Hygopac View

EN

Installation and operating instructions

CE

6024100132L02

DÜRR
DENTAL

1906V003

EN

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Important information

1 About this document

These installation and operating instructions represent 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.

The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual. These installation and operating instructions are the so-called "original operating instructions".

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

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.

Observe the operating instructions.

CE labelling

Disconnect all power from the unit.

Manufacturer

On / off switch

REF Order number

SN Serial number

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

Monitor ambient conditions

Fuses

Wear protective gloves.

Symbols in the display window

Menu

Start screen

1 step back

Enabled

Disabled

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1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property.
Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects on skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose

The unit is intended to be used for the sealing of sterilisation packaging.

2.2 Intended use

The unit is designed to provide validated thermal sealing for sterilisation packaging in accordance with EN ISO 11607-1 (both bags and rolls) in the medical sector, e.g. clinics, dental practices and medical surgeries.

2.3 Improper use

Any use of this appliance / these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.
Sterilisation packaging that does not comply with EN ISO 11607-1 is not suitable.

2.4 General safety information

› Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
› Check the function and condition of the unit prior to every use.
› Do not convert or modify the unit.
› Comply with the specifications of the Installation and Operating Instructions.

› The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.5 Specialist personnel

Operation

Unit operating personnel 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.

2.6 Electrical safety

› Comply with all the relevant electrical safety regulations when working on the unit.

› Never touch the patient and unshielded plug connections on the device at the same time.

› Replace any damaged cables or plugs immediately.

2.7 Only use original parts

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

› Only use only original wear parts and replacement parts.

Dürr Dental accepts no liability for damages or injury resulting from the use of non-approved accessories or optional accessories, or from the use of non-original wear parts or replacement parts.

The use of non-approved accessories, optional accessories or non-genuine wear parts / replacement parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.8 Transport

The original packaging provides optimum protection for the unit during transportation.
If required, original packaging for the unit can be ordered from Dürr Dental.

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

› Only transport the unit in its original packaging.

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

› Screw in the transport protection (see "7.1 Remove the transport locks").

2.9 Disposal

Unit

The unit must be disposed of properly. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

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

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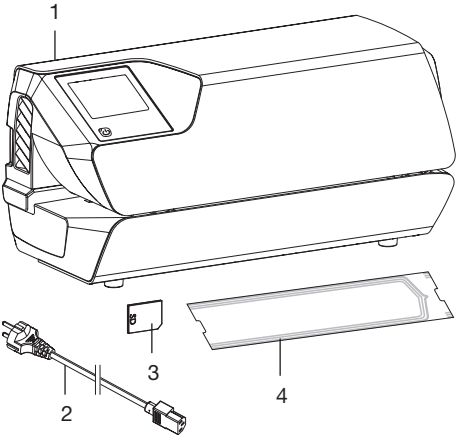
Product description

3 Overview



1 Hygopac View
2 Mains cable
3 SD card
4 Hygofol Set

3.1 Scope of delivery

The following items are included in the scope of delivery:

Hygopac View 6024100001

- Hygopac View
- Mains cable
- SD card
- Hygofol Set
- Hygopac Sealcheck
- Installation and operating instructions
- Quick start instructions
- Handover protocol
- Guidelines for the handover and briefing of the unit
- Information on the validation of the packaging process

3.2 Accessories

The following items are required for operation of the device, depending on the application:

Hygofol transparent sterile product packaging bags

7.5 x 30 cm, 1 x 500 pcs 6020-061-00
10 x 30 cm, 1 x 500 pcs 6020-062-00
15 x 30 cm, 1 x 500 pcs 6020-063-00

Hygofol transparent sterile product packaging rolled foil

5.0 cm x 100 m 6020-050-50
7.5 cm x 100 m 6020-051-50
10.0 cm x 100 m 6020-052-50
15.0 cm x 100 m 6020-053-50
25.0 cm x 100 m 6020-055-50

3.3 Optional accessories

The following optional articles can be used with the unit:

Hygopac Sealcheck 6022100027
Network cable 9000-119-071
Hygofol Station 6022-600-00
Instrument table 6022-700-00
Hygoprint 6020-080-50

3.4 Consumables

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

Hygopac Sealcheck 6022100027

Hygofol transparent sterilisation packaging bags

7.5 x 30 cm, 1 x 500 pcs 6020-061-00
10 x 30 cm, 1 x 500 pcs 6020-062-00
15 x 30 cm, 1 x 500 pcs 6020-063-00

Hygofol transparent sterilisation packaging rolled foil

5.0 cm x 100 m 6020-050-50
7.5 cm x 100 m 6020-051-50
10.0 cm x 100 m 6020-052-50
15.0 cm x 100 m 6020-053-50
25.0 cm x 100 m 6020-055-50

Cleaning and disinfection

FD 322
rapid surface disinfection CDF322C6150
FD 333
rapid surface disinfection CDF333C6150
FD 350 Classic
disinfection wipes CDF35CA0140

3.5 Wear parts and replacement parts

Information about replacement parts is available from the portal for authorised specialist dealers at: www.duerrdental.net.

