

Hygopac Plus

EN



Installation and operating instructions

CE

9000-616-37/02



 **DÜRR
DENTAL**

1807V004

Contents



Important information

| | |
|--|---|
| 1 About this document | 3 |
| 1.1 Warnings and symbols | 3 |
| 1.2 Copyright information | 4 |
| 2 Safety | 4 |
| 2.1 Intended purpose | 4 |
| 2.2 Intended use | 4 |
| 2.3 Improper use | 4 |
| 2.4 General safety information | 4 |
| 2.5 Qualified personnel | 5 |
| 2.6 Electrical safety | 5 |
| 2.7 Only use original parts | 5 |
| 2.8 Transport | 5 |
| 2.9 Disposal | 5 |



Product description

| | |
|--|----|
| 3 Overview | 6 |
| 3.1 Scope of delivery | 6 |
| 3.2 Accessories | 6 |
| 3.3 Optional accessories | 6 |
| 3.4 Consumables | 6 |
| 3.5 Wear parts and replacement parts | 6 |
| 4 Technical data | 7 |
| 4.1 Type plate | 8 |
| 4.2 Declaration of conformity | 9 |
| 5 Operation | 10 |
| 5.1 Display overview | 12 |
| 5.2 Tyscor Pulse (optional) | 13 |



Assembly

| | |
|--|----|
| 6 Requirements | 14 |
| 6.1 Installation/setup room | 14 |
| 6.2 Setup options | 14 |
| 6.3 Information about electrical connections | 14 |
| 7 Installation | 14 |
| 7.1 Electrical connections | 14 |
| 8 Commissioning | 15 |
| 8.1 Monitoring the device with Tyscor Pulse | 15 |
| 8.2 Handover of the device | 16 |
| 9 Settings upon commissioning | 16 |
| 9.1 Language selection | 16 |
| 9.2 Set the date and time | 16 |
| 9.3 Adjusting the temperature | 17 |
| 9.4 User management | 17 |
| 9.5 Set the speed for the belt transport | 17 |
| 9.6 Set standby time | 17 |
| 9.7 Configuring the network | 18 |



Usage

| | |
|--|----|
| 10 Use of suitable sterile product packaging | 19 |
| 10.1 Recommendations for the sterile product packaging | 19 |
| 11 Operation | 20 |
| 11.1 Start the transport belt manually | 20 |
| 12 Monitoring the device with Tyscor Pulse | 21 |
| 12.1 Monitoring operation | 21 |
| 12.2 Completing the task | 21 |
| 12.3 Creating a report | 21 |
| 13 Adjustment of the adjustable stop | 22 |

14 Validation of the sealing process 22
14.1 Validation steps 22
14.2 Daily function assessment 23
14.3 Annual Performance
Qualification 24

15 Disinfection and cleaning 24

EN



Troubleshooting

16 Tips for operators and service technicians 25



Appendix

17 Menu structure 28

18 Sealing log 30
18.1 Securing the sealing log 30



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.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible risks of personal injury or material damage.

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 a description of 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
- **ATTENTION**
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.

 Comply with 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 protective gloves.

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

Symbols used in the display

The following symbols are visible in the unit display during operation.

 Heating. The unit cannot be started while this symbol is visible.

 Ready. This is displayed when image plates can be inserted.

 Result. This is displayed when the sealing parameters are OK.

 Validation reminder. This is displayed when a validation (assessment of function or performance) needs to be carried out.

 Note. This is displayed for a note or for error messages.

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

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. Nevertheless, residual risks can remain. You should therefore observe the following notes.

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

Sterilisation packaging, which do not comply with EN ISO 11607-1, are 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 Qualified 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 transport.

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 transport 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.

