

  Connect components (e.g. computer, monitor, printer) that comply at least with the standard IEC 60950-1 (EN 60950-1) at least.

A copy of the system manufacturer‘s declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

Connecting the network cable

- Connect the network cable (CAT5 or higher) to the network port on the rear of the unit.



EN

8 Configuring the unit

The following settings will need to be checked and possibly adjusted by an administrator or Service Technician.

These settings are made via the touch screen of the unit. For further information about use of the touch screen see "13.2 Touch screen".

8.1 Selecting the access level

The adjustment options depend on the selected access level.

Only a qualified expert is permitted to change the settings in the Service Technician access level.

Access level	Rights
Operator	– Querying device information – Carrying out a vacuum test
Administrator	In addition to the User rights: – System settings (administrative) For operators, e.g. hygiene officer
Service Technician	In addition to the Administrator rights: – System settings (all) – Maintenance For qualified Service Technicians

› Touch *Settings* > *Access Levels*.
› Select the access level.
› Confirm with *OK*.

8.2 Entering dealer information

Under Dealer Info you can save contact data for the dealer or Service Technician.

You can enter text freely in up to 5 rows of text.

Requirements:

– Administrator or Service Technician access level selected.

› Touch *Settings* > *Device Information* > *Dealer Info*.
› Touch *Edit*.
› Touch *Row 1*.
› Enter the information as required and touch ✓ to confirm.
The text appears in row 1.
› Add further rows as required.
› Confirm with *OK*.

8.3 Language selection

Requirements:

– Operator, Administrator or Service Technician access level selected.

› Touch *Settings* > *System Settings* > *Language*.
› Select the language.
› Confirm with *OK*.

8.4 Configuring the device with a network connection

If the unit is connected to the network, then you can send the sterilisation records to a log printer for printing or save them on a network drive and print out labels.

The IP address can either be obtained via DHCP or permanently assigned.

Requirements:

– Administrator or Service Technician access level selected

› Touch *Settings* > *System Settings* > *Network* > *Device*.

Assigning a permanent IP address:

› Deactivate *DHCP*.
› Enter the *IP address*, *net mask* and *gateway*.
› Confirm with *OK*.

8.5 Set the date and time.

The date and time must be set correctly on the device in order for the batch documentation to be correct.

You can manually set the date and time or, if the device is connected to the Internet, you can obtain the correct time and date from a time server.

Requirements:

– Administrator or Service Technician access level selected

› Touch *Settings* > *System Settings* > *Time/Date*.

Manually setting the date and time :

› Touch *Date*.
› Set the date and touch *OK* to confirm.
› Touch *Time*.
› Set the time and touch *OK* to confirm.

Obtaining the date and time from a time server (NTP) server:

› Touch *Time Zone*.

› Select the time zone and touch *OK* to confirm.
› Touch *Time Server*.
› Touch *NTP Server*.
› Enter the address of the NTP server and touch ✓ to confirm.
› Enable *NTP*.
› Touch *OK* to confirm the settings.

8.6 Parameter selection

Depending on how the device is set up you can enable or disable the following parameters:

Water supply	If a water treatment system is connected the fresh water container is automatically filled.
Time preset	The actual start of the sterilisation process can be selected upon program start.
Calendar	The device switches on and off at defined times.
Preheat	When the device is switched on it automatically switches to preheating mode. This setting saves time when starting a sterilisation process.
SD card	Sterilisation logs are automatically saved to the SD card.
Network drive	Sterilisation logs are automatically saved to the preset network drive.
Log printer	Sterilisation logs can be printed out via the connected log printer.
Label printer	After release of the sterilisation cycle the print dialogue for the labels appears automatically.

Requirements:

– Administrator or Service Technician access level selected

› Touch *Settings* > *System Settings* > *Parameters*.
› Enable the required parameters.
› Touch *OK* to confirm the settings.

8.7 Configuring a log printer

In order to be able to print out sterilisation records on the log printer, the network connection needs to be configured and the parameter *Log printer* needs to be enabled.

The log printer must be postscript capable.

Requirements:

– Administrator or Service Technician access level selected

Configuring the network connection:

› Touch *Settings* > *System Settings* > *Network*.
› Touch *Log printer*.
› Enter the IP address or the host name of the log printer.
› Change the port if necessary.
› Touch *OK* to confirm the settings.

Enabling parameters:

› Touch *Settings* > *System Settings* > *Parameters*.
› Enable the parameter *Log printer*.
› Touch *OK* to confirm the settings.

8.8 Configuring the label printer

In order to be able to print out the labels of the released batches on the label printer, the network connection needs to be configured and the *Label printer* needs to be enabled.

Requirements:

– Administrator or Service Technician access level selected

Configuring the network connection:

› Touch *Settings* > *System Settings* > *Network*.
› Touch *Label printer*.
› Enter the IP address or the host name of the label printer.
› Change the port if necessary.
› Touch *OK* to confirm the settings.

Enabling parameters:

› Touch *Settings* > *System Settings* > *Parameters*.
› Enable the parameter *Label printer*.
› Touch *OK* to confirm the settings.

EN

8.9 Configuring the network drive

The network drive needs to be enabled under *Settings* > *System Settings* > *Parameters* so that the data can be output to the network drive.

A user and password need to be entered for access to the network drive. This user must have read and write access rights to the network drive (e.g. approved folder on the server).

Requirements:

– Administrator or Service Technician access level selected

Configuring the network connection:

› Touch *Settings* > *System Settings* > *Network*.
› Touch *Network drive*.
› Enter the network path (UNC address) of the folder on the server, e.g. //10.2.10.163/steridaten.

Always write the network path correctly; use "/" instead of "\".

› Enter the user name and password for log-in on the network.
› Touch *OK* to confirm the settings.

Enabling parameters:

› Touch *Settings* > *System Settings* > *Parameters*.
› Enable the parameter *Network drive*.
› Touch *OK* to confirm the settings.

8.10 User management

The name of every operator needs to be created to ensure that the approval process can be reliably traced after the end of a sterilisation program.

At the end of a sterilisation process, the operator selects his/her name and then adds his/her signature on the touch screen to release the batch. The user name is printed on the sterilisation record and on the labels.

It is also possible to create or change operator names during the release of the batch after the end of the sterilisation program.

Requirements:

– Operator, Administrator or Service Technician access level selected

› Touch *Settings* > *User Administration*.

Creating a new operator::

› Touch *New*.
› Enter the operator name and touch ✓ to confirm.

The operator will then appear in the list.

Changing an operator::

› Select the operator and touch *Change*.
› Change the operator name and touch ✓ to confirm.

Deleting an operator:

› Select the operator and touch *Delete*.

8.11 Setting up the calendar

In the calendar you can define time periods in which the device is to be switched on. The periods marked blue in the calendar represent the periods in which the device is switched on. At the end of each period the device switches back off again.

The device can be switched on or off manually at any time regardless of the calendar entries.

Under *System Settings* > *Parameters* > *Preheating* you can also set the system up so that the device preheats during the ON periods.

You can view and edit the calendar under *Settings* > *Calendar*.

Requirements:

– Administrator or Service Technician access level selected

› Touch *Settings* > *Calendar*.

The calendar is shown in a graphical representation.

› Touch *Edit*.

The calendar entries are shown as a list.

Creating a calendar entry:

› Touch *New*.
› Touch the weekdays that are to be activated. You can choose one or more weekdays.
› Enter the times between which the unit is to be switched on.
› Touch *Save* .

The newly defined calendar entry is then displayed in the list and in the graphical representation.

Changing a calendar entry:

› Touch the calendar entry in the list.
› Change the weekdays and times as required.
› Touch *Save* .

The changed calendar entry is then displayed in the list and in the graphical representation.

Deleting a calendar entry:

› Touch the calendar entry in the list.
› Touch *Delete*.

8.12 Touch screen

You can adjust the brightness and touch calibration (touch accuracy) of the touch screen.
The default value for brightness is 35%.
During touch calibration a wizard will launch that will help you to adjust the required touch accuracy of the touch screen.

Adjusting the touch screen

Requirements:

– Administrator or Service Technician access level selected

› Touch *Settings* > *System Settings* > *Touch Screen*.
› Touch *Brightness*.
› Adjust the brightness.
The default value for brightness is 35%.
› Confirm with *OK*.

Touch screen calibration

During touch calibration a wizard will launch that will help you to adjust the required touch accuracy of the touch screen.
Requirements

– Administrator or Service Technician access level selected

NOTICE
If the touch calibration is incorrectly set up it may become impossible to operate the device
› Accurately follow the instructions provided by the wizard.