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4 Technical data

Electrical data		
Voltage	V	230, 1~
Frequency	Hz	50 - 60
Nominal current	A	4
Power output, max.	W	900
Fuse		2 x T 5.0 AH / 250 V~ (IEC 60127-2)
Type of protection		IP 20
Protection class		I
Degree of soiling (in accordance with EN 61010-1)		2

General data		
Sealing temperature (adjustable in 5 °C steps) Tolerance of the adjusted sealing temperature	°C	 100 - 210 (version 2.0 or higher) + / - 5
Heating performance	W	2 x 400
Warm-up time approx.	min	3
Rate of sealing adjustable	m/min	 5 - 7 - 9
Tolerance of the set throughput speed Limit values	m/min	+ / - 1 min. 4, max. 10
Sealing seam: Total width Sealed width	mm	 17 13
Pressing force, general range	N	60 - 120
Duty cycle	%	80 (S3, 30 min)
Noise level*	dB(A)	<70
Dimensions (W x H x D)	cm	37 x 17 x 14
Weight	kg	7.8
TFT touch screen	"	2.8

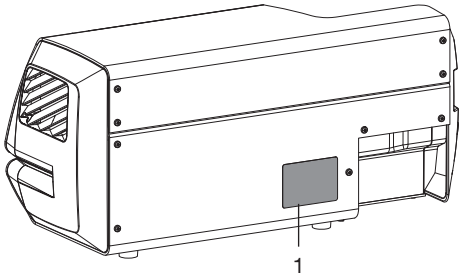
*Noise level in accordance with ISO 3744

Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	< 95

Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70
Altitude above mean sea level	m	< 2000

4.1 Type plate

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



1 Type plate

4.2 Declaration of conformity

Name of manufacturer:	DÜRR DENTAL SE
Address of manufacturer:	Höpfigheimer Str. 17 74321 Bietigheim-Bissingen Germany
Name of product:	Hygopac View

We hereby declare that the above product meets all applicable requirements of the directives listed below:

- Machinery directive 2006/42/EC in its current version.
  Name of the person with responsibility for compiling all technical documentation:
  F. Hatzfeld (Head of Development Equipment).
  The address is identical to the address of the manufacturer.
- Low voltage guideline 2014/35/EU in its valid version.
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU in its current version.
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment in its current version.

Hygopac View REF 6024100001

F. Hatzfeld on behalf of Duerr Dental
Head of Development Equipment

O. Lange on behalf of Duerr Dental
Head of Quality Management

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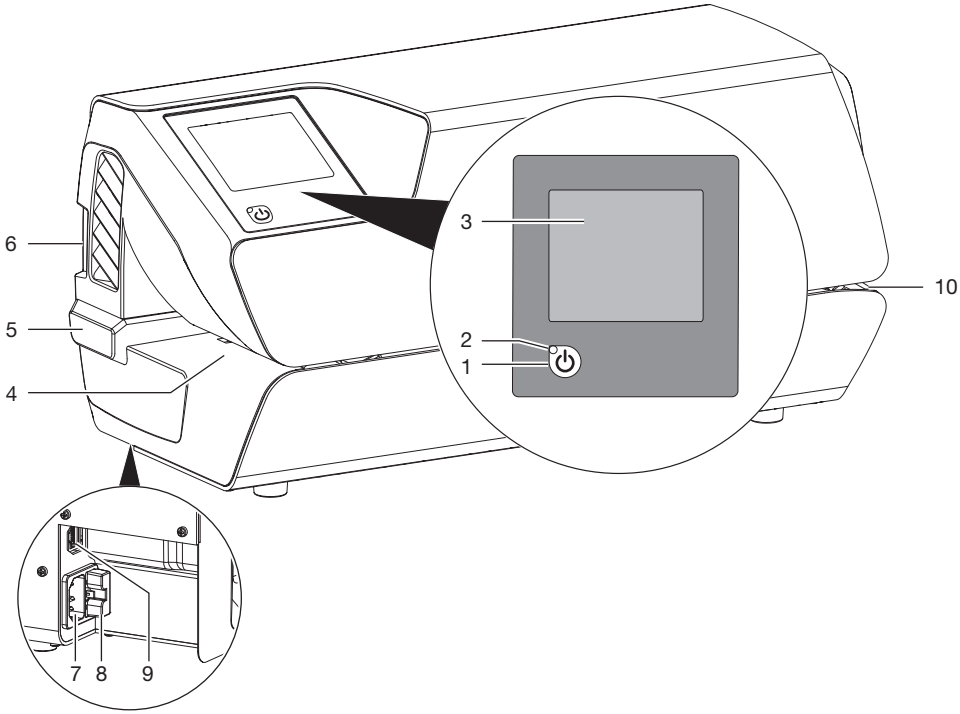
5 Operation



1 On / off switch
2 Standby LED
3 Touch screen
4 Infeed
5 Adjustable stop
6 SD card slot
7 Mains connection
8 Fuse holder
9 Network connection
10 Outlet

The touch screen is used to display information, and settings can be entered here for operation of the device.

Tapping the On/Off switch turns on the device. The device heats up, and both the target temperature and the current actual temperature are shown on the touch screen.

The operator is reminded of the operational qualification every day. This is done after the device reaches the target temperature for the first time at the start of working. To do this, a seam sealing test is performed and then assessed, e.g. with Hygopac Sealcheck. If the seam sealing test is successful, this must be confirmed by pressing a button, so that the device is released for operation. If the seam sealing test is not successful, the target temperature must be corrected.

