Hygopac

EN

Installation and Operating Instructions

CE

9000-616-03/30

DÜRR DENTAL

1801V002

Contents

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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 – hot surfaces


Warning – dangerous high voltage

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


Manufacturer

Order number

Serial number


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


Monitor ambient conditions


Fuses


Wear hand protection.


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


Mains switch ON/OFF

On


Off


Operating temperature reached


Transport


Control range


Direction information, insertion


Heating

1.2 Copyright information

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

This device is designed to provide thermal sealing for sterile product packaging in the medical sector, e.g. clinics, dental and medical surgeries.

2.2 Intended use

Sterile product packaging in accordance with EN ISO 11607-1 and the applicable parts of EN 868 must be used.

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
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
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

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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 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.

2.6 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.
› Never touch the patient and unshielded plug connections on the device at the same time.
› Immediately replace any damaged lines and connections.

2.7 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.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare 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 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.

2.9 Disposal

Unit

The unit must be properly disposed of. 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.

3 Overview

3.1 Scope of delivery

The following items are included in the scope of delivery:

Hygopac 6020-02
– Hygopac
– Mains cable
– Hygofol Set
– Installation and Operating Instructions

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 Special accessories

The following optional items can be used with the device:

Hygoseal Plus 6022-500-10
Hygofol Station 6022-600-00
Hygoprint 6020-080-50

3.4 Disposable materials

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

Hygoseal Plus 6022-500-10

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

3.5 Wear parts and spare parts

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

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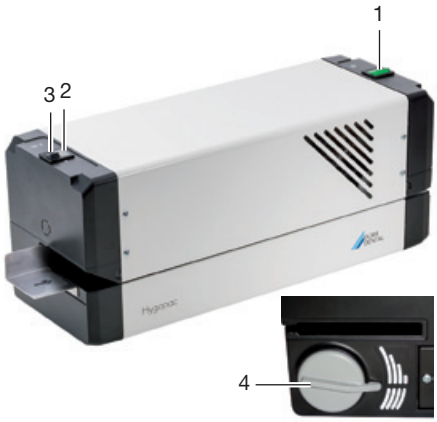
4 Technical data

Electrical data		
Voltage	V	230, 1~
Frequency	Hz	50 - 60
Nominal current	A	2.4
Power output	W	550
Fuses		IEC 127-2/V-T 4.0 AH
Type of protection		IP 20
Protection class		I
General data		
Max. sealing temperature (infinitely adjustable)	°C	240
Heating performance	W	2 x 250
Warm-up time approx.	min.	3
Rate of sealing	m/min	5.3
Sealing seam width	mm	9
Sealing seam strength	N/mm	3/15
Dimensions (W x H x D)	cm	43.5 x 16 x 13.5
Weight	kg	7.2
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

4.1 Type plate

The type plate is located on the underside of the device.

5 Operation



1 Mains switch ON/OFF (green)
2 Orange LED (transport switch)
3 Transport switch
4 Control knob for temperature adjustment

All aspects of the sealing of sterile product packaging are comprehensively defined in corresponding standards. Hygopac satisfies all of the requirements:

– Continuous sealing seams without flaws ensure that no microorganisms can penetrate.
– Sealing seam width of 9 mm (compared with a minimum requirement of 6 mm in the standard)
– Sealing seams can be opened without complications.

Further advantages of the Hygopac:

– Automatic throughput mechanism.
– Automatic contact pressure for consistent sealing seam quality.
– Narrow infeed gap with protection function for instrument and Hygopac.
– The assembly-line principle enables fast and continuous operation.
– The standardised workflow significantly reduces individual errors and ensures consistently good results.
– The Hygopac is space-saving, is maintenance-free in operation and offers exceptionally long service life thanks to its compact and robust design.

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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.

6.2 Setup options

The following options are available for installation of the device:

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

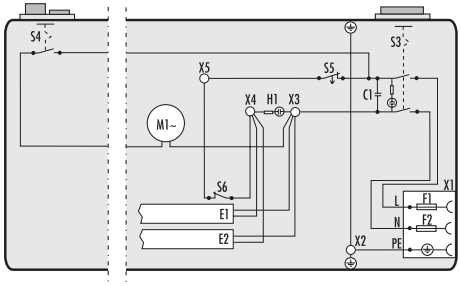
Please note the following when setting up the device:

– 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.

7 Electrical connections

› Before connecting the device, check that the supply voltage matches the voltage specification on the type plate.
› The device must only be connected to a correctly installed power outlet.
› Make sure that none of the electrical cables leading to the device are under any mechanical tension.

