stomdevice

PEOPLE HAVE PRIORITY

W&H

Instructions for Use



CE 0297

proxeo ULTRA

PB-510, PB-520, PB-530

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Symbols in the Instructions for Use



WARNING!
(risk of injury)



ATTENTION!
(to prevent damage occurring)



General explanations,
without risk to persons or objects

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Symbols

on the medical device


Consult Instructions for Use


Follow Instructions for Use


Date of manufacture


Do not dispose of with domestic waste


DataMatrix Code for product information including UDI (Unique Device Identification)



CE mark with identification number of the Notified Body


Foot control


Non-ionizing electromagnetic radiation



Catalogue number



Serial number


DC – direct current

V Supply voltage

W Electric power consumption

Hz Frequency of the alternating current


ESI (External System Interface)


Coolant volume



Upper limit of temperature



MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005, ANSI/AAMI ES60601-1: A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012, CAN/CSA-C22.2 No. 60601-1:2008, CSA CAN/CSA-C22.2 NO. 60601-1:2014.
25UX – Control No.

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Symbols

on the foot control

CE mark
with identification number
of the Notified Body

Non-ionizing electromagnetic
radiation

REF Catalogue number

Do not dispose of with
domestic waste

DC – direct current

SN Serial number

DataMatrix Code
for product information
including UDI (Unique
Device Identification)

IPX1 Protection against
dripping water

Date of manufacture

c UL us UL Component Recognition
Mark indicates compliance
with Canadian and
U.S. requirements

Wireless foot control C-NW

Reset

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Symbols

on the packaging



CE mark with identification number of the Notified Body



This way up



Fragile, handle with care



Keep dry



»Der Grüne Punkt« (The Green Dot) trademark of Duales System Deutschland GmbH



Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard



DataMatrix Code
for product information including UDI (Unique Device Identification)



Data structure in accordance with Health Industry Bar Code



Temperature limitation



Humidity limitation



Caution! According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices and intends to use or order the use of this medical device.

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1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your medical device. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients are of paramount importance to us.


Observe the safety notes.

Intended use
PB-510, PB-520, PB-530:
Drive unit with a piezoceramic oscillating system, which moves the tip in a linear oscillation. The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontic application and preparation of tooth enamel.

C-NF, C-NW: Foot control for operation of medical electrical equipment.


Misuse may damage the medical device and hence cause risks and hazards for user and third parties.

Qualifications of the user
We have based our development and design of the medical device on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

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Introduction

CE 0297

Production according to EU Directive
The medical device meets the requirements of Directive 93/42/EEC.
The foot control meets the requirements of Directive 93/42/EEC and RED Directive 2014/53/EU.

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

- The medical device must be used in accordance with these Instructions for Use.
- Only the components approved by the manufacturer may be replaced (O-ring, coolant filter, pump cartridge).
- Modifications or repairs must only be undertaken by an authorised W&H service partner (see page 47).
- The medical device has no components that can be repaired by the user.
- The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 (»Installation of electrical equipment in rooms used for medical purposes«) or with the regulations applicable in your country.
- Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

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2. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions in regard to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

HF communication equipment

Portable HF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.

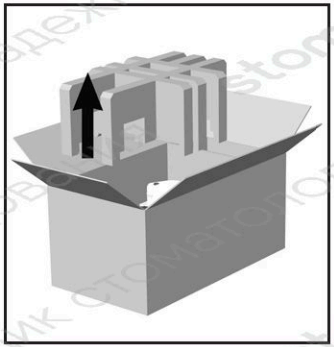
The medical device may be interfered by other equipment, even if these other devices comply with CISPR (International special committee on radio interference) emission requirements.

Use of this medical device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this medical device and the other equipment should be observed to verify that they are operating normally.

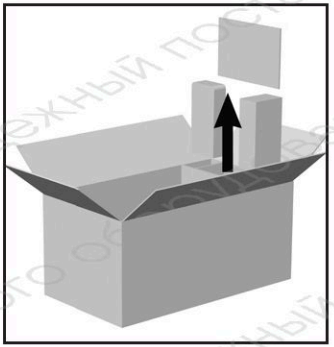
The medical device is not intended for use in the vicinity of HF surgical devices.