In the area of the infeed there is a light barrier that is used to detect inserted sterilisation packaging and start the transport. Then the transport belt runs for a maximum foil width of 75 cm. If a new foil is quickly inserted afterwards but not placed against the adjustable stop, a foil can be picked up by the transport belt without the light barrier being triggered. The infeed is designed so that only the thin sterilisation packaging can be fed into the unit. This ensures that no materials that are to be sterilised can be damaged.
Within the unit, the sterilisation packaging is guided between two heating bars and heated. At the end of the two heating bars there are two rollers that then seal the sterilisation packaging. The pressing force of the rollers is continuously monitored. If the pressing force is outside the tolerance, this is shown on the display window accordingly.
After the sterilisation packaging has been transported through the unit, the transport then switches off after an afterrunning time. The unit is ready for the next sealing process.
The unit has a standby mode. If this is activated in the menu under *System Settings* -> *Standby*, the unit will switch off automatically after the set time if it is not used. 30 minutes are preset.
The unit contains an SD card, on which the relevant sealing parameters are saved. The data can be transferred to a computer using a card reader. Alternatively, the data can be transmitted via a continuous network connection and read and edited using a suitable program.

5.1 Touch screen

The touch screen can be used to navigate through the device and to adjust settings (see "11.2 Touch screen").

Fig. 1: Start screen on the touch screen

5.2 VistaSoft Monitor (optional)

If the device is connected to the network then it can be monitored with the VistaSoft Monitor software. VistaSoft Monitor shows the current status along with messages and faults on the device.
In addition, VistaSoft Monitor also helps with maintenance of the device – the software warns when maintenance work is due.

For further information please refer to the VistaSoft Monitor manual (order number 2110300001).

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Assembly

6 Requirements

6.1 Installation/setup room

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

– Closed, dry, well-ventilated room
– Should not be a room made for another purpose (e. g. boiler room or wet cell)

Ambient and environmental conditions must be taken into account. Do not operate the unit in damp or wet conditions.

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.

6.2 Setup options

The following options are available for installation of the device:

– On a stable, easily accessible surface (e.g. work table).

Please note the following when setting up the device:

– The device warms up during operation; keep a good distance to heat-sensitive devices.
– A minimum gap equal to the width of the packaging must be provided to the side to allow insertion and removal of the sterile product packaging that is to be sealed.
– Do not cover the ventilation slots.

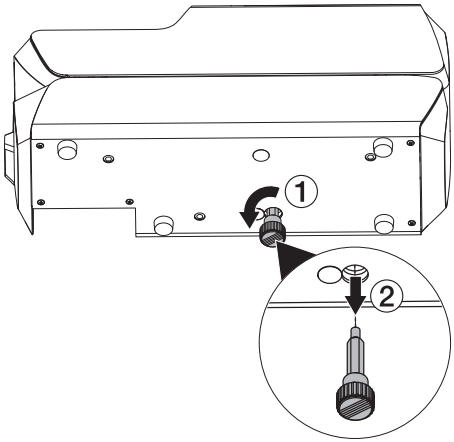
6.3 Information about electrical connections

The unit has no main power switch. The unit must be set up so that the power outlet is easily accessible and the unit can be unplugged from the mains if necessary.

7 Installation

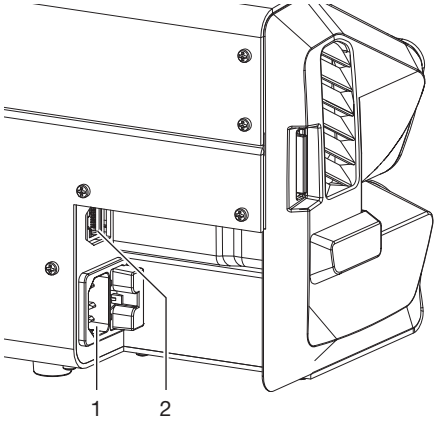
7.1 Remove the transport locks

› Remove the transport protection.



› Store the transport protection (see also "2.8 Transport").

7.2 Electrical connections



1 Mains connection
2 Network connection

› Before connecting the device, check that the supply voltage matches the voltage specification on the type plate.
› Connect the mains cable to the unit and to the power outlet.

› Plug a network cable into the network connection on the unit (optional when using e.g. Tyscor Pulse) and into the network socket.

8 Commissioning

› Insert the SD card into the unit.

› Switching on the unit:
Press the On/Off switch (blue LED lights up).

› A signal sounds, the blue LED flashes and the device is heated to the pre-set temperature. Once the selected temperature is reached, the blue LED goes out and the device is ready for operation.

› Set up the basic settings for the device – e.g. temperature, date and time. The firmware version can be checked under ***Device Information*** > ***Device Data***. Refer to "9 Configuring the unit"

The temperature of the device is pre-set to 180°C for Hygofol transparent sterilisation packaging from Dürr Dental.

The speed of the belt transport is pre-set to *Medium*.

› Carry out a function check of the device.

› Perform a sealing test.
If the test seal is not OK, adjust the temperature and/or speed as required.