2.9 Disposal

Unit

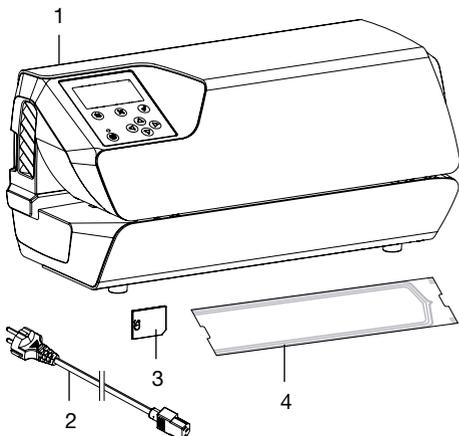


The unit must be disposed of properly. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

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



3 Overview



- 1 Hygopac Plus
- 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 Plus **6022-80**

- Hygopac Plus
- 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 unit and must be reordered 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

3.5 Wear parts and replacement parts



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

4 Technical data

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

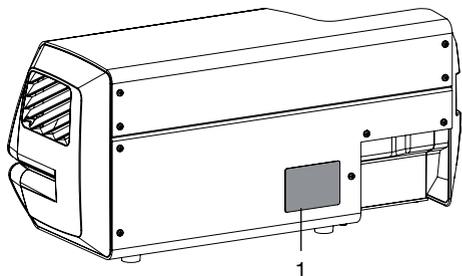
| General data | | |
|---|-------|---|
| Sealing temperature (adjustable in 5 °C steps) | °C | 100 - 200 |
| Tolerance of the adjusted sealing temperature | | 100 - 210 (version 2.0 or higher) |
| Heating performance | W | 2 x 400 |
| Warm-up time approx. | min | 3 |
| Throughput speed: | | |
| Permanently set | m/min | 10 (up to version 2.0) |
| adjustable | | 5 - 7.5 - 10 (version 2.0 or higher) |
| Tolerance of the set throughput speed | m/min | |
| Limit values | | + / - 3 |
| | mm/s | min. 133, max. 200 (up to version 2.0) |
| | m/min | min. 2, max. 13 (version 2.0 or higher) |
| Sealing seam: | | |
| Total width | mm | 15 |
| Sealed width | mm | 12 |
| Pressing force, general range | N | < 45 and > 110 |
| Dimensions (W x H x D) | cm | 37 x 17 x 14 |
| Weight | kg | 7.3 |

| 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 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 Plus

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.

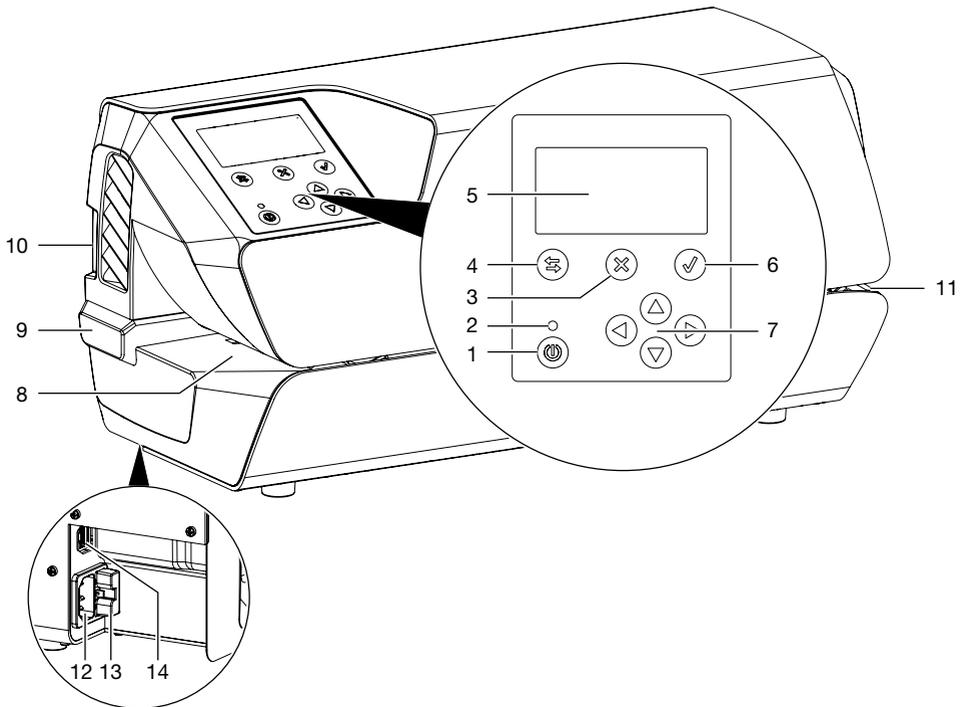
– Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment in its current version.