› Touch *Settings* > *System Settings* > *Touch Screen*.
› Touch *Touch Calibration*.
› Follow the instructions provided by the wizard.

9 Monitoring the device with Tyscor Pulse

Further information on Tyscor Pulse can be found in the software help and in the Tyscor Pulse manual, order number 0949100001.

The following requirements must be met in order to monitor the unit with the software on the computer:

– Unit connected to the network
– Software Tyscor Pulse (version 3.2 or higher) installed on computer

9.1 Network configuration

Various options are available for network configuration:

– Automatic configuration via DHCP (recommended).
– Automatic configuration via Auto-IP for direct connection of unit and computer.
– Manual configuration.

› Configure the network settings of the unit using the software or, if available, the touch screen.
› Check the firewall and release the ports, if applicable.

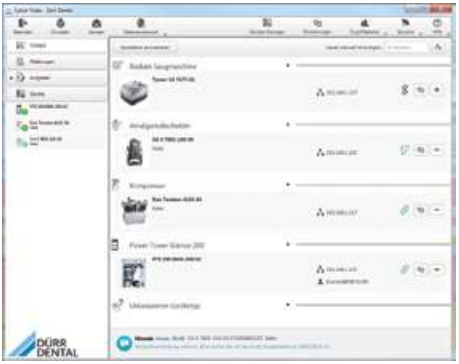
9.2 Network protocols and ports

Port	Purpose	Service
8080[1)] TCP	Tyscor Pulse	JSON
45123 UDP, 45124 UDP	Unit recognition and configuration	

[1)] The port can vary depending on the configuration.

EN

9.3 Add device



Requirements:

– Unit is switched on and connected to the network
– Administrator or service technician access level selected in the software

› Working in the menu bar, click on *Device Manager*.

The list of units appears. A symbol displays the connection status to the software:

The unit is present in the network and connected to the software.

The unit is present in the network but not connected to the software.

The network connection between the software and the unit has been interrupted, e.g. the device is switched off.

The new unit that is not yet connected, is displayed with the connection status .

› Select the unit and click on .

The unit appears in the side bar.

Adding the device in the cockpit

All devices that are connected to the software can be added to the cockpit. When the unit is first connected to the software, the unit is automatically added to the cockpit.

Requirements:

– Administrator or Service Technician access level selected.

› Click on the device in the device list with the left mouse button and keep the mouse button pressed.
› With the mouse key pressed, drag the unit onto the cockpit.
› Release the mouse key.

The block with the current characteristic data and the name of the device appear in the cockpit.

› To change the position of the device block, click on the block and, with the mouse key pressed, drag it to the required location.

10 Test programs

10.1 Vacuum test

The vacuum test is used to test the device for leaks in the sterilization chamber.

A vacuum test should be performed in the following situations:

– Once a week during routine operation
– During commissioning
– After operating pauses longer than 2 weeks
– After replacing the door seal.

Perform the vacuum test with the unit cold and dry.

› Switch on the device.
› Under *Settings* > *Maintenance* > *Diagnostic Functions* > *Vacuum Test* touch *Start*.

Result:

A vacuum test is taken to be passed if the leak rate does not exceed a prescribed value and the temperature does not fluctuate by more than +-3 K during the test.

Recording the vacuum test

The Hygoclave 90 can also generate records for the vacuum tests performed. These are not saved automatically; they can be saved manually.

vacuum tests do not receive their own batch number, as they are not a sterilization program.

› Tip on *Actions* > *print / copy records*.
› Save a record on a pre-selected output medium.

10.2 Bowie-Dick test

The Bowie-Dick test is used to prove steam penetration into the test load. It is designed in such a way that, if proof is obtained that steam has penetrated into the test load, it can be assumed that steam will penetrate into the routine loads.

It is usually not possible to perform a Bowie-Dick test in the original sense on small steam sterilisers, as the test was developed for large-scale sterilisers in accordance with EN 285 and is based on a washing package of 7 kg (or 4 kg for a reduced test package), which would exceed the chamber volume or cause a malfunction. For this reason, either use a standard test package for small steam sterilisers with a suitable indicator system or a corresponding alternative indicator system.

In order to test performance, it is possible to routinely perform proof of steam penetration.

Carry out the test in accordance with the manufacturer's information.

› Switch on the unit.
› Touch *Settings* > *Maintenance* > *Diagnostic Functions* > *Bowie-Dick TestStart*.
› or
› Touch *Settings* > *Start Bowie-Dick-Test*

EN

11 Logging handover and installation

It is necessary for a handover and installation record to be completed as proof of proper setup, installation and commissioning and in order to preserve your entitlement to warranty claims.

› Fill in the handover and installation record and send the copy to Dürr Dental.

12 Validation for commissioning

The device has been subjected to a type test in accordance with DIN EN 13060. Test loads are used for this purpose. In order to ensure correct sterilisation in routine surgery procedures, it is necessary to perform a test with the real routine loading or with a loading that allows conclusions to be drawn about the real loading.

› This validation (inspection qualification (IQ), operational qualification (OQ) and performance qualification (PQ)) should be performed by correspondingly trained experts or by a test laboratory.

Follow the country-specific regulations.

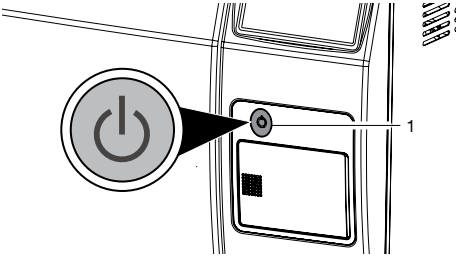
See also DIN EN 13060 and EN ISO 17665-1

EN

13 Operation

13.1 Switching the unit on/off

› To switch the unit on or off: press the on/off key for at least 2 seconds.

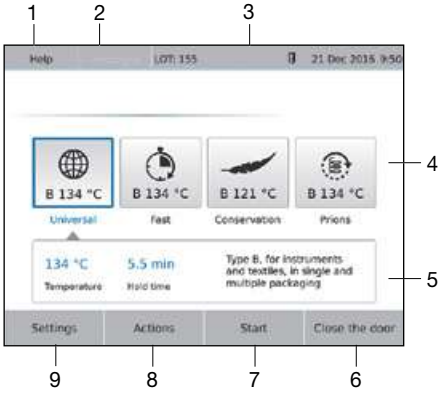


› To disconnect the unit from the power supply: unplug the mains plug.

13.2 Touch screen

The operating panel comprises a colour touch screen.

After the unit is switched on, the icon for the *Universal program* is active by default.



1 Help
2 Messages
3 Status bar
4 Program icons
5 Program information
6 Open door / close door
7 Start / cancel
8 Actions
9 Settings

Via the *Help* button you can access further information and instructions relevant to the screen.

Messages

The *Messages* view shows all currently active messages. Here, the messages are divided into the following categories:

Malfunction	Unit will no longer function. When the error has been remedied, it may be necessary to acknowledge the error message.
Notice	After acknowledgement the unit will continue to work, but only with limited functions.
Information	Important information for the operator, e.g. about the current status of the device. The unit continues to operate.
Note	Information for the operator. The unit continues to operate.

The messages *Fault* and *Caution* are shown in full screen.

The messages *Information* and *Note* are shown in the message area.

The current message can be displayed in full screen via the *Messages* button.

Program icons

Universal program

Quick program

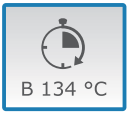
Gentle program

Prions program

EN

Overview of programs

The program selection depends on the load and its temperature resistance, as well as on the type of packaging.

Program	Process parameters / Operating time	Drying	Load	Test	Type
 Universal program	134°C, 5.5 min / 12 - 21 min *	16 min	For 6 kg of instruments or 2 kg of textiles, in single and multiple packaging For 10 kg with container loading.**	Helix test	B
 Quick program	134°C, 5.5 min / 10 - 15 min *	10.5 min	For instruments, up to 1.5 kg (single packaging) or 6 kg (unpackaged) **	Helix test	B
 Gentle program	121°C, 20.5 min / 26 - 39 min *	16 min	For 6 kg of instruments or 2 kg of textiles, in single and multiple packaging, especially for thermolabile sterilisation items	Helix test	B
 Prions program	134°C, 20 min / 26 - 35 min *	16 min	For 6 kg of instruments or 2 kg of textiles, in single and multiple packaging, especially in cases of suspected infection with prions For 10 kg with container loading.**	Helix test	B

* Without drying, minimum – maximum operating time, (without 10 kg container load) dependent on load and installation conditions (e.g. mains voltage, room climate).