8.1 Monitoring the unit via the network

If the device is connected to the network then it can be monitored with the VistaSoft Monitor software.
VistaSoft Monitor shows the current status along with messages and faults on the device.
In addition, VistaSoft Monitor also helps with maintenance of the device – the software warns when maintenance work is due.

For further information please refer to the VistaSoft Monitor manual (order number 2110300001).

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8.2 Handover of the device

A factory calibration is performed on the device at the factory. A printout of these test results is included in the supplied documents. This factory calibration does not replace the initial validation of the sealing process after commissioning at the place of installation. To do this, a performance qualification of the sealing process must be performed after commissioning (see "14.3 Annual Performance Qualification").

Correct handover and installation of the device forms part of the validation process during the Installation Qualification (IQ). This process must be documented like every part of the validation. Please use the enclosed handover record or download and print it out from www.duerrdental.com and then fill it in.

A new **Installation Qualification** always needs to be carried out if major changes are made to general conditions.

9 Configuring the unit

9.1 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 – Sealing parameters
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) For qualified Service Technicians

› Tap *System Settings* > *Access Level*.
› Select the access level.
› Tap ↵ to go back.

9.2 Language selection

› Tap *System Settings* > *Language*.
Language selection:
› Select the language and tap *Save*. Tap ↵ to go back.

9.3 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.

Manual adjustment

› Tap *System Settings* > *Date* / *Time*.
Manual adjustment of date and time:
› Tap *Date*.
› Adjust the date and tap *Save*. Tap ↵ to go back.
› Tap *Time*.

› Adjust the time and tap *Save*. Tap ⮐ to go back.

Automatic adjustment

In order to use automatic time setting, *DHCP* must be activated (see "9.7 Configuring the network").

› Tap *Time Zone*.
› Adjust the time zone and tap *Save*.

9.4 Adjusting the temperature

› Tap *Sealing Parameters* > *Temperature*.
› Adjust the temperature.
› Tap *Save* .

Recommended sealing temperatures:

– 180 °C is recommended for Hygofol transparent sterilisation packaging.
– For sterilisation packaging from other manufacturers, the recommended sealing temperature should be checked with the relevant manufacturer.

After adjusting the temperature, perform a test sealing process.

9.5 Set the speed for the belt transport

The speed of the belt transport can be adjusted between *Slow*, *Medium* and *Fast*.

› Tap *Sealing Parameters* > *Speed*.
› Select the required speed, tap e.g. *Medium*.
› Tap ⮐ to go back.
› Perform a sealing test, see "14.2 Daily function assessment").

After changing the speed it may be necessary to adjust the sealing temperature (see "9.4 Adjusting the temperature").

9.6 Set standby time

› Tap *System Settings* > *Standby*.
› Tap + or - and adjust the time.
It is set to 30 minutes by default.
› Tap *Save* .

9.7 Configuring the network

After the network settings have been changed it is necessary to restart the device. This saves the changed settings.

Requirements:
✓ Access level *Administrator* or *Service Technician* selected.

If DHCP is activated then the settings are applied automatically.
Deactivate DHCP if you wish to adjust the settings manually.

› Tap *System Settings* > *Network*.
› Deactivate *DHCP*.
› Tap *IP Address*, enter the data and tap *Save*.
› Tap *Net Mask*, enter the data and tap *Save*.
› Tap *Gateway*, enter the data and tap *Save*.

Syslog settings

If the unit is monitored using third-party documentation software for documentation of the sealing processes, Syslog settings will still need to be adjusted for it.
Syslog IP address: IP of the computer on which the documentation software is running.
Syslog port: The port via which the units are communicating (default setting: 514).
It is important that no other program is allowed to access the same port on the computer on which the documentation software is installed, as otherwise that port will be blocked and the documentation software will not be able to receive any data.

› Tap *System Settings* > *Network* > *Syslog IP Address*, enter the data and tap *Save*.
› Tap *Syslog Port*, enter the data and tap *Save*.

Syslog Heartbeat is activated at the factory, which allows the network stability to be improved.

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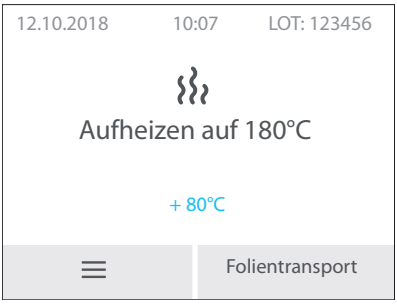
9.8 Touch screen calibration

The touch screen is calibrated at the factory. However, if touch screen operation does not work it is properly to calibrate the touch screen on site.

Calibration after starting the device

The touch screen can only be calibrated immediately after the device is switched on.

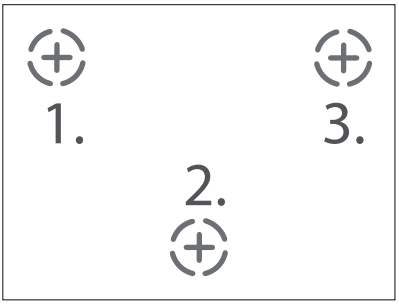
Once the device has been switched on and as soon as the start screen appears on the touch screen:



› press the touch screen and keep pressing until the symbol ⊕ appears.