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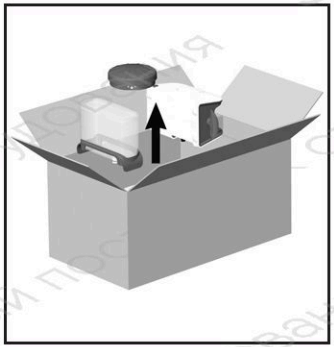
3. Unpacking



❶ Remove the insert.



❸ Remove the Instructions for Use and the accessories.



❷ Remove the control unit, the coolant tank and the foot control.

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies. However, we recommend that you keep the original packaging.

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4. Scope of delivery

	Control unit (100–230 V)	PB-510 30323000	PB-520 30324000	PB-530 30325000
REF 02675000	Coolant filter	X		
REF 05075600	Coolant hose (Ø 6 mm, approx. 2 m)	X		
REF 08016690	Power supply with adaptor	X	X	X
REF 07991190	Coolant tank		X	X
REF 08014700	Cable (pairing/charging)			X

	Optional
REF 30316000	Foot control C-NW
REF 04717300	Foot control C-NF
REF 30326000	Handpiece PB-5 L
REF 30327000	Handpiece PB-5 L Q
REF 30328000	Handpiece PB-5 L S

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> Before using the medical device for the first time, store it at room temperature for 24 hours.
> Check the medical device for damage and loose parts each time before using.
> Do not operate the medical device if it is damaged.
> Always ensure the correct operating conditions and cooling function.
> Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction (the exception are endodontics applications).
> In case of coolant supply failure, the medical device must be stopped immediately. The exception to this is in endodontic applications, where coolant is not used.
Maximum operating time without coolant: > 2 minutes for the power range 1–30
> 30 seconds for the power range 31–40
> Perform a test run each time before using.
> Never touch the patient and the electrical contacts on the medical device simultaneously.
> Check the parameter settings every time you restart.
> Make sure that the supply hose is dry. Moisture in the supply hose can lead to a malfunction (risk of short circuit).
> Replace damaged or leaking O-rings immediately.



> Do not twist, kink or squeeze the supply hose (risk of damage).

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The medical device is classed as »conventional equipment« (closed equipment without protection against the ingress of water).

The medical device is not approved for operation in potentially explosive explosive atmospheres.

Disconnect the medical device in dangerous situations from the power supply.

> Pull the power supply out of the socket.

> Only use the cable supplied for the foot control (C-NW).

System failure

A total system failure does not constitute a critical fault.

Pull the power supply out of the socket and then connect again.

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Control unit PB-510

> Disconnect the medical device from the water supply connection after each use (the medical device does not have an automatic aquastop).
> The medical device is approved for use only with supply units with category 5 backflow prevention devices as defined in EN 1717.
> Do not connect the medical device to the hot water supply (>30°C/86°F).

Control unit PB-520, PB-530

> Never fill or top up the coolant tank with liquids hotter than 30°C/86°F.
> Replace a faulty or leaky pump cartridge immediately.

Control unit PB-510, PB-520, PB-530

Risks due to electromagnetic fields

This medical device complies with the reference values defined in EN 50527-2-1/2016 for active implantable medical devices (AIMD) and with cardiac pacemakers.

The control unit is designed for use with the W&H handpiece PB-5 L/L S/L Q so only this is to be used with the control unit. The use of other handpieces could lead to a malfunction or destruction of the electronics.

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> Keep the foot control (C-NW) away from magnetic fields.
> Replace the foot control as soon as the resistance is noticeably reduced.

> Do not expose the medical device to any violent mechanical impacts.

Battery (C-NW)

> Do not charge the battery unattended.
> As soon as the charging cycles start to deteriorate send the medical device to an authorized W&H service partner.
> Defective or worn-out batteries must only be replaced by an authorized W&H service partner.

> Charge the battery of the foot control as soon as the status LED flashes.
> Incorrect use of the rechargeable battery can cause fire or corrosion.

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Foot control C-NW

Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillators (ICD) can be affected by electric, magnetic and electromagnetic fields. This medical device complies with the reference values defined in EN 50527-2-1/2016 for unipolar and bipolar pacemakers and is therefore suitable for patients with pacemakers.

