

Hygojet

EN



Installation and operating instructions

CE 0297

9000-616-04/02



 **DÜRR
DENTAL**

21102V004

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Appendix

EN **! 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 operating instructions are valid for Hygojet, order number: 6040-000-00.

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
-  Warning - automatic start-up of the unit
-  Biohazard warning

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.
-  Wear protective gloves.
-  Observe the operating instructions.
-  CE labelling with the number of the notified body
-  Manufacturer
-  Serial number
-  Order number
-  Medical device
-  Air
-  Water
-  Drain connection
-  Compressed air connection
-  Compressed air connection on the pressure reducer unit
-  Water connection on the pressure reducer unit

 Open the water tap before starting work

 Close the water tap after finishing work

 Pre-clean impressions with water

 The force of the spray jet can be increased by pressing the air button as well; this button can also be used to manually blow out any remaining water after cleaning.

 Manual application of disinfectant, e.g. MD 520

 Observe the required reaction time as required (10 minutes for MD 520)

 Manual subsequent cleaning with water

 Manual drying

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 developed and designed the unit in such a way that dangers are effectively ruled out if the unit is used in accordance with the Intended Use.

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 radiation
- Personal injury due to fire
- Personal injury due to thermal effects to skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose

The Dürr Dental Hygojet is a hygiene lock in which water, compressed air and disinfectant are applied for cleaning and disinfection of impressions and prosthetic works.

2.2 Intended use

The Dürr Dental Hygojet is a hygiene device in which water, compressed air and disinfectant are applied for cleaning and disinfection of impressions and prosthetic works. Thanks to the enclosed housing, the risk of any aerosols escaping and the surroundings becoming contaminated as a result is prevented. Dürr Dental Hygojet is approved for use with MD 520 Impression disinfection (Dürr Dental).

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.

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.

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 Essential performance characteristics

The Hygosuc device does not have any essential performance characteristics as set out in IEC 60601-1 (EN 60601-1) section 4.3.

2.7 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.8 Only use original parts

- › Only use accessories and optional items that have been recommended or specifically approved by Dürr Dental.
- › Only use only original wear parts and replacement parts.

2.9 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.

2.10 Disposal



An overview of the waste keys for Dürr Dental products can be found in the download area at www.duerrdental.com (document no. P007100155).

Unit



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

- › Decontaminate potentially contaminated parts before disposing of them.
- › Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
- › If you have any questions 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 (possible variations due to country-specific requirements and/or import regulations):

Accessories Hygojet 6040-004-00

- MD 520 Impression disinfection
- Hoses
- Gloves

Console for wall mounting with pressure reducer 6040-060-00

3.2 Optional accessories

The following optional items can be used with the device:

Conversion kit for arm reach-through 6040-023-00

3.3 Wear parts and replacement parts

- Hose set 6040-981-00
- O-ring 10 mm 9000-401-05
- O-ring 18 mm 9000-401-93



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

4 Technical data

Water connections

Flow pressure	mbar/hPa	2500
Consumption*	l/min	2
Connection	Inches	R3/4

* Min. 2 bar, max. 3 bar

Compressed air

Flow pressure	mbar/hPa	2500
Consumption*	l/min	88
Quick release connection	mm	Diameter 12

* Min. 2 bar, max. 3 bar

Draining

Continuous downward gradient required	mm	Diameter 20
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General data

Dimensions (W x H x D)	cm	36 x 34 x 32
Dimensions of the unit chamber (W x H x D)	cm	30 x 20 x 25
Weight	kg	12.7
Amount of disinfectant used after every press of the disinfection button*	ml	10

* Until the "chem control" display is shown again

Ambient conditions during storage and transport

Temperature	°C	-25 to +70
Relative humidity	%	< 95

Ambient conditions during operation

Temperature	°C	-10 to +40
Relative humidity	%	< 80

Classification

Medical Device Class	IIa
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4.1 Evaluation of conformity

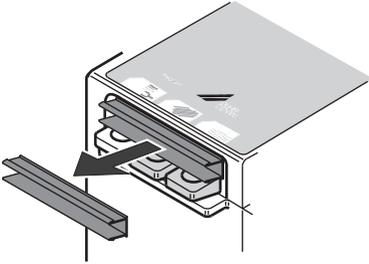
This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation

Dürr Dental Hygojet is used for manual application of water, compressed air and (if applicable) MD 520 Impression disinfection (Dürr Dental). Thanks to the closed system, the risk of aerosols escaping and contaminating the surroundings is avoided. Dürr Dental Hygojet is approved for use with MD 520 Impression disinfection (Dürr Dental).