› Press the centre of the circle and keep pressing until the colour changes (to green).

› Repeat this process at three different points (these are automatically chosen).



› The display then shows *Calibration successful*.

› Tap *OK* to confirm.

The calibration can be performed again if you don't confirm by tapping *OK*.

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Usage

10 Use of suitable sterile product packaging

The following may be used:
Sterile product packaging in accordance with DIN EN ISO 11607-1 and the applicable parts of EN 868, e.g. Hygofol from Dürr Dental.

– Recommended sealing temperature for Hygofol: 180°C.
– Recommended sealing temperatures for other foil brands must be obtained directly from the relevant manufacturers.

The following materials must not be used:
Sterile product packaging with side gussets.

NOTICE

Device malfunctions or damage due to use of incorrect materials

Incorrect materials can stick to the heating channel or to the press rollers. In addition, these materials do not permit the flow of air or steam in an autoclave.

› Do not use any PE foil material
› Do not use polyamide/nylon foil materials
› When using foils from the roll, it is possible for adhesive residue to be on the start of the roll. Remove this part.

10.1 Recommendations for the sterile product packaging

Here are various recommendations for working with sterile product packaging:

– Select sufficiently large packaging.
– Only fill packaging to 75% of its capacity to ensure that the sealing seams are tension-free.
– The distance between the sealing seam and the sterilised material should be at least 3 cm.
– To the packaging from being cut or pierced, sharp instruments should be covered with suitable protective equipment (e. g. protective caps).
– When using multiple packaging, always place the paper sides on top of each other to provide unhindered steam and condensate transport. Select the exterior packing so that it is sufficiently large. The criteria for sealing the exterior packaging are the same as those for the final packaging.
– Allow at least 2 cm foil distance to protrude to the back behind the sealing seam. This ensures unhindered peeling of the seam and is used for applying the labels or stickers. Can be set with adjustable stop.
– The sterilised material that is to be packaged should be dry.
– The sterilised material must be free of contamination.
– Clamps and blades loosely opened. Clamps, max. first lock-in position.

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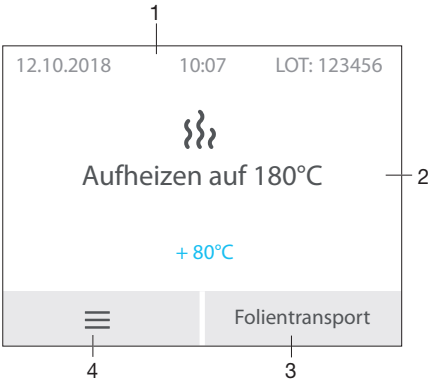
11 Operation

11.1 Switching the unit on/off

› Switching on the unit:
Press the On/Off switch (blue LED lights up).
› A signal sounds, the blue LED flashes and the device is heated to the pre-set temperature. Once the selected temperature is reached, the blue LED goes out and the device is ready for operation.

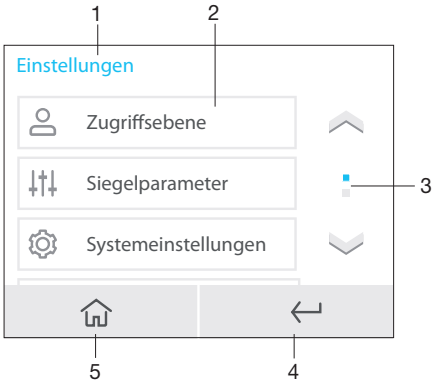
11.2 Touch screen

Start screen



1 Status bar (e.g. LOT, Time, Date)
2 Information area
3 Function for manual foil transport
4 Menu

Menu screen



1 Context area
2 Menu items
3 Scroll bar, active if there are more than three entries
4 1 step back
5 Start screen

Messages

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

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

The messages *Fault*, *Notice*, *Note* and *Information* are shown on the full screen.

Display of messages (see "Troubleshooting").

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.

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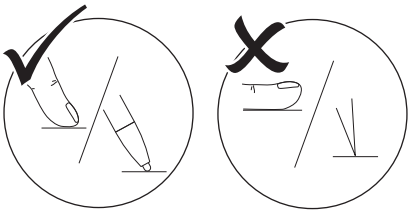
› Operate the touch screen by tapping it with a fingertip or the stylus to select a menu or input field.



Navigating

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

› Tap ^ or v to move the displayed section of the window.

11.3 Sealing the sterilisation packaging

› Place the sterilisation packaging onto the adjustable stop and guide it into the transport mechanism until the unit starts up and the sterilization packaging is drawn in (see "13 Adjustment of the adjustable stop").

NOTICE

Incomplete sealing seam or blocked sterilisation packaging due to wrong infeed

Incorrect (e.g. half) sealing seam. No/ inadequate foil protrusion for peeling and labelling (< 1 cm). Foil can get caught on the transport belt. Foil remains in the device without an error message being generated.

› Place the sterilisation packaging up against the stop (this is the only way to ensure that the light barrier will be triggered).
› Observe the maximum foil width of 75 cm.

› Assess the sealing seam after process is completed (see "14.2 Daily function assessment").

› Label the packaging with the expiry date and required additional information (e.-g. steriliser no., personnel, program etc.)