> Find out if patient and user have implanted systems before using the medical device and consider the application.
> Keep a safe distance of at least 7 cm between the medical device and the cardiac pacemakers.
> Make appropriate emergency precautions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.

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6. Description

Control unit PB-510



1	Power range		**Connections**	11	Status LED
2	Power regulator	6	Power supply	12	Cover
3	»OFF«	7	ESI (external service interface)		
4	Handpiece support (adjustable)	8	Foot control		
5	Supply hose	9	Coolant hose		
		10	Coolant regulator		

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Description

Control unit PB-520



❶	Power range	❻	Coolant tank	⓫	Status LED
❷	Power regulator	❼	Filling level indicator	⓬	Coolant regulator
❸	»OFF«		**Connections**	⓭	Cover
❹	Handpiece support (adjustable)	❽	Power supply		
❺	Supply hose	❾	ESI (external service interface)		
		❿	Foot control		

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Description

Control unit PB-530



❶	**LED display** > Power range > Battery status foot control > Error message > Rinsing function > Cleaning function > Pairing	❷	Power regulator	❺	Coolant tank		**Connections**
		❸	»OFF«	❻	Filling level indicator	❾	Power supply
		❹	**Function button** > Rinsing function > Cleaning function > Pairing	❼	Handpiece support (adjustable)	❿	ESI (external service interface)
				❽	Supply hose	⓫	Cable (pairing/charging)
						⓬	Coolant regulator
						⓭	Cover

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Description



❶	Charging LED (orange)
❷	Status LED (green)
❸	Connection for cable (pairing/charging)
❹	Cable (pairing/charging)

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Description

Status LED foot control C-NW



Standby mode

> The foot control can be activated by pressing.

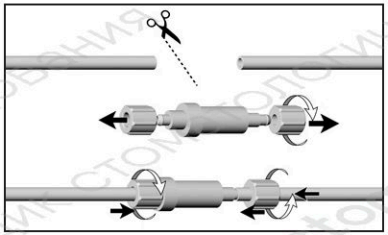
LED	steady	steady	flashes	flashes intermittently*
				
GREEN		→ Connection to paired medical device established	→ Foot control is attempting to establish a connection to the paired medical device	→ Battery is flat > Charge the battery
ORANGE	→ Battery is charging			

* LED flashes for 40 milliseconds every 4 seconds

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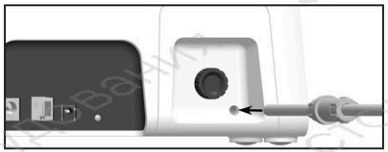
Ensure that the medical device can be disconnected from the power supply at any time.

Place the medical device on a flat, level surface.

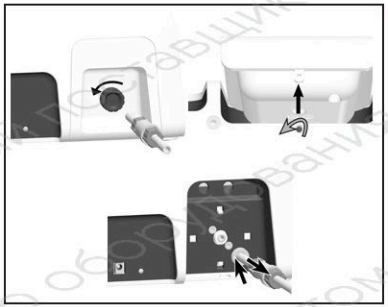


Control unit PB-510
Mount the coolant filter

1. Cut through the coolant hose.
2. Unscrew the cap nut from the coolant filter.
3. Attach the coolant hose through the cap nut onto the coolant filter. Screw the cap nut tight.



4. Push the coolant hose until the limit stop.



Control unit PB-510
Remove the coolant hose

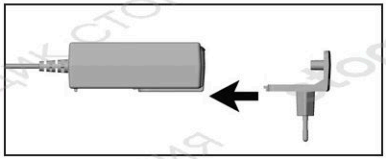
1. Screw off the coolant regulator.
2. Uncrew the cover and remove it.
3. Push the connection ring and simultaneously remove the coolant hose.

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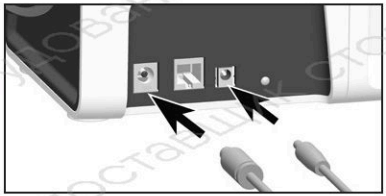
Control unit PB-520, PB-530
Coolant tank

❶ Fill the coolant tank and attach it. The coolant tank snaps audibly into place.