6 Remove the transport locks

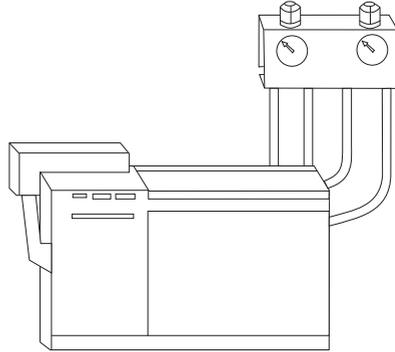
- › Remove the transport protection before taking the unit into operation.



7 Requirements

7.1 Installation/setup room

- › Position the unit around 2 m from the fresh water and compressed air connections.
- › Attach the wall console with the pressure reducer device at a distance of around 1 m to the unit.



7.2 Fresh water connection

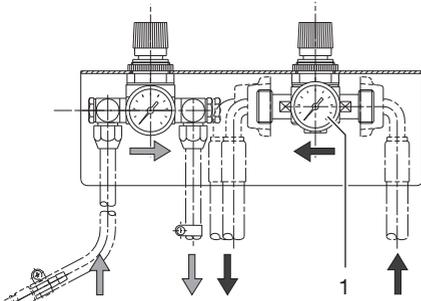


WARNING

Risk of infection due to backflow of contaminated liquid into the drinking water

- › When connecting to the public water supply, make sure that a suitable check valve in accordance with EN 1717 is installed. Local regulations must be complied with as the implementation of the relevant European standard EN 1717 varies from country to country.

- › Connect the two supplied blue water hoses to the water pressure reducer. Pay attention to the correct flow direction when doing this.



1 Water pressure reducer

- › On the right of the water pressure reducer, route the water hose to the in-house water connection and connect.
- › On the left of the water pressure reducer, route the water hose to the Hygojet and connect it to the water connection.



The water connection on the Hygojet is an R3/4" connection. For safety, a check valve is installed in the unit.

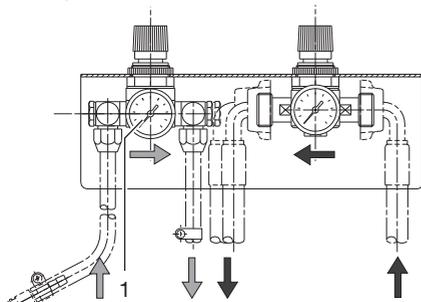
- › Set the flow pressure on the water pressure reducer to 2.5 bar.

7.3 Compressed air connection



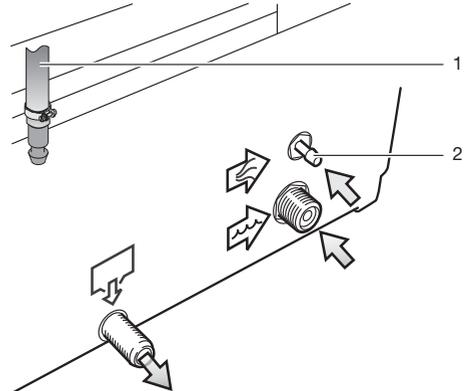
We recommend using oil-free compressed air.

- › Connect the two supplied compressed air hoses to the compressed air pressure reducer. Pay attention to the correct flow direction when doing this.



1 Compressed air pressure reducer

- › On the right of the compressed air pressure reducer, route the compressed air hose (without the quick release coupling) to the Hygojet unit, shorten as required, connect to the compressed air connection and fasten with a hose clamp.

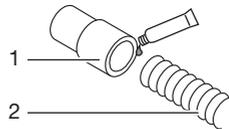


1 Quick release coupling Ø12 mm
2 Compressed air connection

- › On the left of the compressed air pressure reducer, route the compressed air hose with the quick release coupling to the in-house compressed air connection and connect.
- › Set the flow pressure on the compressed air pressure reducer to 2.5 bar.

7.4 Waste water connection

- › Screw the adapter onto the spiral hose and push it onto the wastewater connection on the Hygojet.