Hygopac Plus REF 6022-80

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

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

5 Operation



- 1 On / off switch
- 2 Standby LED
- 3 Button – "Cancel" or "No"
- 4 Shift key – switching between display / menu
- 5 Display
- 6 Button – "Confirm" or "Yes"
- 7 Arrows for navigation
from version 2.0: Press arrow "right" to start the transport belt manually
- 8 Infeed
- 9 Adjustable stop
- 10 SD card slot
- 11 Outlet
- 12 Mains connection
- 13 Fuse holder
- 14 Network connection

The device is equipped with an operating panel with display. Information is displayed here and settings are performed for the operation of the device.

Pressing the On/Off switch starts the device. The device heats up, and both the target temperature and the current temperature are shown on the display.

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. The request for an operational qualification can be deactivated via the menu if required. The operational qualification can be retrieved again at a later time via the menu if it was not be carried out with the first sealing process.

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 50 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 accordingly.

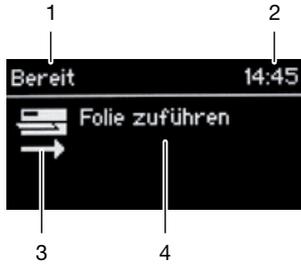
After the sterilisation packaging has been transported through the unit, the transport then switches off after an afterrunning time. The unit is ready for the next sealing process.

The unit has a standby mode. If this is activated in the menu under **Settings** -> **Standby**, the unit will switch off automatically, following non-use, after the set time. 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.

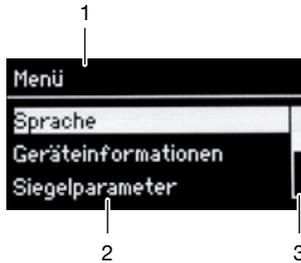
5.1 Display overview

Display window



- 1 Context area (e.g. Ready, Heating, Note)
- 2 Time
- 3 Symbol area
- 4 Content area for text

Menu window



- 1 Context area
- 2 Menu items
- 3 Scroll bar for more than three entries

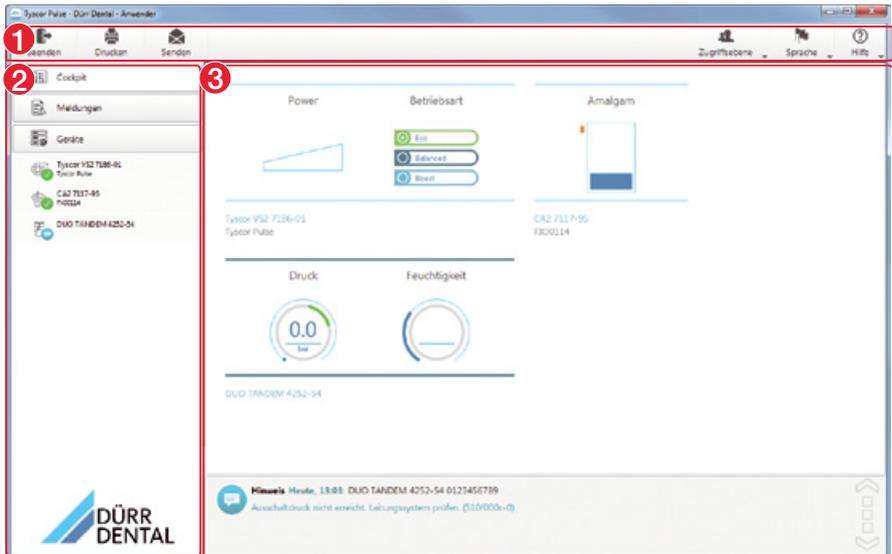
5.2 Tyscor Pulse (optional)

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

All messages are logged and can be printed or sent.