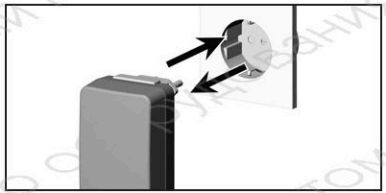


Control unit PB-510, PB-520, PB-530

❶ Slide the adapter onto the power supply.



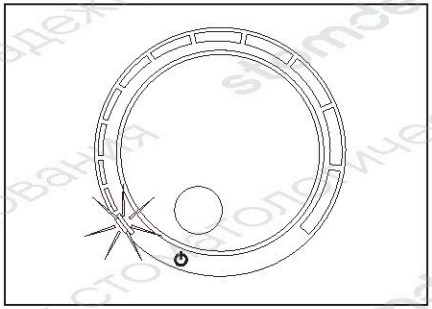
❷ Connect the power supply.
❸ Connect the foot control C-NF (controll units PB-510, PB-520).



❹ Plug the power supply into a socket.

❺ Pull the power supply out of the socket.

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Control unit PB-530

Power regulator »OFF«

> 1. LED display flashes white

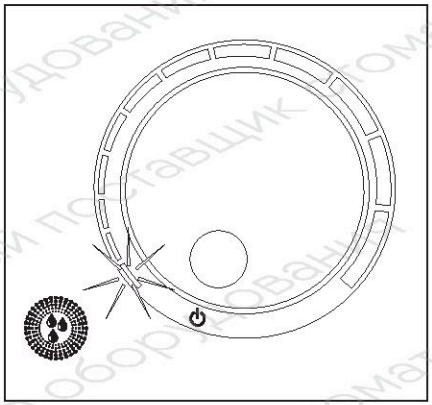
Next steps:

> Pairing foot control C-NW with control unit PB-530

> Charging the battery of the foot control C-NW with control unit PB-530

Coolant and handpiece inactive

The foot control C-NW and control unit PB-530 are not paired when delivered!



Pairing foot control C-NW with control unit PB-530

❶ Set power regulator to »OFF«

❷ Connect the cable to the control unit and foot control

> 1. LED flashs orange/red = not paired

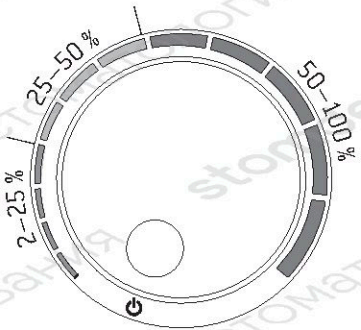
❸ Press function button for 5 seconds

> Sequential white LED during pairing

> 1. LED flashes white = pairing successful

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Charge the foot control fully before you use it for the first time.

Battery status

orange 2–25 %
yellow 25–50 %
green 50–100 %

Charging foot control C-NW with control unit PB-530

❶ Connect the cable to the control unit and foot control

> Power regulator »OFF«: The charging level is visible for 5 seconds at the LED display.

Query battery status during charging process with one of these options:

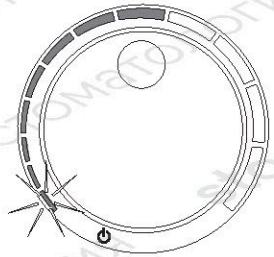
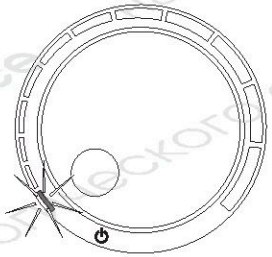
> Press foot control, battery status visible for 5 seconds
> Press function button, battery status visible for 5 seconds
> Disconnect charging cable, battery status visible for 5 seconds
> Set power

> Power set: The battery status is visible on the LED display.

During the charging process the LED display flashes.
The LED display flashes completely when the battery is charged.

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Control unit and foot control are not connected with the cable.

Indication: battery of foot control is flat	
	
→ Power setting: 1. LED flashes green, remaining LEDs are flashing green > Charge the battery	→ Power setting 0: 1. LED flashes white/blue > Charge the battery

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> Before every patient: Perform rinsing funcion for automatic internal cleaning of the coolant channels.
> W&H recommends performing the cleaning function once a month using the active substance chlorhexidine 0.2%. Fill coolant tank with at least 200 ml cleaning liquid. Then perform a rinsing function with tap water.