11.4 Start the transport belt manually

If the sterilisation packaging is not completely transported out of the unit and gets stuck, it is possible to manually start the foil transport (see also"11.2 Touch screen").

› On the start screen tap *Foil Transport*.
› Press the ⏩ button until the sterilisation packaging has been completely transported out of the unit.

Press and hold the button for continuous transport.
The transport belt will stop as soon as you release the button.

› Tap *Exit*.

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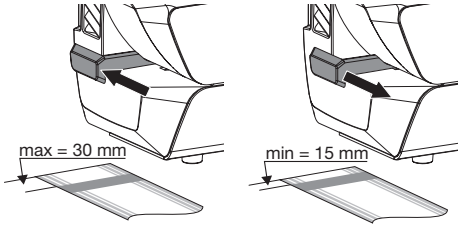
12 Monitoring the unit with VistaSoft Monitor

If the device is connected to the network then it can be monitored with the VistaSoft Monitor software.
VistaSoft Monitor shows the current status along with messages and faults on the device.
In addition, VistaSoft Monitor also helps with maintenance of the device – the software warns when maintenance work is due.

For further information please refer to the VistaSoft Monitor manual (order number 2110300001).

13 Adjustment of the adjustable stop

The adjustable stop allows the distance between the sealing seam and the edges to be adjusted to one of four different distances.



The foil protrusion provides sufficient material for opening the sterilisation packaging, and thus ensures sterile removal as well as a sufficient surface for writing on or attaching labels (depending on the label size).

14 Validation of the sealing process

14.1 Validation steps

The validation of the sealing process consists of the following steps:

– Installation qualification; this must be performed during commissioning of the device, see 8.2 Handover of the device.
– Operational qualification; to be performed daily.
– Performance testing; to be performed annually.

14.2 Daily function assessment

If the menu item *Operational qualification* (OQ) is activated in the menu of the unit, then a request to perform an operational qualification of the sealing process will appear every day after the unit is switched on for the first time.

This is only a reminder function and does not remove the responsibility for carrying out the operational qualification for the validation.

› Switch on the unit with button ⏻.
The display window shows the setpoint temperature and the actual temperature.
The blue LED flashes during the heat-up phase.
As soon as the target temperature has been reached, the unit is ready for operation.
The blue LED goes out.
› Insert a seam sealing test, e.g. Hygopac Sealcheck, as directed in the instructions into the transport until the unit starts up and the seam sealing test is drawn in.
The batch number is briefly displayed in the display window.
› After the sealing process, check the quality of the sealing seam:
  › Uniform and fully executed
  › Free of folds and flaws
  › Free of delamination
  › Colour corresponds to the industrial seam
  › Peelability corresponds to the industrial seam
› If the outcome of the operational qualification is satisfactory, tap *Yes* in the *Seam sealing test OK?* screen to switch the unit to 'ready for operation'.
› If the **outcome of the operational qualification is not satisfactory**, tap *No* in the *Seam sealing test OK?* screen.
The following appears on the screen: *Please adjust temperature*
› Tap *OK*.
› Adjust the temperature (directly via the menu) as required.
› Tap *Save* .
› Repeat the operational qualification.

If the operational qualification is unsuccessful despite adjusting the temperature several times, please contact a Service Technician.

14.3 Annual Performance Qualification

If, in the menu of the unit, the menu item *Performance Qualification* (PQ = Performance Qualification) is activated, a request will appear once a year to carry out a performance qualification of the sealing process.

This is only a reminder function and does not remove the responsibility for carrying out the performance qualification for the validation.

› Switch on the unit with button ⏻.
The display window shows the setpoint temperature and the actual temperature.
As soon as the target temperature has been reached, the unit is ready for operation.
› The following is shown on the display:
Start performance qualification?
Tap *Yes*.
› The following is shown on the display:
Apply 3 seals for each foil type (e.g. manufacturer, material, foil width).
› Tap *Start*.
The following is shown on the display:
Supply test foil.
› Perform all the required sealing processes one after the other, i.e.
seal **3 sets** of unfilled sterilisation packaging of the same type (e.g. manufacturer, material, foil width) for each one.
› Tap *Exit*.
› Label the sterilisation packaging with the device name and serial number of the sealing device and the parameters of the sealing process and document this information.

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› The sealed and empty sterilisation packages of the same type should be added to different sterilisation batches of the defined sterilisation program (the batch documentation for the sterilisation processes forms part of the validation). The different sterilisation packages only need to be included in the sterilisation programs in which they are used.
› Send the sterilisation packages that have been prepared in this way to Dürr Dental – further information on "Seal Test Order – the Certificated Service from Dürr Dental" can be found in the Download Center at www.duerrdental.com.

15 Document the sealing process

The batch documentation is required as proof of successful completion of the sterilisation process and as a mandatory quality assurance measure. It is possible to output the sealing records to the following output media and to archive them accordingly.
– SD memory card
– Computer (via the network)

15.1 Securing the sealing log

› Remove the SD card from the unit.
› Read the sealing records (see "20 Sealing log") on the PC and save them.
› After saving the data, delete the sealing records from the SD card.
› Insert the empty SD card into the unit.

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

NOTICE

Data loss due to removal of the SD card during read/write access

› Never remove the SD card while it is being read/written to.