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 "Symbols"). If a new message appears, a speech bubble tip also appears.



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).

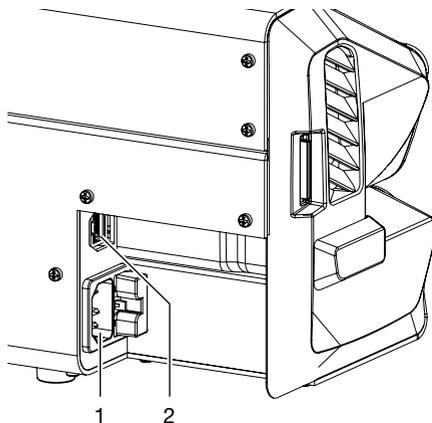
Please note the following when setting up the device:

- 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



- 1 Mains connection
- 2 Network connection

7.1 Electrical connections

- › 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



NOTICE Damage to the device

- For units with firmware version 2.0 or higher, an older version may not be played.

- Insert the SD card into the unit.
- Switch the unit on via the on / off switch.
- Perform a basic set-up for the unit – e.g. language, temperature, date and time (required for logging the seal parameters). The firmware version can be seen under **Unit information**. Refer to "9 Settings upon commissioning"



The temperature setting of the unit is factory pre-set for Dürr Dental Hygofol transparent sterilisation packaging.

- Carry out a function check of the device.
- Perform a sealing test.

8.1 Monitoring the device with Tyscor Pulse

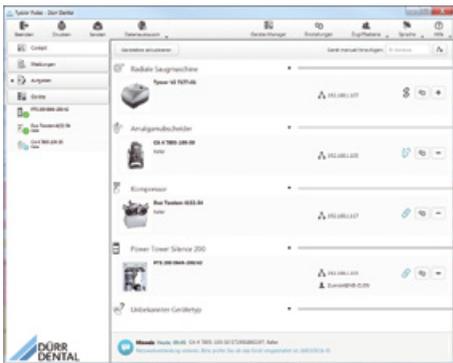


Further information on Tyscor Pulse can be found in the software help and in the Tyscor Pulse manual, order number 0949100001.

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

- Unit connected to the network
- Latest Tyscor Pulse software installed on computer

Add device



Requirements:

- Unit 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 device is present in the network and connected to the software.



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

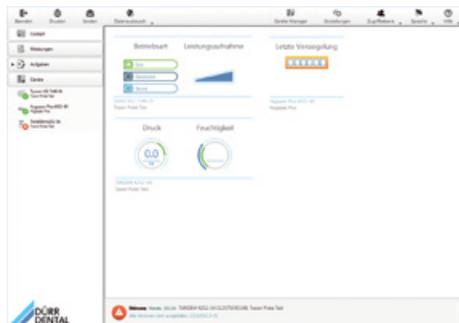


The network connection between the software and the device is interrupted, e.g. the device is switched off.

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.

8.2 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 "14.3 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 Settings upon commissioning

 **NOTICE**
Damage to the device

- › For units with firmware version 2.0 or higher, an older version may not be played.



- 1 Display window
- 2 Menu window

9.1 Language selection

- › Press the  button to switch from the display screen to the menu screen. The menu item **Language** is highlighted.
- › Press the  button to select the menu item. The available languages that can be selected are displayed in the next window.
- › Select the language with  or  and click  to confirm.
- › Use the  button to switch back to the display window.

9.2 Set the date and time.

- › Press button  to switch from the display window to the menu window.
 - › Use button  to scroll to the menu item **Settings** and confirm with .
 - › Use  to scroll to the menu item **Date & Time** and confirm with .
 - › Use  or  to select between **Automatic** or **Manual** and confirm with .
- When manually adjusting the settings for date & time, the buttons  and  can be used to change between the individual items and the digits can be selected with  or .
- › Use button  to switch back to the display window, or use  to get back to the higher menu option.