Proxeo Ultra	PB-510	PB-520	PB-530
Rinsing function for automatic internal cleaning of the coolant channels	✔	✔	✔
Cleaning function for automatic internal cleaning of the coolant channels	–	–	✔

W&H recommends performing a rinsing function with tap water after using one of the approved liquids.

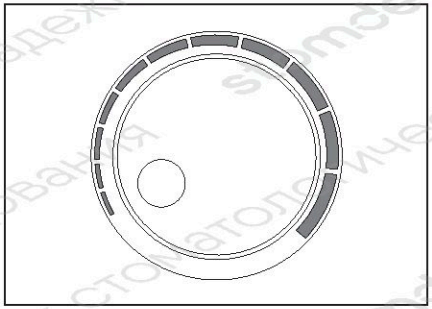
Approved coolants and rinsing liquids

> Physiological saline solution (NaCl, 0.9%)
> Hydrogen peroxide (H_2O_2, 1–3%)
> Liquids with the active substance chlorhexidine (CHX, 0.2%)
> Tap water

Approved cleaning agents

> Liquids with the active substance chlorhexidine (CHX, 0.2%)

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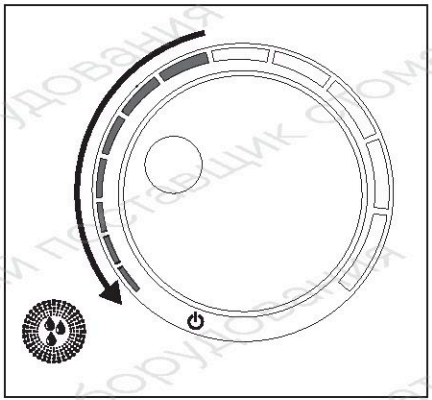
Control unit PB-510, PB-520

1. Remove the handpiece from the supply
2. Set power to 0
3. Press foot control 3 times within 3 seconds

> Rinsing function active for 30 seconds

Cancelling the rinsing function with one of these options:

> Press foot control
> Adjust power regulator



Control unit PB-530

1. Remove the handpiece from the supply
2. Adjust power
3. Press funtion button 1 second

> Rinsing function active for 30 seconds, visible by blue LEDs
> Rinsing function finished after all blue LEDs go out

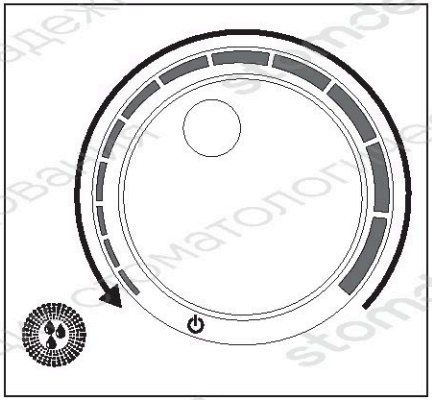
Cancelling the rinsing function with one of these options:

> Press foot control
> Press funtion button 1 second
> Set power regulator to »OFF«

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Operation control unit

Cleaning function



Control unit PB-530

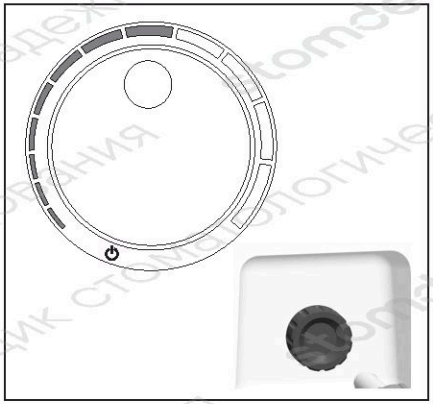
1. Remove the handpiece from the supply hose
2. Set power
3. Press funtion button 3 seconds

> Cleaning function active for 8 minutes, visible by blue LEDs
> Pump stops several times during the cleaning function
> Cleaning function finished after all blue LEDs go out

Cancelling the cleaning function with one of these options:

> Press foot control
> Press function button 1 second
> Set power regulator to »OFF«

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Control unit PB-510, PB-520, PB-530

❶ Attach the handpiece to the supply hose. Insert tip.