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

We recommend always operating the unit with an SD card inserted.

If the unit is not integrated in a network, this will avoid the risk of documentation being lost.

Even if the the device is also integrated in a network, the sealing records will still be saved on the SD card in the event of a transmission error.

16 Cleaning and disinfection

Disconnect all power from the unit.

When cleaning and disinfecting the unit and its accessories, observe country-specific directives, standards and specifications for medical products as well as the specific specifications for dental practices and clinics.

NOTICE

The use of unsuitable agents and methods can damage the unit and accessories.

Do not use any products based on phenolic compounds, halogen-releasing compounds, strong organic acids or oxygen-releasing compounds, as they may damage the materials.

› Dürr Dental recommends using disinfectants from the Dürr Dental product range. Only the products specified in these instructions have been subjected to material compatibility testing by Dürr Dental.
› Read the operating instructions for the disinfectants.

Wear protective gloves.

16.1 Unit surfaces

The unit surface must be cleaned and disinfected of any contamination or visible soiling.
Dürr Dental recommends using the disinfectants FD 322, FD 333 and FD 350.

NOTICE

Liquid can cause damage to the unit.

› Do not spray the unit with cleaning and disinfectant agents.
› Make sure that liquid does not get inside the unit.

› Remove any coarse soiling with a soft, lint-free cloth that has been dampened with cold tap water.
The unit must be dry before the disinfection step starts.
› Disinfect the surfaces using a disinfection wipe. Alternatively, use disinfectant on a soft, lint-free cloth.

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Troubleshooting

17 Messages

17.1 "Caution" messages

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

Message: Caution
No SD card present. Insert the SD card and restart the device.
SD card write error. Restart the device.
Pressing force too high. Please repeat the sealing process.
Pressing force too low. Please repeat the sealing process.
Sealing temperature too high. Please repeat the sealing process.
Sealing temperature too low. Please repeat the sealing process.
Light barrier triggered for too long.
Sealing speed too high. Please repeat the sealing process.
Sealing speed too low. Please repeat the sealing process.

17.2 "Fault" messages

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

Message: Fault
Power supply unit defective.
Device overheating. Please wait.
Temperature sensor defective.
Foil transport blocked.
Heating defective. Contact a Service Technician.
Pressing operation defective.
Motor current too high.

17.3 "Note" messages

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

Message: Note
Restart device to apply language

18 Tips for operators and service technicians

Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

Prior to working on the unit or in case of danger, disconnect it from the mains.

18.1 Displaying the sealing parameters

› Tap *Sealing Parameters* > *Live Display*.
› Feed through a test foil.
In this mode the device settings, such as the sealing temperature, sealing speed and contact pressure, are displayed in real time.

18.2 Fault on the unit

Error	Possible cause	Remedy
Clicking noise during sealing process.	Transport roller dirty.	› Inform your Service Technician.

18.3 Error messages on the touch screen

Error	Possible cause	Remedy
No SD card present. Insert the SD card and restart the device.	No SD card has been inserted.	› Insert an SD card when the unit is switched off. › If no SD card is to be used, deactivate the function in the menu.
	SD card not detected.	› Remove the SD card with the unit switched off and re-insert it.
	SD card write-protected.	› Remove the write protection.
	SD card defective.	› Replace the SD card with a new one.
SD card write error. Restart the device.	SD card defective.	› With the device switched off, replace the SD card with a new one. › Restart the device.
SD card full. Insert an empty SD card and restart the device.	Maximum data volume reached.	› Save data on PC. › Insert an empty SD card and restart the device.
Device overheating. Please wait.	Inadequate ventilation of the unit.	› Acknowledge the message. Provide sufficient ventilation. Wait until the temperature has settled within the required range. In the event of a persistent fault, contact a Service Technician.
	Defective heating system.	

Error	Possible cause	Remedy
Light barrier triggered for too long.	Light barrier was triggered for too long. The unit can process foils up to a total width of 75 cm.	› Acknowledge the message. In the event of a persistent fault, contact a Service Technician.
	Light barrier dirty.	
Pressing force too high. Please repeat the sealing process.	Foil in the sealing seam area is too thick.	› Use a suitable foil (see "3.4 Consumables") and repeat the sealing process.
	Defective force measuring system.	› Acknowledge the message. Check the sealing seam for dirt and inclusions. Check the pressing force with no load on the system via the menu under *Sealing parameters*. See also "18.1 Displaying the sealing parameters". The value when a load is applied can be checked in the log file on the SD card. For pressing force, see"4 Technical data". In the event of a persistent fault, contact a Service Technician.
	Pressing force set incorrectly	
Pressing force too low. Please repeat the sealing process.	One-off fault.	› Please repeat the sealing process.
	Defective force measuring system.	› Acknowledge the message. Check the sealing seam for dirt and inclusions. Check the pressing force in the load-free state via the menu under *Sealing Parameters* (see also "18.1 Displaying the sealing parameters"). The value when a load is applied can be checked in the log file on the SD card. For pressing force, see"4 Technical data". In the event of a persistent fault, contact a Service Technician.
	Pressing force set incorrectly.	
Sealing temperature too high. Please repeat the sealing process.	Temporary fault on the temperature control	› Please repeat the sealing process; if the sealing temperature continues to be too high then the temperature control is defective. › Inform your Service Technician.
	Temperature control is defective.	› Inform your Service Technician.