9.3 Adjusting the temperature

- › Press the  button to switch from the display screen to the menu screen.
- › Use the  button to scroll to the menu item **Settings** and press  to confirm.
The menu item **Setpoint Temperature** is highlighted.
- › Press the  button to select the menu item.
- › Press  or  to change the temperature.
- › Use the  button to switch back to the display window or use  to switch to the next higher menu level.

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.

9.4 User management

Version 2.0 or higher

Different access levels can be selected with the corresponding functionalities: **Operator**, **Administrator** and **Service Technician** (see "17 Menu structure").

- › Press button  to switch from the display window to the menu window.
- › Use button  to scroll to the menu item **Access Levels** and confirm with .
- › Use buttons  or  to choose between **Operator** or **Administrator** or **Service Technician** and confirm with .
- › Use button  to switch back to the display window.

9.5 Set the speed for the belt transport

Version 2.0 or higher

- › Press button  to switch from the display window to the menu window.
- › Use button  to scroll to the menu item **Settings** and confirm with .
- › Use button  to scroll to the menu item **Speed** and confirm with .
- › Use buttons  or  to choose between **Slow** or **Medium** or **Quick** and confirm with .
- › Use button  to switch back to the display window.

9.6 Set standby time

Version 2.0 or higher

- › Press button  to switch from the display window to the menu window.
 - › Use button  to scroll to the menu item **Settings** and confirm with .
 - › Use button  to scroll to the menu item **Standby** and confirm with .
 - › Use buttons  or  to choose between **Activated** or **Deactivated** and confirm with .
- If **Activated** was selected, the time **Timeout** can additionally be set until the change to Standby.
It is set to 30 minutes by default.
- › Use button  to switch back to the display window.

9.7 Configuring the network

 Restart the device after performing a menu change.

- > Press the  button to switch from the display screen to the menu screen.
- > Use the  button to scroll to the menu item **Settings** and press  to confirm.
- > Press  to scroll to the menu item **Network** and click  to confirm.

Get IP automatically is displayed as the first menu item.

- > Press  to confirm and press  or  to select **Activated** or **Deactivated**, and press  to confirm.

If "Activated" is selected, you can exit the "Network" menu item again – the remaining settings will be copied from the router via DHCP. A fixed IP address should be assigned here (router setting).

- > Press  to continue to **IP address** and click  to confirm.
Use the  and  buttons to switch between the individual positions and use  or  to select the numbers. At the end, confirm the settings with .

Adjust the settings for **Subnet mask** and **Gateway** in the same manner.

- > Use the  button to switch back to the display window or use  to switch back to the next higher menu level.

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.

The network integration of the unit can be carried out via the following third-party software: DIOS MP, SEGOSOFT, DOCma, MELAssoft.

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.

- > Press the  button to switch from the display screen to the menu screen.
- > Use the  button to scroll to the menu item **Settings** and press  to confirm.
- > Press  to scroll to the menu item **Network** and click  to confirm.
- > Press  to scroll to the menu item **Syslog IP address**, then click  to confirm.
Use the  and  buttons to switch between the individual positions and use  or  to select the numbers. At the end, confirm the settings with .
- > Press  to scroll to the menu item **Syslog port**, then click  to confirm.
Use the  and  buttons to switch between the individual positions and use  or  to select the numbers. At the end, confirm the settings with .
- > Use the  button to switch back to the display window or use  to switch back to the next higher menu level.



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

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.

11 Operation

- › Switch on the unit with button .

The display will show the setpoint temperature and the actual temperature.

The blue indicator light flashes during the heat-up phase (version 2.0 or higher).

As soon as the target temperature has been reached, the unit is ready for operation.

The blue indicator light extinguishes.
- › 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

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.

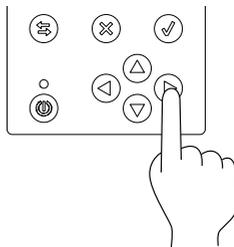
- › Place the sterilisation packaging up against the stop (this is the only way to ensure that the light barrier will be triggered).
 - › Observe the maximum foil width of 50 cm.
- › Assess the sealing seam after process is completed (see "14.2 Daily function assessment").
 - › Label the packaging with the expiry date and required additional information (e.-g. steriliser no., personnel, program etc.)