Follow the directions and safety notes in the Instructions for Use of the W&H handpieces.

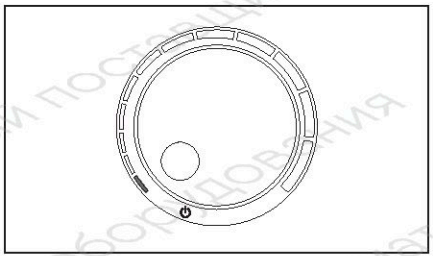
❷ Set power and coolant (variable)

❸ Press foot control

> Release foot control: Fade-out time of the handpiece LED 30 seconds

Control unit PB-530

> Coolant in coolant tank <50 ml: handpiece LED flashes



Subgingival flushing
Control unit PB-530

❶ Set power to 0

> 1. LED flashes blue

❷ Press foot control

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Test run

Do not hold the handpiece at eye level!

> Attach the handpiece to the supply hose.
> Insert the tip.
> Put the medical device into operation.

In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) **stop the medical device immediately** and contact an authorized W&H service partner.

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The error messages are indicated at the rear of the control unit by the status LED (flashing green).

Flashing cycle	Description of error	Solution
1x	Overheating	> Switch off conrol unit > Allow the control unit to cool for at least 10 minutes > Observe permissible ambient temperature/operating mode
2x	Foot control	> Release foot control
5x	Time-out (> 15 min)	> Release foot control (must not be active for longer than 15 minutes without interruption)
6x	Handpiece	> Check tip (full engagement, damage, torque) > Dry the handpiece/supply hose > Check plug-in connection of the handpiece/supply hose > If the error message appears again, contact an authorized W&H service partner immediately.
8x	System error	> Start the medical device again > Contact an authorized W&H service partner.

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The error messages are indicated by the LED display (LED steady).

LED display	Colour	Description of error	Solution
1. LED	orange	Overheating	> Switch off control unit > Allow the control unit to cool for at least 10 minutes > Observe permissible ambient temperature/operating mode
2. LED	orange	Foot control	> Release foot control
4. LED	orange	Function button	> Release function button
5. LED	orange	Time-out (> 15 min)	> Release foot control (must not be active for longer than 15 minutes without interruption)
6. LED	orange	Handpiece	> Check tip (full engagement, damage, torque) > Dry the handpiece/supply hose > Check plug-in connection of the handpiece/supply hose > If the error message appears again, contact an authorized W&H service partner immediately.
12. LED	red	System error	> Start the medical device again > If the error message appears again, contact an authorized W&H service partner immediately.

If the error messages described cannot be resolved, a check by an authorized service partner is required.

> In case of a total system failure, switch the medical device off and on again.

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10. Hygiene and maintenance

General notes

Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

> Wear protective clothing, safety glasses, face mask and gloves.

> Wipe the entire medical device and the foot control with disinfectant.

> Ensure that no fluids enter the medical device.

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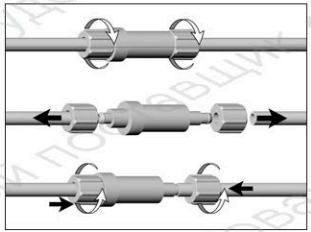
11. Maintenance

Proxeo Ultra	PB-510	PB-520	PB-530
Replacing the O-ring of the coolant tank	–	✔	✔
Replacing the coolant filter of the coolant hose	✔	–	–
Replacing the pump cartridge	–	✔	✔



Replacing the O-ring of the coolant tank

1. Remove the O-ring with tweezers.
2. Slide on the new O-ring.



Replacing the coolant filter of the coolant hose

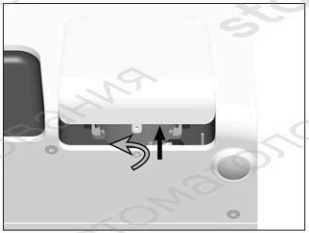
Replace the coolant filter if it is soiled or after 1 year at the latest.