1 Adapter
2 Spiral hose

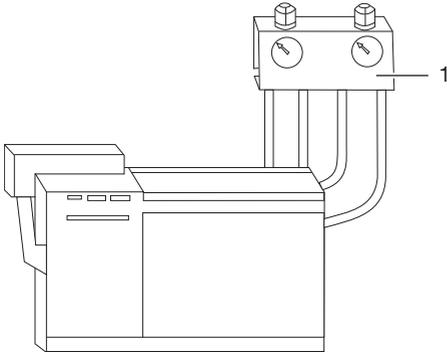
- › Route the spiral hose with a continuous downward gradient and connect it via a vented siphon trap with a 20 mm washing machine connection.



The distance between the siphon trap and the Hygojet unit must not exceed 2 m.

7.5 Mount the wall console with pressure reducer

- › Mount the wall console using the supplied screws and wall anchors at the designated point on the wall.



1 Wall console

 Usage

8 Operation

 Open the water tap before starting work

 Close the water tap after finishing work

8.1 Insert the bottle of disinfectant

We recommend using MD 520 for Impression disinfection.



WARNING

Danger due to re-use of products intended for single use

The disposable item is damaged after use and cannot be reused.

› Dispose of disposable items after use.

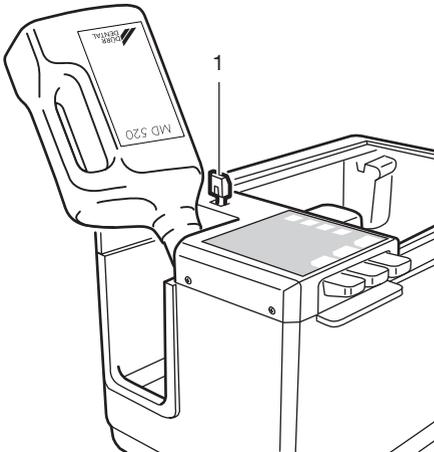


Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).



The use of MD 520 in the Hygojet unit has been tested and approved. Dürr Dental will not accept any warranty claims if other preparations are used.

› Remove the cover. Press the catch inwards.



1 Catch

- › Check the use-by-date of the MD 520 Impression disinfection.
- › Unscrew the lid from the bottle of MD 520 Impression disinfection.



Never insert the MD 520 bottle in the Hygojet without a nonreturn valve fitted, as otherwise fluid can escape.

- › Attach the supplied bottle closure with nonreturn valve to the MD 520 bottle.



- › Insert the MD 520 bottle in the mounting fixture in the Hygojet.

8.2 Application process



Since this is a manual process, the requirements of the material and disinfectant manufacturers will need to be taken into account depending on the application. The operator must check that the items are properly wetted and rinsed off and that the required reaction time is satisfied.

Insert the materials

Example: impression

- › Use a permanent marker to write on a label and stick this label to the impression.



Up to 6 impressions can be placed simultaneously in the hygiene lock.

- › Place the impression in the hygiene lock.
- › Close the glass lid.

Pre-cleaning with water

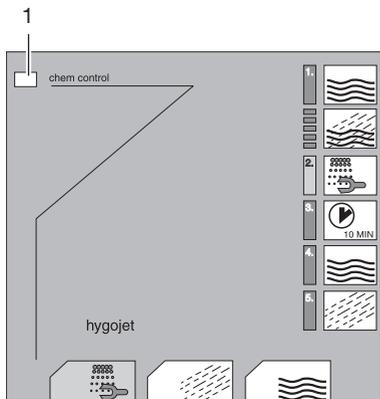
Example: impression

- › Wearing the protective glove, hold the impression under the spray head.
- › Press the  button.

- › Thoroughly rinse off both sides of the impression under the water jet. Press the  button to intensify the spray jet.
- › Press the  button and dry off the impression.

Apply disinfectant

- › Press the  button until the impression is sufficiently coated on all sides and the *chem control* display lights up yellow. Repeat the process if required.



1 *chem control*

-  One push of the button will apply around 10 ml of disinfectant. To ensure that the disinfection is carried out properly, it is important to make sure that the disinfectant used is allowed to soak in for the correct length of time (10 minutes for MD 520).

- › Set the action time on the timer.



Rinse with water

- › Press the  button.
- › Thoroughly rinse off both sides of the impression under the water jet. Press the  button to intensify the spray jet.

Drying

- › Press the  button and dry off the impression.