Error	Possible cause	Remedy
Sealing temperature too low Please repeat the sealing process.	Temporary fault on the temperature control	› Please repeat the sealing process; if the sealing temperature continues to be too low then the temperature control is defective. › Inform your Service Technician.
	Temperature control is defective.	› Inform your Service Technician.
	Temperature control fuse is triggered	
	Heating element is defective	
Sealing speed too low. Please repeat the sealing process.	Foil held back in the unit during transport.	› Repeat the sealing process.
	Transport system dirty.	› Acknowledge the message. Carry the foil along with the same speed that is specified by the unit, or use an instrument table. Check the transport system for any visible signs of dirt or contamination. For information about the throughput speed see"4 Technical data" In the event of a persistent fault, contact a Service Technician.
	Speed measuring system defective.	
Sealing speed too high. Please repeat the sealing process.	One-off fault.	› Repeat the sealing process.
	Speed measuring system defective.	› Acknowledge the message. Carry the foil along with the same speed that is specified by the unit, or use an instrument table. Check the transport system for any visible signs of dirt or contamination. For information about the throughput speed see"4 Technical data" In the event of a persistent fault, contact a Service Technician.
Foil transport blocked.	Transport system blocked by foreign bodies or as a result of a malfunction; or the transport system has been brought to a standstill during transport due to excessive pulling forces.	› See "11.4 Start the transport belt manually". Carry the foil along with the same speed that is specified by the unit, or use an instrument table. Check the transport system for any visible signs of dirt or contamination. In the event of a persistent fault, contact a Service Technician.

Error	Possible cause	Remedy
Power supply unit defective.	The voltage of the power supply unit is possibly too low.	› Inform your Service Technician.
Temperature sensor defective.	Possibly due to a short circuit or broken cable	› Inform your Service Technician.
Heating defective.	It is possible that the heat-up phase is not reached.	› Inform your Service Technician.
Pressing operation defective.	The pressing force is possibly insufficient.	› Inform your Service Technician.
Motor current blocked.	The mechanical system is possibly stiff/sluggish.	› Inform your Service Technician.

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Appendix

19 Menu structure

Level 1	Level 2	Level 3	Level 4
Access levels	Operator		
	Administrator		
	Service Technician		
Sealing parameters	Temperature [1-3]	+ / -	
	Speed [1-3]	Slow	
		Medium	
		Fast	
	Live display [3]	Temperature	
		Speed	
		Pressing force	
System settings	Language [1-3]	German (DE)	
		English (EN)	
		...	
	Date / time [2-3]	Automatic	Enabled Disabled
		Date	
		Time	
		Time zone	UTC+2 - / +
	Network [2-3]	DHCP	Enabled Disabled
		MAC	
		IP address	000.000.000.000
		Netmask	000.000.000.000
		Gateway	000.000.000.000
		Syslog IP address	000.000.000.000
		Syslog port	514
		Syslog heartbeat	Enabled Disabled
	Standby [2-3]	Enabled Disabled	+ / -
Validation [1-3]	Operational qualification		
	Performance qualification		

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Level 1	Level 2	Level 3	Level 4
Device information [1-3]	Device data	REF:	
		SN:	
		Firmware:	
		Lib:	
		PCB SN:	
	Device usage data	LOT:	
		Operating hours:	
		Path counter:	
Alarm history [3]	see "17.1 "Caution" messages"		

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

20 Sealing log

After the sealing process, the relevant sealing data is stored in a text file. The file can be saved to the SD card in the unit or to a connected PC via a documentation program. The individual fields are separated by a semicolon.

A	B	C	D	E	F	G
Hygopac View	6024100001	xxxxx	yyyyy			
Time	LOT	Temperature[°C]	Press force[N]	Speed[m/min]	Result	
2018-04-06 02:22:09 +02:00	72	181	90	7	Pass	OQ:PASS
2018-04-06 02:22:17 +02:00	73	181	90	7	Pass	PQ
2018-04-06 02:22:20 +02:00	74	181	90	7	Pass	PQ
2018-04-06 02:22:24 +02:00	75	181	90	7	Pass	PQ
2018-04-06 02:22:31 +02:00	76	181	90	7	Pass	PQ
2018-04-06 02:22:37 +02:00	77	181	90	7	Pass	PQ
2018-04-06 02:22:44 +02:00	78	181	90	7	Pass	PQ
2018-04-06 02:22:50 +02:00	79	181	90	7	Pass	
2018-04-06 02:22:54 +02:00	80	181	90	7	Pass	

Explanation

1 Hygopac View; item description
2 6024100001; order number
3 xxxxx; serial number
4 yyyyy ; firmware version
5 Time; comprising the date, time and **time zone**.
6 LOT; sequential batch number.
7 Temperature; temperature during the sealing process.
8 Pressing force during sealing.
9 Speed; the speed at which the sealing process took place.
10 Result; this indicates whether the seal was OK.
11 OQ; Daily operating qualification, see "14.2 Daily function assessment".
12 PQ; Annual performance qualification. This entry appears automatically once a year and requests permission to carry out the performance qualification, see "14.3 Annual Performance Qualification".

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