1. Unscrew the cap nut from the coolant filter.
2. Pull off the coolant hose from the coolant filter.
3. Attach the coolant hose through the cap nut onto the new coolant filter. Screw the cap nut tight.

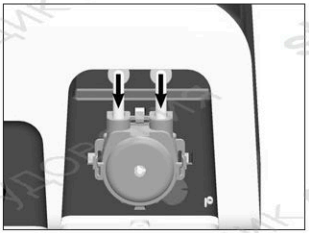
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Maintenance

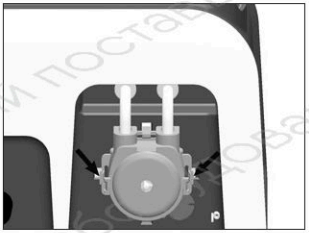
Replacing the pump cartridge



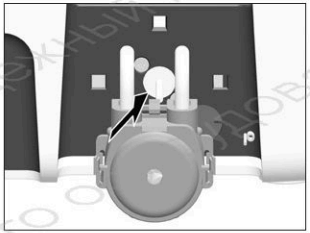
❶ Uncrew cover and remove.



❷ Pull off coolant hoses.

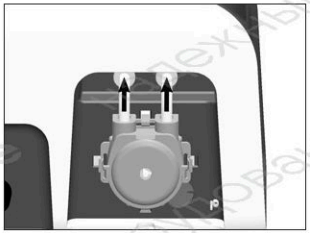


❸ Unlock pump cartridge and pull it out.



❹ Attach new pump cartridge.

Snaps audibly into place.



❺ Attach the coolant hoses until the limit stop.



❺ Attach cover and screw tight.

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12. Servicing

Regular checks

Regular servicing of function and safety including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.

The inspection must be undertaken by a qualified organisation and must include the following procedures:

Control unit

> External visual inspection
> Measurement of the device leakage current
> Measurement of patient leakage current
> Visual inspection of internal components on suspicion of safety interference, e.g., mechanical damage of the enclosure or indicators of overheating

Foot control

> External visual inspection
> Function test with check to see if the maximum speed can be reached

The regular checking must only be performed by an authorised W&H service partner.

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Servicing

Repair and returns

In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

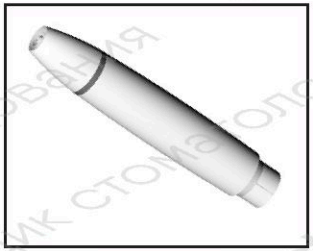


> Always return equipment in the original packaging!

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13. W&H accessories and spare parts

Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners



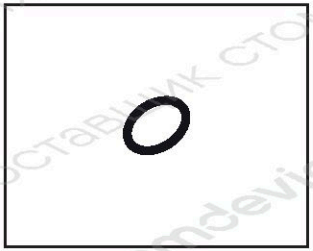
30326000
Handpiece PB-5 L
30327000
Handpiece PB-5 L Q
30328000
Handpiece PB-5 L S



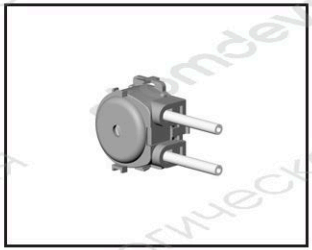
02675000
Coolant filter
05075600
Coolant hose



07991190
Coolant tank



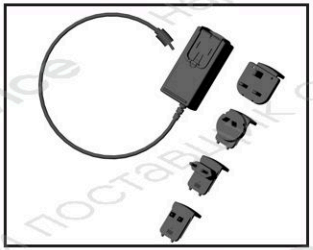
07960870
O-ring for coolant tank



08001660
Pump cartridge



08014700
Cable
(pairing/charging)



08016690
Power supply
with adaptor

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W&H accessories and spare parts