11.1 Start the transport belt manually

Version 2.0 or higher

In standby mode, the transport belt can be started manually by pressing the arrow (right). This can be used to remove packaging that has become stuck.

- › Press and hold down button  until the sealing of the sterilisation packaging is completed, or until stuck packaging that was stuck has been transported to the end.

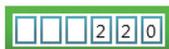


12 Monitoring the device with Tyscor Pulse

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

12.1 Monitoring operation

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



Hygopac Plus 6022-80
Hygopac Plus

The following is shown in the unit block of the Hygopac Plus:

- Sequential number of the last sealing process
- Whether the process parameters of the sealing process are within the tolerance (= green frame) or not.

Unit details

Depending on the access level, the last sealing processes incl. parameters and further unit details can be displayed in the unit details.

It is also possible to import log data from the SD card of the unit here or to export recorded log data.

Symbols

-  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.

12.2 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.

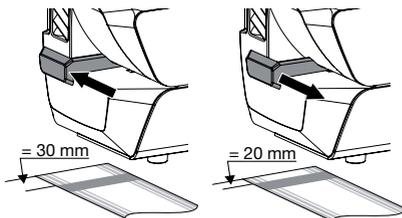
12.3 Creating a report

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.

13 Adjustment of the adjustable stop

With the aid of the adjustable stop, the distance between the sealing seam and the edge can be adjusted to one of three different distances (2, 2.5 or 3 mm).



- Set the adjustable stop to the rear to maximise the distance (3 mm).
- Set the adjustable stop to the front to minimise the distance (2 mm).



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" on page 16.
- 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 will show the target temperature and the actual temperature.
The blue indicator light flashes during the heat-up phase (version 2.0 or higher).
As soon as the target temperature has been reached, the unit is ready for operation.
The blue indicator light extinguishes.
- › Seam sealing test, insert e. g. Hygopac Seal-check as directed in the instructions into the infeed until the unit starts up and the seam sealing test sample is drawn in.
- › 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 result of the operational qualification is satisfactory, press button  to switch the unit to ready for operation. If the result of the operational qualification is not satisfactory, press the  button.
- › Set the temperature as described in "9.3 Adjusting the temperature", and repeat the operational qualification.

Starting further operational qualifications

Version 2.0 or higher

A further operational qualification can be started independently of the initial work day request.

The operational qualification is also recorded in the log.

- › Press button  to switch from the display window to the menu window.
- › Use button  to scroll to the menu item *Operational Qualification* and confirm with .
- › Supply test foil.
- › Use button  to switch back to the display window.

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 will show the target temperature and the actual temperature.
As soon as the target temperature has been reached, the unit is ready for operation.
- › Seal 3 empty sterilisation packages of the same material and size; then label them with the sealing unit, machine number and the sealing parameters or document this information suitably elsewhere.
- › 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.duer-dental.com.

15 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.



16 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 device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).



Error messages with a **Note** must be acknowledged by pressing to get the unit ready for operation again.

| Fault | Probable cause | Solution |
|--|--|--|
| Note No SD card present | No SD card has been inserted. | <ul style="list-style-type: none"> › 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. |
| Note SD card write error | SD card defective. | › Replace the SD card with a new one. |
| Note SD card full | max. data volume reached. | › Save data on PC. |
| The sealing parameters have not been written on the SD card | The SD card was removed and then replaced while the device was running. | › Only remove and replace an SD-card when the device is switched off. |
| Sterilisation packaging is stuck in the transport mechanism | Sterilisation packaging was inserted during the after-running period of the machine without the light barrier being activated. | <ul style="list-style-type: none"> › Up to version 2.0 , Activate the light barrier again by slowly feeding in a new sterilisation packaging. Remove it as soon as the transport starts up. Make sure that the sterilisation packaging is not drawn into the unit. › From version 2.0 The transport belt can be started manually with the arrow key pressed down (right) (see "11.1 Start the transport belt manually"). |