** Sufficient drying may not be ensured in all cases during the sterilisation of plastics, in particular plastic trays (e.g. implant sets).

*** Tested with sterile containers made of aluminium and each with two permanent filters (one in the cover and one in the base tray). Weight includes sterile containers and accompanying cartridges.

Test program	Process parameters	Use / function
Bowie-Dick test	134°C, 3.5 min.	Steam penetration test for special test package or test body (available from specialist retailers)
Vacuum test	< 35 °C, 15 min	For measurement of the air leakage rate, with dry and cold unit, without loading

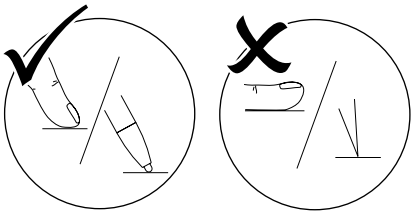
EN

Operating the touch screen

NOTICE
Damage to the touch screen due to incorrect handling

- Only operate the touch screen using your fingertips or the stylus.
- Do not use a sharp instrument (e.g. ballpoint pen) to operate the touch screen.
- Protect the touch screen against water.

- Operate the touch screen by tapping it with a fingertip or the stylus to select a menu or input field.



- For further information about any window tap on the *Help* field.

Navigating

If the contents of the window cannot be completely displayed on the touch screen, a scroll bar appears.

- Tap or or to move the displayed section of the window.

13.3 Time preset

With the aid of the *Time preset* function it is possible to select any program and start it at a user-defined time.

- Activate *Settings* > *System Settings* > *Parameters* > *Time Preset*.
- Enter the required time after starting a programme.
- Touch *Start*.

Result:

The selected program will start with the time preset.

After the start of the time preset it is no longer possible to select any other menu.

The time preset is only active for the one-off time and program selection, i.e. the time preset expires after the end of the program.

While the time preset is activated the unit must not be switched off.

13.4 Monitoring the device with Tyscor Pulse

Further information on Tyscor Pulse can be found in the software help and in the Tyscor Pulse manual, order number 0949100001.

Monitoring operation

The device must have been added to the cockpit for the graphical device block to be shown in the cockpit.

The current programme status is displayed e.g. *Ready, pre-heating, conditioning* etc.

Querying messages

Trouble-free operation

Fault
Operation of the device interrupted

Warning
Operation of the device restricted

Note
Important information about the device

Information

Establishing a connection to the device

Connection to the device interrupted

If a message occurs for an device, the symbol next to the device in the side bar changes. The message appears in the cockpit and in the device details.

If several messages occur, the symbol of the highest message level in each case is displayed.

As soon as a message concerning a device occurs, the symbol in the task bar (or Mac OS menu bar) also changes to the relevant message symbol. If required by the message an acoustic signal also sounds.

› To query the message details, switch to the cockpit or to the device.

Completing the task

Due tasks appear as a message in the cockpit.

The task can be assigned to an access level (operator, administrator or service technician), which then means that it can only be confirmed from this access level.

› Perform the task.

› Confirm the task in the software.

Result:

The due date of the task is set to the next date.

Creating a report

You can print out a current report or sent it via e-mail.

The report contains all messages and a screenshot of the view that is displayed when the report is created.

Save the sterilisation record

The sterilization records can be saved at a selectable memory location.

A selection list is generated listing all records in the memory.

The selection list can be filtered and sorted (LOT, date, time, etc.).

13.5 Opening and closing the door

Opening and closing the door is only possible when the unit is switched on.

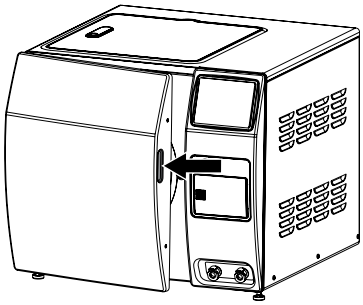
The door is locked when the unit is switched off.

Open the door

› Touch *Open door* – the door will open automatically.

› Use the recessed grip to fully open the door.

If the door is open, the display on the operating panel changes to *Close door*.



Closing the door

CAUTION
Risk of injury due to trapped fingers

› Firmly press the door shut with your flat hand.

NOTICE
Damage to the door locking mechanism due to incorrect handling

The unit is equipped with a motor-driven automatic door locking mechanism with door spindle.

› Close the door firmly and centrally.

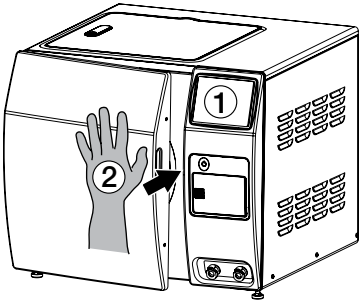
› Do not slam the door shut.

› Carefully close the door so that contact is made.

EN

EN

› Touch *Close door*.



› Firmly press the door shut with your flat hand for at least 3 seconds.

The door is automatically pulled in and closed, and is then pressure tight when the program starts.

When the door is closed the note *Open door* is displayed.

13.6 Preparations for steam sterilisation

Getting the fresh water supply ready

› If the internal fresh water container in the unit is used:

Check the fill level of the fresh water container and fill up to the top mark if necessary.

› If a water treatment system is used:

Check whether the water supply is open and open it if not.

If the supply container of the water treatment system is empty, open the water tap for at least 1 prior to the steam sterilisation.

Switch on the unit.

› Touch the on/off button for at least 2 seconds

Once the unit is switched on the start screen will appear after approx. 1 minute.

The software of the unit is initialised and the device components are checked.

The sterilisation chamber is automatically preheated to 121 °C in the default settings.

At average room temperatures the preheating will take approx. 15 minutes.

It is possible to select a program during the preheating phase. The program starts automatically as soon as the preheating temperature is reached. The preheating phase is shorter during normal operation.

Getting the trays ready

WARNING
Disinfectant residue on the tray will jeopardise sterilisation success.

Some disinfectants leave layers behind on surfaces after surface drying, which can then react with sterile product packaging in the steam steriliser, e.g. causing the paper side on the tray to stick.

› Always thoroughly remove all disinfectant residue from the tray prior to sterilisation, e.g. in an RDG or manually.

The highly corrosion-resistant stainless steel trays from Dürr Dental can be prepared in a thermal disinfector (RDG).

Trays for loading of items for sterilisation must be perforated so that condensation can drain off. We recommend using Dürr Dental trays.

Avoid using non-perforated trays, because the drying results will be poor.

Getting the packaging materials ready

Only use packaging materials and systems that are suitable for steam sterilisation according to the manufacturer information, or which satisfy the standards DIN EN ISO 11607-1, standards series DIN EN 868.

It is possible to use e.g. reusable container systems or soft packaging, such as transparent sterile product packaging, paper bags, sterilisation paper, textiles or non-woven material.

In addition, it is also possible to use e.g. standard tray cassettes or cassettes for implants in conjunction with sterile product packaging.

Systems made of aluminium should be used in cases where the sterilisation containers that are used are not sold or recommended by Dürr Dental.

Closed standard tray cassettes must be perforated on at least one side, preferably the bottom, or equipped with valves. This will ensure that steam can penetrate and condensation can drain off.

Where possible, textiles and instruments should be sterilised separately from each other in separate sterilisation containers or sterile product packaging.

Preparation of textiles

The following must be taken into account when reprocessing textiles and placing the textiles in the sterilisation container:

DANGER
Sterilisation success at risk

Inadequate steam penetration into the washing package and/or poor drying will jeopardise the sterilisation success. This represents a health risk for patients and surgery personnel.

› Follow the instructions of the textile manufacturers for reprocessing and sterilisation, as well as all relevant directives and standards, e.g. DIN EN 13795.

› Align the folds of the textiles so that they are parallel to each other.
› Stack the textiles as vertically as possible and not too tightly in the sterilisation containers so that flow channels can form.
› If textile packages will not hold themselves up, wrap them in sterilisation paper.
› Only sterilise dry textiles.
› The textiles must not be in any contact with the walls of the sterilisation chamber, as they will otherwise suck up condensation until they are full.

WARNING
Sterilisation success at risk

Depending on the textile load, hygroscopic condensation can occur, particularly on cotton fabrics. This phenomenon can lead to overheated, unsaturated steam, which can no longer have the necessary sterilising effect.

› Allow textile loads to acclimatise sufficiently under room climate conditions. In particular, make sure that the relative humidity is sufficient (> 40%).
› Do not sterilise any warm, dry washing from an ironer or drier. Allow the items to acclimatise first.
› Do not leave textile loads to rest for an unnecessarily long time in the heated steriliser before the start of sterilisation. Start the program immediately after loading.