7.1 Electrical connection plan



C1 Interference suppression capacitor
E1/E2 Heating 2 x 250-300 W
F1/F2 Fuses
H1 Heating indicator LED
M1 Motor 230 V~
S3 Mains switch ON/OFF with indicator LED
S4 Transport switch
S5 Capillary tube controller
S6 Temperature safety limiter
X1 Appliance connection port
X2-X5 Flat connector distributor 6.3 x 0.8

8 Commissioning and first start-up

› Switch on main power supply (1).
The green (1) and orange (2) LEDs light up.
The warm-up time is around 3 minutes.
Once the orange LED goes out, wait approx. 2 minutes.

› Switch on the transport switch (3).
› Carry out a function check of the device.
› Perform a sealing test (see "10 Operation").

8.1 Handover of the device

A performance test is carried out on the device at the factory, and a printout of these test results is included in the supplied documents. This test only relates to Dürr Dental Hygofol transparent sterile product packaging. If other sterile product packaging (from other manufacturers) is to be sealed with the device, this must be subjected to performance tests "11.4 Annual Performance Qualification" after commissioning.

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 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.

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

9.1 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.

10 Operation

› Switch on main power supply (1).
The green (1) and orange (2) LEDs light up. The warm-up time is around 3 minutes. Once the orange LED goes out, wait approx. 2 minutes.

› Switch on the transport switch (3).
› Feed the Hygofol from the left. The Hygofol is automatically and evenly transported through the heating channel via a transport belt.

NOTICE
Incomplete sealing seam or blocked sterile product packaging due to wrong infeed
No correct (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.
› Position the sterile product packaging at the stop.

› Check the sealing seam after the pass, and adjust the sealing temperature if required (see "10.1 Adjusting the sealing temperature").
› Label the packaging with its expiration date and any other required information (e.g. steriliser-no., personnel etc.)

10.1 Adjusting the sealing temperature

› The temperature is infinitely variable and can be set using the rotary knob (5).

› The usual temperatures for sealing are in the range between 150°C and 220°C.
Depending on the actual sterilised packaging material being used, perform a test sealing process to determine the suitable sealing temperature.
› After the sealing process, wait for the sealing seam to cool down.
› Perform a function assessment (see "11.3 Daily function assessment").

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11 Validation of the sealing process

11.1 Validation steps

As a general rule, please note that the Hygopac does not meet all of the requirements of DIN EN ISO 11607-2, as the relevant process parameters of the Hygopac are not monitored and documented by the device(temperature, contact pressure and speed). We recommend seeking clarification from the relevant authorities in advance whether the degree of process validation that can be attained with the Hygopac is sufficient.

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

– Installation qualification; this must be performed during commissioning of the device, see see "8.1 Handover of the device" on page 9.
– Operational qualification; to be performed daily.
– Performance testing; to be performed annually.

11.2 Installation Qualification (IQ)

Installation Qualification (IQ)

Handover of the device

A performance test is carried out on the device at the factory. A printout of these test results is included in the supplied documents.

This test only relates to Dürr Dental Hygofol transparent sterile product packaging. If other sterile product packaging (from other manufacturers) is to be sealed with the device, this must be subjected to performance tests "11.4 Annual Performance Qualification" after commissioning. 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.

11.3 Daily function assessment

Function assessment

A function assessment of the sealing process must be performed every day when the device is first switched on.

› Switch on the main power supply.
  The green and orange LEDs light up. The warm-up time is around 3 minutes. Once the orange LED goes out, wait approx. 2 minutes.
› Switch on the transport switch.
› Feed a seal test (e.g. Hygoseal Plus) into the infeed in accordance with the instructions.
› After sealing assess the sealing seam:
  – Uniform and fully executed
  – Free of folds and flaws
  – Free of delamination
  – Colour corresponds to the industrial seam
› If the function assessment is OK, document the outcome with the date and initials of the person who performed the test in a list.
  If required you can download a template from the Download Center:
  www.duerrdental.com

Possible faults	Cause	Solution
– Paper goes brown – Holes are produced in the foil – Foil sticks to the roller – Extreme creasing	– Sealing temperature too high (Foil and paper fail to combine) – Sealing temperature too low	Adjust the sealing temperature (see "10.1 Adjusting the sealing temperature")

11.4 Annual Performance Qualification

Performance Qualification (PQ)

Once a year perform a Performance Qualification on the sealing process.

› Switch on the main power supply.

The green and orange LEDs light up. The warm-up time is around 3 minutes. Once the orange LED goes out, wait approx. 2 minutes.

› Seal 3 empty sterile product packages with the same material and size.

› Mark the sterile product packages with

– Sealing device
– Serial number of the device
– Documentation of the temperature settings of the control knob

› and/or document this information.

› The sealed and empty sterile product 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 sterile product packages only need to be included in the sterilisation programs in which they are used.

› Send the sterile product 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.

12 Disinfection and cleaning

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

Only damp-wipe the unit when it is cold.

Disinfect and clean the external surfaces using disinfectant and cleaning wipes that are compatible with the material and have been specifically approved by Dürr Dental, e.g. FD 350 disinfection wipes.

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