30316000
Foot control C-NW
with Stick



04717300
Foot control C-NF

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14. Technical data

Control unit	PB-510	PB-520	PB-530
Power supply:	28.3–31.5 V⎓		
Mains voltage:	100–230 V		
Nominal current:	max. 830 mA		
Permissible voltage fluctuation:	±10%		
Max. output power to the handpiece under load (ultrasonic):	12 W		
Frequency (ultrasonic):	22–35 kHz		
Operating mode:	S3 (14sec/6sec)		
Max. oscillation amplitude (Tip 1U):	0.2 mm		
Max. water pressure:	1–6 bar		
Max. coolant flow (adjustable):	ca. 50 ml/min		
Dimensions in mm (WxDxH):	120 x 185 x 110	120 x 185 x 205	120 x 185 x 205
Weight:	807 g	1,064 g	1,106 g

Ambient conditions	
Temperature during storage and transport:	-20°C to +60°C (-4°F to +140°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relative), non-condensing

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Technical data

Foot control	C-NW
Battery type:	Li-Ion
Runtime:	approx 2 months
Standby:	automatically if not actuated
Charging time:	approx. 3 h
Nominal voltage:	3.7 V
Nominal capacity:	680 mAh
Dimensions (WxDxH):	117 x 117 x 38 mm
Weight:	190 g

Ambient conditions	
Temperature during storage and transport:	-20°C to +60°C (-4°F to +140°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relative), non-condensing

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Technical data

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/ANSI/AAMI ES 60601-1



Charger: Class II medical electrical equipment



The C-NF/C-NW foot control is protected against vertically falling drops of water (IPX1 as per IEC 60529)

Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

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15. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.

> Medical device
> Waste electrical equipment
> Packaging

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Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase. Accessories and consumables (pump cartridge, coolant hose, coolant filter, O-rings) are excluded from the warranty.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty accompanied by proof of purchase must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 months warranty

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Authorised W&H service partners

Find your nearest W&H service partner at http://wh.com
Simply go to the menu option »Service« for full details.
Alternatively please contact:

W&H (UK) LIMIT, 6 Stroud Wood Business Centre, Park Street, St Albans, Hertfordshire AL2 2NJ, United Kingdom
t +44 1727 874990, f + 44 1727 872254, E-Mail: technical.uk@wh

W&H Impex Inc., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
t +1 800 2656277, 1 519 9446739, f + 1 519 9746121, E-Mail: service.ca@wh.com

W&H Impex Inc., 33091 W Jefferson Ave., Brownstown, MI 48173, USA
t + 1 800 2656277, 1 519 9446739, f + 1 519 9746121, E-Mail: service.us@wh.com

A-DEC AUSTRALIA CO. INC., Unit 8, 5-9 Ricketty Street, Mascot NWS 2020
t + 61 2 83324000, f + 61 2 83324099, E-Mail: a-dec@a-dec.com

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Manufacturer's declaration

Electromagnetic compatibility (EMC)
WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity. Only use original W&H accessories.

cables and accessories	length	reference
foot controller C-NW	wireless transmission	Manufacturer: W&H GmbH REF: 30316xxx
foot controller C-NF	1.8 m	Manufacturer: W&H GmbH REF: 04717300
power supply (GTM96300-3036-6.0-R2)	1.8m	Manufacturer: GlobTek, Inc. REF: 08016690

Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

Electromagnetic Immunity I (Table 2, IEC 60601-1-2:2007)
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 5kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines Both repetition rates	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	0% U_T 0.5 cycle @ 0°,45°,90°,135°,180°,225°,270° & 315° 0% U_T 1 cycle and 70% U_T 25/30* cycles @ 0° 0% U_T 250/300* cycle	Complies to both editions requirements	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3A/m	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the mains (AC) voltage before apply test levels
* 25/30 (250/300) means cycles at 50/60Hz

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Electromagnetic Immunity II (Table 4, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM and amateur radio bands* between 0,15 MHz and 80 MHz	6 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level [b] in each frequency range  Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Manufacturer's declaration

Immunity level of RF fields from wireless communication devices (Table 9, IEC 60601-1-2:2014)

Test frequency	Band[a]	Service[a]	Modulation[b]	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 – 390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[c] ±5 kH deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the product may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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Recommended Separation Distances between portable and mobile HF- communications equipment and the product (Table 6, IEC 60601-1-2:2007)

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Electromagnetic Emission (Table 1, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF-emission CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2 (*)	N/A (P<75W)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 (*)	N/A (P<75W)	

(*) Remark: for devices with power consumption of 75 W to 1000 W only

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