Preparing the instruments

NOTICE
Increased need for maintenance and functional impairment of the unit.

Any present dirt residue can be detached during sterilisation under steam pressure. Disinfectant or cleaning agent residue can lead to corrosion.

› Comply with the instructions of the instrument manufacturers regarding reprocessing and sterilisation, as well as all relevant guidelines and standards, e.g. DIN EN ISO 17664.

› We recommend using suitable cleaning agents and disinfectants for the cleaning and disinfection of instruments, and where possible the use of cleaning and sterilisation machines. Manual cleaning and disinfection should only be performed in exceptional cases.
› Clean the instruments very thoroughly.
› After the end of manual reprocessing, rinse the instruments with suitable water (preferably demineralised or distilled water).
› If necessary thoroughly dry the instruments with a clean, lint-free cloth.
› Only use care products that are suitable for steam sterilisation. Check with the manufacturer of the care product.

The use of unsuitable care products, e.g. water-repellant care products or oils that are impermeable to steam, may result in the instruments not being sterile after sterilisation.

EN

13.7 Loading the items for sterilisation into the unit

Correct loading of the unit has an impact on the efficacy of sterilisation, good drying of the items for sterilisation and therefore also on the warranty.

WARNING
The sterilisation of liquids can cause a risk of explosion, risk of burns, boiling retardation and vapours that are hazardous to health.
› Do not sterilise liquids in the unit.

WARNING
Sterilisation success at risk
Incorrect loading with items for sterilisation will result in inadequate steam penetration and therefore jeopardise the success of the sterilisation process. This represents a health risk for patients and surgery personnel.
› Make sure that the unit is correctly loaded.

NOTICE
Damage to the unit or to the items being sterilised due to unsuitable materials
› Only sterilise instruments, packaging and textiles that are suitable for steam sterilisation according to the manufacturer's information.

› Do not exceed the maximum load.
› Trays or standard tray cassettes should only be placed in the carrier in the sterilisation chamber. This ensures optimum steam penetration and drying.
› When using several standard tray cassettes, make sure that steam penetration is not obstructed by covering of the perforations.
› Where possible, only stack sterilisation containers of the same size above each other on which the condensation can run off to the side.
› When using stackable container systems, these can be placed without a carrier in the sterilisation chamber provided the maximum individual or overall weight is not exceeded.
› Soft sterile product packaging should be arranged preferably standing upright and with small gaps between each packaging.
› Do not lay multiple items of soft sterile product packaging flat one above the other on a tray or into a container.
› If a sealing seam of the sterile product packaging breaks open or tears during sterilisation, the items for sterilisation will need to be sterilised again in new sterile product packaging. Check the sealing process.

Mixed loads

Avoid mixed loads. If this is not possible for practical reasons in day to day surgery operations, then the combination of textile and bulky loads used should always be checked via on-site validation by correspondingly trained expert personnel or by a validation officer.
› Always position textiles at the top.
› Textiles packaged in transparent sterilisation packaging should be placed with the paper side facing up on a tray.
› Transparent sterilisation packaging and paper packaging at the top. Exception: in combination with textiles at the bottom.
› Transparent sterilisation packaging should preferably be inserted upright. If this is not possible, insert the packaging with the paper side facing down.
› Sterilisation containers at the bottom.

13.8 Steam sterilising

Starting the program

› Close the door (see "13.5 Opening and closing the door").

› Touch the chosen program, e.g. *Quick program*.

› Touch *Start*.

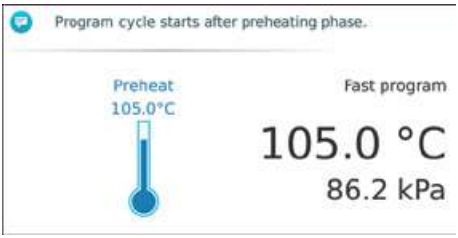
The unit will automatically check the amount and conductance value of the fresh water. The cycle sequence is displayed schematically, as are the current values for status description/ pressure/time.

The program can be cancelled at any time.

Programme sequence

After the start of the program the current program status is displayed on the touch screen.

Preheat



The program cycle starts after the preheating phase

Conditioning

In the overpressure range steam is let off and regenerated, as a result of which the load is conditioned.

Fractionation

A vacuum is generated in several phases depending on the program.

The air is removed and replaced with steam. This process is repeated until the preset venting capacity is reached.

Sterilisation

Saturated steam is generated inside the steriliser chamber until the specified values are reached. The actual sterilisation takes place during the predefined hold time. At the end of the sterilisation phase the steam is let off.

Drying

The parts for sterilisation in the sterilisation chamber are dried under vacuum. Afterwards the sterilisation chamber is vented via the sterile air filter and the door can be opened.

EN

Vacuum drying ensures optimum drying results even when the parts for sterilisation are packaged.

Program end

At the end of a program the pressure in the sterilisation chamber is matched to the ambient pressure.

Once venting has been completed the program is finished.

The following is displayed when the sterilisation phase has finished successfully:

Cycle successfully completed. Caution, sterilisation chamber is hot.

CAUTION
The parts for sterilisation, chamber and inner door are very hot.

Touching hot objects can cause skin burns.

› Do not touch hot objects.
› Use the tray grip for removing the trays.
› Allow the trays and parts for sterilisation to cool down.

If a fault report is shown: see "Troubleshooting".

The sterilisation logs are automatically saved.

Program cancellation

Manually cancelling the program

A program that has already been started can be cancelled at any time.

› Touch *Cancel*.

If the program is cancelled, then depending on the timing of the cancellation in the program sequence it is possible for hot steam to escape when the door is opened.

CAUTION
The parts for sterilisation, chamber and inner door are very hot.

Touching hot objects can cause skin burns.

› Do not touch hot objects.
› Use the tray grip for removing the trays.
› Allow the trays and parts for sterilisation to cool down.

› Touch *Open door*.

If the program is aborted **during the "Drying" phase** then the parts for sterilisation are sterile. This step is available so that the parts for sterilisation can quickly re-available.

Unpackaged parts for sterilisation will dry during cooling as a result of their own heat.

Drying is important for sterile storage. However, if the drying process is cancelled, incomplete drying should be expected in the case of packaged parts for sterilisation.

We do not recommend cancelling drying during the Universal, Gentle or Prions programs on packaged parts for sterilisation.

WARNING
Sterilisation may be incomplete if the program is cancelled before the start of "Drying"

The sterilisation load will not be sterile. An error message will be generated.

› Sterilise the load again in new sterile product packaging.

Cancellation by the system

The length of time taken to open the door will vary depending on the phase in which the program is cancelled. The system will analyse the current phase and transfer the steam steriliser into a safe status. For example, if overpressure is present then the unit is briefly evacuated to drain off any condensation that has arisen.

› Follow the messages on the touch screen and contact a Service Technician to have the unit checked.

Removing parts for sterilisation

CAUTION
The parts for sterilisation, chamber and inner door are very hot.
Touching hot objects can cause skin burns.
› Do not touch hot objects.
› Use the tray grip for removing the trays.
› Allow the trays and parts for sterilisation to cool down.

› Remove the trays from the unit using the tray handle.

DANGER
Sterilisation success at risk due to defective sterile product packaging
If a sterile product packaging tears open during sterilisation, sterile storage is no longer possible.
› Sterilise the parts for sterilisation again in new sterilisation packaging. If necessary check the sealing parameters.
› Follow the manufacturer's instructions on how to use the sealing device, referring also to the packing instructions (e.g. there must be a sufficiently large distance between the product to be sterilised and the sealing seam).
› Check the sealing device if necessary.

Residual condensation on the parts for sterilisation

Sufficient drying is a prerequisite for sterile storage. After execution of the complete program sequence (drying not aborted), very good drying results are achieved on this Hygoclave provided the loading information is followed.

Immediately after sterilisation it is possible that there may still be residual condensation on the parts for sterilisation or on the transparent sterile product packaging.

The formation of puddles on the top side of the parts for sterilisation is not permitted. Individual droplets on the inside of the transparent sterile product packaging must evaporate within 5 minutes. The paper side must not be wet through.

Frequency of sterilisation

After the end of the program or even after cancellation of the program the unit can be restarted immediately once it has been reloaded.

Approval process

According to the Robert Koch Institute (RKI) ("Hygiene requirements during the reprocessing of medical devices"), the reprocessing of instruments ends with the documented approval for storage and use of the parts for sterilisation.