8.3 Overview of the application process

1.  Pre-clean the materials with water
2.  Apply disinfectant
3.  Leave to soak for the required action time
4.  Rinse with water
5.  Drying

8.4 Moving the unit to a different location

- › Take out the bottle of disinfectant.
- › Close the water tap and interrupt the compressed air supply.
- › Depressurise the system by pressing the  and  buttons.
- › Disconnect all hose connections from the back of the unit.
- › Disconnect the hose connections from the wall console and take off the wall console.
- › Properly package the unit, wall console and hoses to prevent the risk of transport damage.

9 Maintenance



All maintenance work must be performed by a qualified expert or by one of our Service Technicians.



WARNING

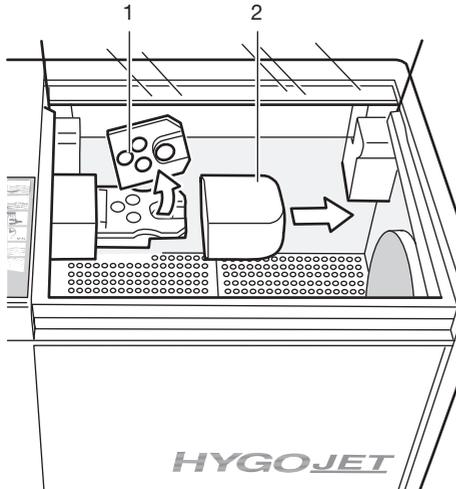
Infection due to contaminated unit

- › Clean and disinfect the suction before working on the unit.
- › Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Maintenance interval	Maintenance work
After every change of disinfectant bottle	› Clean the spray head.
	› Clean the drainage mesh.
	› Function test
	› Check the intake and drain hoses for leaks.
Clean the outside of the unit	› After every application process, clean the unit from the outside and disinfect it using a surface disinfectant approved by Dürr Dental, e.g. FD 322.
Every 3 years	› Replace the hoses – see "3.3 Wear parts and replacement parts".

9.1 Cleaning the spray head housing

- › Pull out the spray head housing to the side.
- › Clean the O-rings and nozzles in the spray head with water. Replace any O-rings that are damaged – see "3.3 Wear parts and replacement parts".

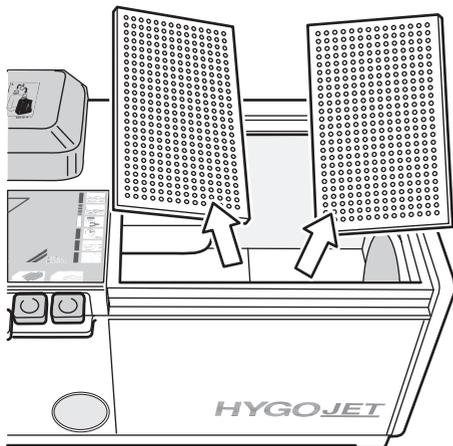


- 1 O-rings, nozzles
- 2 Spray head housing

- › Refit the spray head housing.

9.2 Cleaning the drainage mesh

- › Take out the drainage mesh and clean it under running water.



9.3 Performing a functional test

- › Press the  button.
Water will come out from the spray head.
- › Press the  button.
Compressed air will come out from the spray head.
- › Press the  button.
Disinfectant will come out from the spray head.

? Troubleshooting

10 Tips for operators and service technicians



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



WARNING

Infection due to contaminated unit

- › Clean and disinfect the suction before working on the unit.
- › Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Error	Possible cause	Remedy
No jet of disinfectant at the spray head when the  button is pressed	Disinfectant supply interrupted	<ul style="list-style-type: none"> › Clean the nozzles in the spray head – "9.1 Cleaning the spray head housing". › Check all O-rings to make sure they are correctly seated. › Replace the disinfectant bottle.
No water jet at the spray head when the  button is pressed	Water supply interrupted	<ul style="list-style-type: none"> › Clean the nozzles in the spray head – "9.1 Cleaning the spray head housing". › Check all O-rings to make sure they are correctly seated. › Open the water tap.
No compressed air at the spray head when the  button is pressed	Compressed air supply interrupted	<ul style="list-style-type: none"> › Check that the compressed air supply is connected. › Clean the nozzles in the spray head – "9.1 Cleaning the spray head housing". › Check all O-rings to make sure they are correctly seated.

 Appendix

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- Visual inspection of the packaging for any damage
- Unpacking the medical device and checking for damage
- Confirmation of the completeness of the delivery
- Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction:

Signature:

Name and address of the qualified adviser for the medical device:

Date of handover:

Signature of the qualified adviser for the medical device:

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Hersteller / Manufacturer:

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