EN

| Fault | Probable cause | Solution |
|---|---|---|
| <p><i>Note</i> Unit overheating!</p> | <p>Inadequate ventilation of the unit. Defective heating system.</p> | <p>› 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.</p> |
| <p><i>Note</i> Sealing temperature too high (version 2.0 or higher)</p> | <p>Temperature control is defective.</p> | <p>› Inform your Service Technician.</p> |
| <p><i>Note</i> Sealing temperature too low (version 2.0 or higher)</p> | <p>Temperature control is defective. Temperature control fuse is triggered Heating element is defective</p> | <p>› Inform your Service Technician.</p> |
| <p><i>Note</i> Sealing temperature not reached (version 2.0 or higher)</p> | <p>Temperature control is defective. Temperature control fuse is triggered Heating element is defective</p> | <p>› Inform your Service Technician.</p> |
| <p><i>Note</i> Notice Pressing force too high</p> | <p>Foil in the sealing seam area is too thick. Defective force measuring system. Pressing force set incorrectly</p> | <p>› 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. 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.</p> |
| <p><i>Note</i> Notice! Pressing force too low</p> | <p>Defective force measuring system. Pressing force set incorrectly</p> | <p>› 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. 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.</p> |

| Fault | Probable cause | Solution |
|--|--|--|
| <p><i>Note</i> Notice Speed too low</p> | <p>Foil held back in the unit during transport.</p> <hr/> <p>Transport system dirty.</p> <hr/> <p>Speed measuring system defective.</p> | <p>› 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 throughput speed, see "4 Technical data" In the event of a persistent fault, contact a Service Technician.</p> |
| <p><i>Note</i> Notice Speed too high</p> | <p>Speed measuring system defective.</p> | <p>› 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 throughput speed, see "4 Technical data" In the event of a persistent fault, contact a Service Technician.</p> |
| <p><i>Note</i> Notice Image foil transport blocked</p> | <p>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.</p> | <p>› Acknowledge the message. Trigger the light barrier on the foil infeed again with foil and remove the blocked foil. 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.</p> |
| <p><i>Note</i> Notice Input sensor occupied too long</p> | <p>Input sensor was occupied too long. The unit can process foils up to a total width of 50 cm. Input sensor dirty.</p> | <p>› Acknowledge the message. In the event of a persistent fault, contact a Service Technician.</p> |
| <p><i>Note</i> Error in internal power supply unit</p> | <p>Internal power supply defective, thus insufficient power supplied to the microcontroller. Mains fluctuations.</p> <p>This message can also appear temporarily on the display after unplugging of the mains plug when the unit is still switched on before it is completely currentless.</p> | <p>› Acknowledge the message. Contact customer service. › Replace electronics.</p> |



17 Menu structure

| Level 1 | Level 2 | Level 3 | Level 4 | Level 5 | |
|--|---|--|------------|---|--|
| Language ¹ | <input checked="" type="checkbox"/> German (DE) | | | | |
| | <input type="checkbox"/> English (EN) | | | | |
| | ... | | | | |
| Access level ¹ | <input checked="" type="checkbox"/> Operator | | | | |
| | <input type="checkbox"/> Administrator | | | | |
| | <input type="checkbox"/> Service technician | | | | |
| Device Information ¹ | REF: | | | | |
| | SN: | | | | |
| | Firmware: | | | | |
| Operational qualification ¹ | Supply test foil | | | | |
| Settings ² | Setpoint temperature | xxx °C | | | |
| | Speed | <input type="checkbox"/> slow | | | |
| | | <input checked="" type="checkbox"/> medium | | | |
| | | <input type="checkbox"/> quick | | | |
| | Validation | Operational qualification | | <input checked="" type="checkbox"/> Activated | <input type="checkbox"/> Deactivated |
| | | Performance qualification | | <input checked="" type="checkbox"/> Activated | <input type="checkbox"/> Deactivated |
| | Date & time | <input type="checkbox"/> Automatic | NTP server | | 000.000.000.000 |
| | | | Time zone | | UTC -12, UTC -11:30, ... , UTC +13:30, UTC +14 |
| | | <input checked="" type="checkbox"/> Manual | Date | | YYYY-MM-DD |
| | | | Time | | hh:mm |
| | Network | Get IP automatically | | <input checked="" type="checkbox"/> Activated | <input type="checkbox"/> Deactivated |
| | | IP address | | 000.000.000.000 | |
| | | Subnet mask | | 000.000.000.000 | |
| | | Gateway | | 000.000.000.000 | |
| | | Syslog IP address | | 000.000.000.000 | |
| Syslog port | | | 00514 | | |
| SD card | <input checked="" type="checkbox"/> Activated | | | | |
| | <input type="checkbox"/> Deactivated | | | | |
| Standby | <input checked="" type="checkbox"/> Activated | | | | |
| | <input type="checkbox"/> Deactivated | | | | |

| Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---------------------------------|--|-----------|---------|---------|
| Sealing parameters ³ | Temperature: xxx °C | | | |
| | Pressing force: xx N | | | |
| | Speed: Up to version 2.0: xx mm/s From version 2.0: xx m/min | | | |
| Statistics ² | Batch counter | xxx foils | | |

- 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

18 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.

Example up to version 2.0

| Hygopac Plus | 6022-80 | | 1.4.4.3726 | | | |
|----------------------------|---------|-----------------|-------------------|-------------|--------|--|
| Time | LOT | Temperature[°C] | Pressure Force[N] | Speed[mm/s] | Result | |
| 2015-01-22 13:25:11 +00:00 | 11 | 181 | 76 | 166 | Pass | |
| 2015-01-22 13:25:20 +00:00 | 12 | 180 | 74 | 166 | Pass | |
| 2015-01-22 13:25:26 +00:00 | 13 | 180 | 88 | 150 | Pass | |
| 2015-01-22 13:25:33 +00:00 | 14 | 181 | 77 | 166 | Pass | |
| 2015-01-22 13:25:48 +00:00 | 15 | 180 | 77 | 166 | Pass | |

Example from version 2.0

| Hygopac Plus | 6022-80 | F308030216 | 2.0.20.7879 (OS: 4.6.7.3594) | | | |
|----------------------------|---------|-----------------|------------------------------|--------------|---------------|---------|
| Time | LOT | Temperature[°C] | Press force[N] | Speed[m/min] | Result | |
| 2018-07-05 12:48:36 +02:00 | 135 | 179 | 67 | 7 | Pass | OQ:PASS |
| 2018-07-05 12:48:42 +02:00 | 136 | 179 | 71 | 7 | Pass | |
| 2018-07-05 12:48:48 +02:00 | 137 | 179 | 63 | 7 | Pass | |
| 2018-07-05 12:48:53 +02:00 | 138 | 179 | 92 | 6 | Fail(Force) | |
| 2018-07-05 12:49:08 +02:00 | 139 | 179 | 68 | 7 | Pass | |
| 2018-07-05 12:49:17 +02:00 | 140 | 179 | 68 | 7 | Pass | PQ |

Explanation

- Hygopac Plus; item designation
- 6022-80; order number
- EX00112; serial number
- 1.4.2.3677; firmware version
- Time; comprising the date, time and ****time zone****.
- LOT; sequential batch number.
- Temperature; temperature during the sealing process.
- Pressing force; pressing force exerted during the sealing process.
- Speed; the speed at which the sealing process took place.
- Result; this indicates whether the seal was OK.
- OQ; Daily operating qualification, see see "14.2 Daily function assessment" on page 23.
- PQ; Annual performance qualification. This entry appears automatically once a year and requests permission to carry out the performance qualification, see see "14.3 Annual Performance Qualification" on page 24.

18.1 Securing the sealing log

- › Secure the sealing log on the SD card at least twice a year.
- › After securing the data, delete the sealing log from the SD card.
- › Insert the empty SD card into the unit.



Hersteller/Manufacturer:

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