The approval process consists of the batch indication and batch release and must be performed by authorised and competent personnel.

Batch indication

This includes checking on the basis of indicators carried at the same time, e.g. individual indicators or indicator systems (test body and indicator) during the cycle.

The indicators can only be approved after a full colour changeover of the indicator strips.

Batch release

The batch release comprises:
– checking the process parameters on the basis of the sterilisation result in the unit
– the sterilisation record
– checking the individual packages for damage and residual moisture

The approval of the batch and any indicators carried at the same time is documented on the sterilisation record (see "14.4 Printing out records").

Approval or non-approval is granted by signature directly on the touch screen, unless the automatic process evaluation system of the steriliser deems the process to have been a failure. In this case the batch is marked as "Not approved" even without a signature.

EN

13.9 Storing parts for sterilisation

› Only use standards-compliant packaging for the products to be sterilised.

› Comply with the stated storage conditions:

– Store the parts protected against contamination
– Dust-protected, e.g. in a locked cabinet
– Protected against moisture
– Protected against excessive temperature fluctuations
– Protected against damage

The loss of integrity of the packaging of a sterile medical device is usually linked to a particular incident, rather than being time-related. Potential external contamination of the sterile barrier system should be taken into account under the aspect of aseptic preparation when defining the acceptable storage duration and storage conditions.

Taking into account the packaging and storage conditions, the maximum length of time for which sterile product packaging (e.g. transparent sterile product packaging) can be stored is 6 months, but this must not exceed the expiry date. The maximum storage time for packaging systems (combination of sterile barrier system and protective packaging) is 5 years, unless another expiry date has been specified by the manufacturer.

Comply with country-specific laws and regulations.

14 Documenting the sterilisation

14.1 Batch documentation

The batch documentation is required as proof of successful completion of the sterilisation process and as a mandatory quality assurance measure.

The data, such as the program type, batch and process parameters for all executed programs, is saved in the internal protocol logger of the unit.

For the batch documentation, the internal protocol logger can be read out and the data transferred to various output media. This can be done immediately after every cycle that has been run or at a later time, e.g. at the end of the surgery day.

Internal protocol logger

The memory capacity of the internal protocol logger is sufficient for approx. 10,000 cycles.

If the internal protocol logger is nearly full and at least one record has not yet been output to an activated output medium, the message "Caution – *Internal protocol logger almost full*" is displayed.

Specify the defined output media under *Settings* > *System Settings* > *Parameters* > *Logging* and output the affected records.

If the records are not output, the message "Caution – *Internal protocol logger full*" is displayed.

This is the last opportunity to archive records that have not yet been output. Then the data in the protocol logger of the unit is automatically deleted apart from the last 40 records.

Output media

It is possible to output the records for the programs that have run via the following output media and to archive them accordingly.

– SD memory card
– Computer (via the network)
– Label printer
– Record printer

The required output media can be selected under *Settings* > *System Settings* > *Parameters*.

SD memory card

In the delivery state of the unit, the integrated SD memory card is enabled as the output medium for the sterilisation record.

When using the SD memory card as the storage medium, make sure that it is correctly inserted and insert it if not.

We recommend taking out the SD memory card at regular intervals and additionally backing up the cycle data on a computer.

NOTICE
Data loss due to removal of the SD memory card during read/write access
› Never remove the SD memory card while it is being read/written to.

If no SD memory card is inserted but this option is enabled, a warning will appear on the touch screen.

Label printer

Use of a label printer ensures traceability of the batch.

With the aid of the following information the sterilised instruments can be assigned to the patient and batch:

– Date of sterilisation
– Expiration date
– Device ID
– Sterilisation program
– Batch number
– Operator ID

The sterile product packaging is marked with the label. With this, all of the prerequisites for proper approval by the person instructed with reprocessing are met.

This means that all of the information about the correct sterilisation procedure can therefore be assigned in the patient file to the instruments used.

14.2 Automatic record output

It is possible to automatically output the corresponding record to an output medium (SD memory card, printer) immediately after the end of a program.

The following prerequisites are required for this:

– Activate the required output media under *Settings* > *System Settings* > *Parameters*.
– The enabled output medium must be inserted (SD memory card) or connected (computer, printer).

If it is not possible to automatically output a record, for example because the enabled output medium is not connected, then a warning will be displayed.

14.3 Subsequent output of saved records

Records can be output subsequently, i.e. at a later time than when the program ends. The output media can then be chosen by the operator.

In the delivery state of the unit, automatic immediate output is enabled and certain output media are preselected.

14.4 Printing out records

For every cycle a record is saved in the protocol logger in PDF format.

The internal protocol logger saves the last 10,000 cycles.

If the protocol logger is full, then a warning message is displayed: *Caution – Protocol logger full*. In this case save the records to the SD memory card and then delete the contents of the protocol logger.

Provided the SD memory card is inserted, the record is automatically also saved to the SD memory card at the end of the program.

The record can be viewed, saved and if necessary printed out via a computer.

In order to print out the record the network printer needs to be postscript capable.

EN

Example of a sterilisation record

Hygoclave 90

Sterilisation log 3 Feb 20XX
116

DÜRR DENTAL

Device data

Type	Hygoclave 90
REF	6046-01
SN	Hooo149
Firmware	2.1.0.6343
GUI	2.1.0.3820

Program and batch data

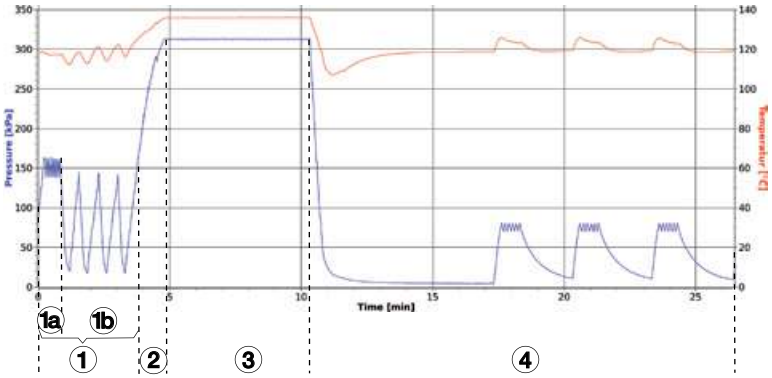
Program	Universal-Programm 134°C
LOT	116
Date	3 Feb 20XX
Automatic process evaluation	Cycle successful
Indicators switched over	Not present
Packaging undamaged	Not present
Batch released	Yes
Sterilisation batch	**Successfully released**
Started	8:40:01
Finished	9:06:26
Duration	26:25
Sterilisation temperature	135.0 °C +1.2 °C / +0.8 °C
Sterilisation pressure	312.0 kPa +1.6 kPa / -0.6 kPa
Hold time	05:30 min
Feed water conductivity value	3.7 µS/cm
User name	Mrs. Musterfrau
Signature	Musterfrau

Cycle log

	Time [mm:ss]	Pressure [kPa]	Temp [°C]	ID	
1	00:00	75.0	117.4	START	
2	00:00	75.0	117.4	COND.BEGIN	
3	00:29	164.3	117.0	COND.PMax	1a
4	00:43	136.7	117.4	COND.PMin	
5	00:52	138.0	117.6	COND.END	
6	01:13	19.9	112.3	FRAC1.EVAC	
7	01:33	143.5	118.4	FRAC1.STEAM	
8	01:53	17.0	112.6	FRAC2.EVAC	1
9	02:18	144.2	121.1	FRAC2.STEAM	
10	02:37	17.0	114.0	FRAC3.EVAC	1b
11	03:02	141.6	122.0	FRAC3.STEAM	
12	03:19	16.9	116.1	FRAC4.EVAC	
13	03:19	16.9	116.1	FRAC.PMin	
14	03:43	142.3	124.3	FRAC.TMax	
15	04:49	312.5	135.8	STER.BEGIN	2
16	04:49	312.5	135.8	STER.TMin	
17	05:53	311.4	135.8	STER.PMin	
18	06:17	313.6	135.9	STER.PMax	
19	08:45	313.0	136.1	STER.TMax	3
20	10:20	313.4	136.0	STER.END	
21	17:20	4.3	118.6	DRY1.EVAC	
22	17:20	4.3	118.6	DRY1.VENT.BEGIN	
23	17:38	80.5	125.8	DRY1.PMax	
24	17:59	69.5	123.8	DRY1.PMin	
25	18:20	77.9	123.2	DRY1.VENT.END	
26	20:20	10.6	119.4	DRY2.EVAC	
27	20:20	10.6	119.4	DRY2.VENT.BEGIN	
28	20:45	80.4	124.8	DRY2.PMax	
29	21:15	69.5	123.1	DRY2.PMin	4
30	21:20	75.9	123.2	DRY2.VENT.END	
31	23:20	10.3	119.2	DRY3.EVAC	
32	23:20	10.3	119.2	DRY3.VENT.BEGIN	
33	23:54	80.7	123.9	DRY3.PMax	
34	24:15	69.4	122.8	DRY3.PMin	
35	24:21	74.9	122.9	DRY3.VENT.END	
36	26:24	9.7	118.9	DRY4.EVAC	
37	26:25	9.5	118.9	END	

Additional data

Cycle diagram



1	Fractionated pre-vacuum	2	Pressure and temperature build-up
1a	Conditioning	3	Plateau time (holding time)
1b	Fractionation	4	Vacuum drying

15 Messages on the touch screen

For information about the display of *Caution* and *Fault* messages refer to "Trouble-shooting".

15.1 Note

Information for the operator.
The unit continues to operate.

Message: Note
Program cycle starts after preheating phase.
Cycle type B running.
Cycle successfully completed. Caution, sterilisation chamber is hot.
Manual cancellation. Load is sterile but possibly not yet dry.
Program has been cancelled. Load is sterile but possibly not yet dry.
The batch record has been saved.
Printing labels.
Test program: No sterilisation.
Process running.
Process finished.
Generating vacuum.
The vacuum has been tested and is in the permissible range.
Vacuum test was cancelled.
Chamber temperature must be below 40°C.
Please hold the door shut for 3 sec.
The door closes automatically after contact is made.
The door has been closed. The vacuum can be generated after locking.
The door has been locked.
Please wait. The sterilization chamber is being ventilated and will then open automatically.
Rinsing process successfully completed.
Upper and lower fill levels detected.
Generator test successfully completed: Heating works correctly, water pump works correctly.
Poor water quality: Conductivity value exceeds 15 µS. Please check the water supply.
Service interval reached: Please replace the door seal.
Service interval reached: Please replace the sterile air filter.
The system will switch off...
Copying record
Printing record

15.2 Information

Important information for the operator, e.g. about the current status of the device.
The unit continues to operate.

EN

Message: Information
Select the days for which a new preheating time is to be set.
Test criteria: integrity, dryness, leak tightness
Drying process manually cancelled
Drying process cancelled

16 Operating pauses

16.1 Pause times

Short pauses between sterilisation runs

› Keep the door closed when the unit is switched on.

The unit thus requires less energy and can be maintained at temperature.

Pauses that last more than an hour

› Switch off the unit to save energy.

If the unit was previously switched off, it will take a few minutes to heat up the unit back up so that it is ready to start.

Prolonged pauses in operation

The following must be taken into account in the event of prolonged pauses in operation, e.g. overnight, weekend:

› Position the door so that it is slightly ajar. This relieves the door seal and prevents premature fatigue or any sticking.

› Switch off the unit(s).

› Close the main tap for the water supply.

Pauses in operation longer than 2 weeks

In the event of pauses in operation longer than 2 weeks, take the unit out of operation (see "17 Taking out of operation").

17 Taking out of operation

If the unit is to be taken out of operation for an extended period, e.g. due to a holiday, proceed as follows:

› Remove the plug from the power outlet.

› Drain, clean and if necessary disinfect the internal fresh water and waste water containers.

› Shut off the water supply if using a water treatment system.

17.1 Transport

NOTICE

Equipment damage and malfunctions during transport over longer distances and/or under risk of frost

› For shipment, the unit should be prepared by an authorised person in accordance with the instructions.

Before transporting the unit, ensure that the following steps are performed:

› Remove the carrier, trays etc. from the unit.

› Empty or drain the fresh water and used water tanks.

› If using a water conditioning system, close the water supply and remove the hose connections on the rear of the unit.

› Close the door.

› Switch off the unit and allow it to cool.

› Transport the unit.

18 Restarting after an extended pause in operation

EN

› Manually fill the fresh water container.
› Open the water supply if using a water treatment system.
› Perform a vacuum test.
› Perform a Bowie-Dick test.
› Perform an empty sterilisation with the quick program.

19 Maintenance

To ensure proper operation and maintain the service life of the appliance, it is necessary to carry out cleaning and maintenance work diligently.
Inadequately or not carried out maintenance work can cause premature defects that are not covered by the warranty.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

19.1 Maintenance schedule

Service interval	Maintenance work
Daily, before commencing work	Perform a Helix test, following your country-specific regulations.
Every time the device is switched on	Automatic self-diagnosis
Before each sterilisation process	– Check the chamber, door seal and carrier for contamination, deposits and damage. – Carefully clean, disinfect and maintain the parts for sterilisation
Weekly, before commencing work	– Perform a vacuum test with the device cold and dry. – Wipe clean and dry the covers of the waste water and fresh water containers on a regular basis.
Monthly	Check the hinge and oiling the door spindle (see "19.4 Checking the hinge and oiling the door spindle").
As required	Clean and disinfect accessory parts (e.g. tray, tray handle).
If there is soiling	– Carry out complete cleaning (see "19.2 Complete cleaning"). – Clean or replace the water filter (see "19.5 Clean or replacing water filters"). – Clean the tray handle and trays. – Clean and dry the sterilisation chamber. – Clean the door seal.
After 1000 cycles or 1 year	Replace the door seal (see "19.3 Cleaning or replacing the door seal").
After 2000 cycles or 2 years	Change the sterile air filter (see "19.6 Changing the sterile air filter").
After 4000 cycles or 2 years	– Arrange for **maintenance** to be performed by a trained service technician a few weeks before repeated performance qualification (revalidation). ***Any modifications to the system must be subject to evaluation and may require a renewed performance qualification.*** – Renewed **performance qualification** to maintain the efficacy of the process performed by correspondingly trained expert personnel or a test laboratory, see also EN ISO 17665 1:2006, DIN SPEC 58929; comply with country-specific regulations.
Every 2 years	Have electrical safety testing performed, e.g. in accordance with DIN VDE 0701 0702, and ensure compliance with country-specific regulations.
Every 4 years	Arrange for replacement of the safety valve. Notify customer service.

EN

19.2 Complete cleaning

For problem-free operation of the unit, correct cleaning and maintenance are necessary.

Only carry out cleaning measures when the appliance is cold.

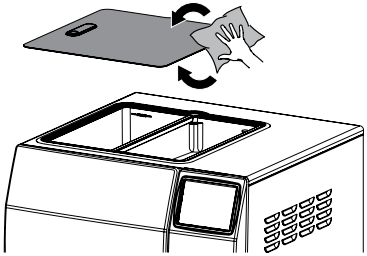
› Switch on the unit and open the door.
› Switch off the unit.
› Unplug the mains plug.
› Use a soft, lint-free cloth.

NOTICE
Leaks in the unit.
Abrasive cleaners can cause leaks.
› Do not use abrasive cleaners.

› Do not use hard objects, such as pot scourers made of metal or steel brushes. Similarly, avoid using abrasive or scratchy cleaning sponges.
› Use cleaning agents that are free of chlorine and acetic acid.
› First soak the cloth with cleaning alcohol or methylated spirits, and then wipe off the dirt or contamination.
› In the case of stubborn dirt in the chamber or on the carrier, use a mild, chlorine-free cleaning agent that is suitable for stainless steel and has no abrasive properties (ph value: 5-8).
› Use a neutral liquid cleaner for housing parts and the door seal.
› Make sure that no cleaning agents get into the pipes that come out from the chamber.

Clean the cover

› Wipe clean and dry the covers of the waste water and fresh water containers on a regular basis.



Avoid the formation of stains.

Proper instrument preparation can prevent residue from being loosened from the load under steam pressure during sterilisation.

Loosened remains of dirt can clog the filters, nozzles and valves of the unit and settle as stains and deposits on the instruments and the chamber.

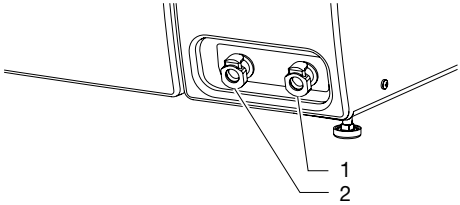
A single rusting instrument can be enough to cause external rust to form on the other instruments or in the unit.

All steam-conducting parts of the appliance are made of non-rusting materials. This prevents the formation of rust being caused by the unit.

› Only use high-quality distilled or demineralised water.
The extent of stains forming on the instruments can also depend on the quality of the fresh water.

Replacing the water

Manual emptying of the water containers



1 Connection for manual fresh water emptying
2 Connection for manual waste water emptying

NOTICE
The water in the waste water container is contaminated.
› Take corresponding precautionary measures when draining it.
› Carry out disposal in accordance with national regulations.

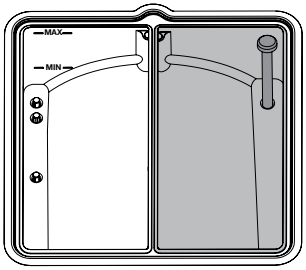
› Place an empty container at the ready with a capacity of at least 5 litres.
› Place one end of the drain hose into the container provided.
› Push the drain hose onto a quick release coupling until it noticeably engages to drain the corresponding water container.
› Allow all of the fresh water to drain out into the container, then empty the container.

› Allow all of the waste water to drain out into the container, then empty the container.
› Press the release mechanism on the quick release coupling and remove the drain hose again.
› For this reason the drain hose comes into contact with contaminated water, as does the container used for emptying. These objects must be cleaned and disinfected accordingly after use. The drain hose consists of a silicone hose and a quick release coupling adapter that can be separated from it. The silicone hose can be sterilised in the steriliser after prior cleaning. The quick release coupling adapter can be disinfected e.g. in instrument disinfectant ID 212, ID 212 forte or ID 213 from Dürr Dental.

Cleaning the water containers

If the fresh water is supplied via the internal fresh water container then the following must be noted:

› Before every refilling of the fresh water, check the fresh water and waste water containers for dirt and contamination and clean and disinfect them if required, e.g. wipe-disinfect them with FD 322 or FD 333 from Dürr Dental.
› After cleaning, make sure that the stopper is inserted in the waste water container.



Manually filling the fresh water container

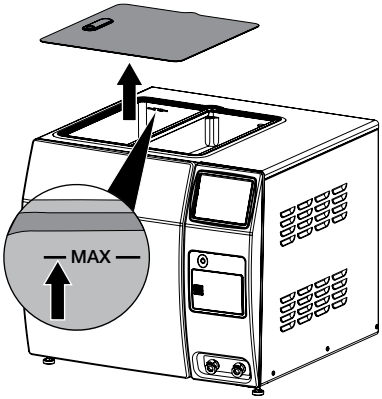
The capacity of the fresh water container is 4 litres. Depending on the selected program and the load, an average of approx. 7 sterilisation cycles is possible.

WARNING
Use of tap water compromises sterilisation

The use of tap water can lead to the following problems: Sterilisation cycles may be unsuccessful due to the introduction of incondensable gases. Formation of spots on sterilised objects. The unit may be damaged.

› Only use high-quality distilled or demineralised water. Guideline values for water quality in accordance with DIN EN 13060 Appendix C.

› Empty the waste water container.
› Remove the covers of the waste water and fresh water containers.



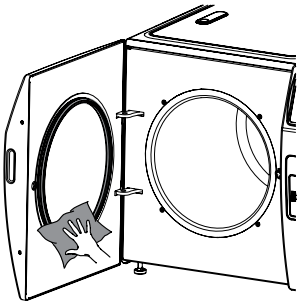
› Fill the fresh water container with distilled or demineralised water to the MAX mark (approx. 4 litres).

Make sure that the water does not overflow.

EN

19.3 Cleaning or replacing the door seal

› Regularly clean the door seal and check it for damage and correct positioning. If necessary press the door seal carefully and evenly back into the sealing groove.
Replace the door seal if it is worn.

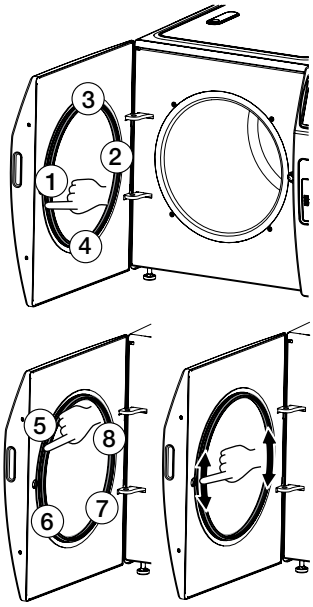


Replacing the door seal

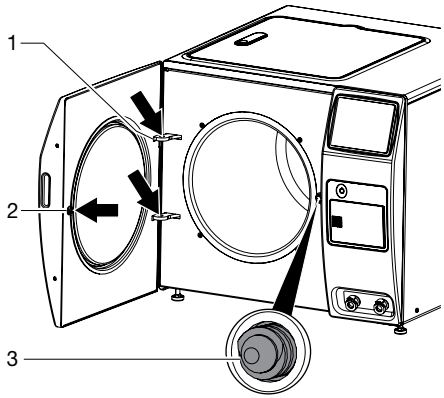
It is best to replace the door seal when the unit is cold.

Do not use any sharp objects that could scratch the unit or damage the seal.

› Open the door.
› Remove the door seal by hand from the sealing groove.
› If the groove is dirty, carefully clean it with a cleaning sponge and clear water.
› Then re-wipe the sealing groove with a soft cotton cloth.
› Insert a new door seal by hand.
Observe the correct sequence when inserting the door seal. The door seal must lie evenly in the sealing groove. Smooth out any waviness or elevations by pressing in with your finger.



19.4 Checking the hinge and oiling the door spindle



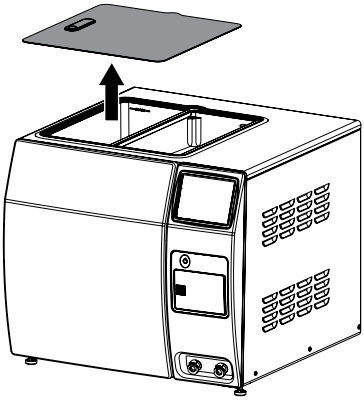
1 Hinge
2 Threaded bush
3 Door spindle

› Check the hinge for ease of movement.
› Clean the door spindle with a lint-free cloth.
› Oil the door spindle every 2 months.

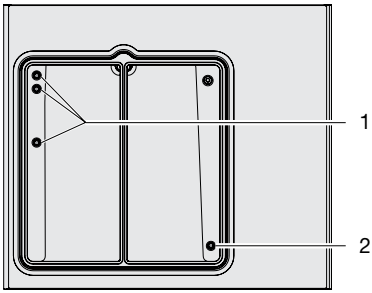
› Apply a small amount of oil in the threaded bush (in the door of the unit).

19.5 Clean or replacing water filters

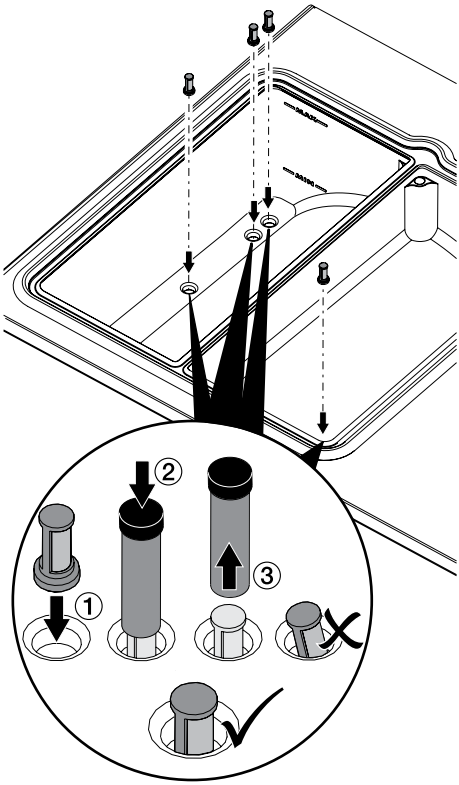
› Remove the covers of the waste water and fresh water containers.



› Change the water filter in the fresh water container when soiled or if required. Use the installation aid to insert the water filter.



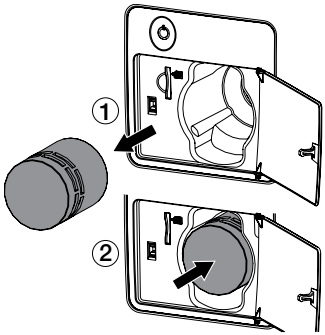
1 Water filter in the fresh water container
2 Water filter in the waste water container



19.6 Changing the sterile air filter

› Change the sterile air filter.

When pushing in the sterile air filter, make sure that it is pushed in all the way.



19.7 Function check

Automatic function check

Thanks to the electronic parameter control, the interactions between the sterilisation-relevant parameters pressure, temperature and time is constantly and automatically monitored.

The process evaluation system of the unit compares the process parameters with each other while the program is running and monitors them in relation to their limit values.

The device monitoring system tests the device components to make sure they are working correctly and that their interactions are plausible. If the parameters exceed defined limits, warnings and fault reports are displayed. If necessary the program is cancelled and a corresponding note is displayed.

If the program is successfully completed, a corresponding message is displayed.

Test programs (see "10.1 Vacuum test" and "10.2 Bowie-Dick test").

Helix test

The Helix test is a disposable testing system for steam sterilisers with fractionated pre-vacuum for the monitoring of sterilisation cycles at 121°C or 134°C.

This test must only be used for sterilisation processes with upstream vacuum phase.

20 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

Fault	Probable cause	Solution
Touch screen incorrectly calibrated, operation is not possible	Touch calibration incorrectly performed	› Inform a Service Technician.

20.1 "Caution" messages

After acknowledgement the unit will continue to work, but only with limited functions.

Message: Caution	Remedy
Manual cancellation. Load not sterile. Possibly re-pack.	› Apply parts for sterilisation directly or sterilise in new packaging.
Program has been cancelled. Load not sterile. Possibly re-pack.	› Possibly re-pack and sterilise.
Pressure change exceeds 10 bar/min.	
Process cancelled.	› Assess the messages on the touch screen.
Vacuum test failed.	› Check the door seal, replace if necessary.
The fresh water level is low. Please fill up with fresh water.	› Fill up with fresh water.
The fresh water container is not full. Please fill up with fresh water.	› Fill up with fresh water.
The waste water container is full.	› Empty the waste water container.
Automatic fresh water filling failed.	› In the menu check the parameter *Water supply*.
The door has not been locked.	› Open the door again and close it. Start a program, contact customer service if necessary.
The last cycle was not documented in full, e.g. due to a power failure.	› Repeat the sterilisation process, if necessary re-pack the parts for sterilisation. Restart the program.
Maintenance interval reached: Please contact a Service Technician.	› Notify customer service.

20.2 "Fault" messages

The unit will no longer function.
When the error has been remedied, it may be necessary to acknowledge the error message.

EN

Message: Fault	Remedy
Sterilisation process failed	› Repeat the sterilisation process, if necessary re-pack the parts for sterilisation. Restart the program.
Manual cancellation. Load not sterile. Possibly re-pack.	› Possibly re-pack and sterilise.
Program has been cancelled. Load not sterile. Possibly re-pack.	› Possibly re-pack and sterilise.
Process cancellation: Temperature outside the tolerance range.	› Notify customer service.
Process cancellation: Pressure outside the tolerance range.	› Notify customer service.
Process cancellation: Phase timeout.	› Check the installation conditions and notify customer service if necessary.
Vacuum not attained.	› Check the door seal, replace if necessary. › Notify customer service if necessary.
Fresh water filling time for the steam generator has elapsed.	› Check the water treatment system and its connections. Is the fresh water supply ensured? › Notify customer service if necessary.
Fresh water filling aborted. Overpressure in the steam generator.	› Notify customer service.
The water temperature is too high in the steam generator.	› Notify customer service.
The water level in the steam generator is too low.	› Check the fresh water supply, notify customer service if necessary.
Preheating temperature not attained.	› Notify customer service.
Overpressure in the steam generator.	› Notify customer service.
The water quality is too low: conductivity value exceeds 40 µS. Please replace the fresh water and check the water supply.	› Empty the fresh water, clean the container and fill up with new fresh water. › Check the cartridges of the water treatment system. › Notify customer service.
The pressure sensor of the chamber is defective.	› Notify customer service.
The pressure sensor of the steam generator is defective.	› Notify customer service.
The temperature sensor is defective.	› Notify customer service.
The hardware is defective.	› Notify customer service.
Program phase duration exceeded.	Unit possibly overloaded. › Check the load amount and packaging type. › Notify customer service if necessary.
Calendar entry is invalid.	› Set up the calendar (see "8.11 Setting up the calendar").
Calendar memory space is full.	› The maximum number of entries has been reached.
The door could not be closed.	› Check the door seal, replace if necessary.
Unable to copy to SD card.	› Check the SD card, replace if necessary.
Unable to copy to network drive.	› Check the network connection.
Unable to print.	› Check the connection to the printer, if necessary establish the connection.

21 Emergency opening of the door

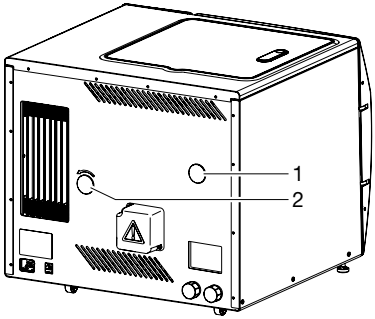
If the steam steriliser loses power during operation as a result of an incident, e.g. due to a power outage, it is possible to manually open the door in order to access the items being sterilised. This feature is provided as a way to open the door in an emergency only and should not be used when the unit is working normally.

If the steam steriliser is de-energised during operation, then depending on the phase in the program either the sterilisation chamber will be automatically vented (under vacuum) or the steam will be condensed in the condenser (under overpressure). Since the condenser is no longer actively cooled when the unit is de-energised, a small amount of steam or condensation may leak from the lower area of the condenser during a program phase in the overpressure area.

If the program is cancelled, then depending on the timing of the cancellation in the program sequence it is possible for hot steam to escape when the door is opened.

CAUTION
The parts for sterilisation, chamber and inner door are very hot.
Touching hot objects can cause skin burns.
› Do not touch hot objects.
› Use the tray grip for removing the trays.
› Allow the trays and parts for sterilisation to cool down.

› Unplug the mains plug.
› Remove the covers from the motor shaft and pressure gauge on the rear of the unit.

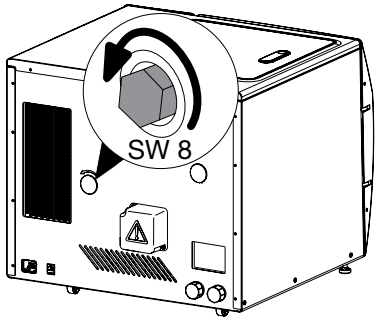


1 Pressure gauge cover
2 Motor shaft cover

› Check the pressure equalisation using a pressure gauge.

CAUTION
Risk of injury due to pressure in the sterilisation chamber
› Do not open the door until the pressure gauge shows "0".

› Rotate the motor shaft (hexagon, SW 8) with the enclosed tool (hexagon key) anti-clockwise (manual movement of the door spindle) until the door fully opens.



› Take out the items for sterilisation and mark them as "non-sterile".
› The items for sterilisation will need to be repackaged before they can be sterilised again.

22 Settings menu layout

EN

Level 1	Level 2	Level 3	Level 4
Access level[1]	Operator		
	Administrator		
	Service Technician (password)		
Device Information[1]	Unit data		
	Dealer Info		
System Settings[1+2]	Language[1]	German (DE)	
		English (EN)	
	Time/Date[2]	Date	
		Time	
		Time zone	
		Time server	
	Network[2]	Device[2]	Mac
			Name
			Interface
			DHCP
			IP address
			Netmask
			Gateway
		Label printer[2]	Name/addr.
			Port
		Record printer[2]	Name/addr.
			Port
		Network drive[2]	Server
			User name
			Password
	Parameters[2]	Water supply	
		Time preset	
		Calendar	
		Preheat	
		SD card	
		Network drive	
		Record printer	
		Label printer	
	Touch screen[2]	Brightness[2]	
		Touch calibration[2]	

Level 1	Level 2	Level 3	Level 4
Calendar[2]			
User management[1]	Select the user		
Maintenance[1-3]	Device maintenance[2]	Door seal	
		Sterile air filter	
	Validation[3]		
	Diagnostic functions[1-3]	Water[2]	
		Steam generator[2]	
		Locking/opening the door[2]	
		Generating pressure[2]	
		Generating a vacuum[3]	
		Emptying the steam generator[3]	
		Performing a vacuum test[1]	

1 Visible from access level ***Operator*** or higher
2 Visible from access level ***Administrator*** or higher
3 Visible from access level ***Service Technician*** or higher

The access level "Service Technician" offers additional functions that must only be adjusted by Dürr Dental or by individuals/companies authorised to do so by Dürr Dental. Corresponding documents for this can be downloaded from www.duerrdental.net.

Hersteller/Manufacturer:
DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL