

Instructions for use



CE
0297

proxeo^{TWIST}

PL-40 HW

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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



Not for re-use



Sterilizable up to
the stated temperature



Thermo washer disinfectable



Class II medical
electrical equipment

Symbole

on the handpiece drive



Follow instructions for use



Data Matrix code
for product information
including UDI (Unique Device
Identification)



Catalogue number



Date of manufacture



Serial number



Do not dispose of with
domestic waste



CE mark
with identification number
of the Notified Body



DC – direct current



Non-sterilizable



Non-ionizing electromagnetic
radiation




Type BF applied part (not
suitable for intracardiac
application)





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.


Symbols

on the foot control


 CE mark
with identification number
of the Notified Body


 Non-ionizing electromagnetic
radiation


 Catalogue number

 Do not dispose of with
domestic waste

 DC – direct current


 Serial number

 Data Matrix code
for product information
including UDI (Unique Device
Identification)


 Protection against
dripping water

 Date of manufacture

 Manufacturer

 Foot control
cordless C-NW

 Reset

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

Symbols

radio symbol on the medical device / foot control



R 209 - J00204

GITEKI (MIC) – Japan



ANATEL – Brazil

12880-20-03402

Contains FCC ID: QOQBGM113
Contains IC: 5123A-BGM113


FCC / IC – USA / Canada





RCM – Australian / New Zealand

Symbols


on the packaging


 CE mark with identification number of the Notified Body


 This way up


 Fragile, handle with care

 Keep dry

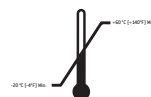
 [®] “Der Grüne Punkt” (The Green Dot) trademark of Duales System Deutschland GmbH


 Date of manufacture


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

 Data Matrix code for product information including UDI (Unique Device Identification)

 Data structure in accordance with Health Industry Bar Code

 Temperature limitation

 Humidity limitation

 **Rx**only
Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

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

PL-40 HW: Battery driven electrical drive unit with wireless foot controller to perform cleaning and polishing of tooth surfaces and fillings.

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



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

Qualifications of the user

We have based our development and design of the medical device on the target group “dentist, dental hygienist, dental employees [prophylaxis] and dental assistants”.

Introduction

Hereby, W&H declares that the foot control is in compliance with Directive 2014/53/EU (RED).

The full text of the EU declaration of conformity is available at the following internet address <https://wh.com>

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).
- > Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 47).
- > The foot control 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.



Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

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 (11.8 inch) 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.

3. Scope of delivery

REF	Description
30410000	Handpiece drive
30316000	Foot control C-NW with Stick
07969610	Charger with adaptor
05882600	Handpiece holder

4. Safety notes

Handpiece drive / Foot control



- > 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.
- > Perform a test run each time before using.
- > Never touch the patient and the electrical contacts on the medical device simultaneously.
- > Keep the foot control 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.
- > The handpiece drive must not be disassembled.


Battery





- > 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 medical device as soon as the status LED flashes.
- > Incorrect use of the rechargeable battery can cause fire or corrosion.

 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 atmospheres.

 **Charger**
> Only use chargers approved by W&H.

 **Hygiene and maintenance prior to initial use**
> Clean and disinfect the handpiece drive and the foot control.

 **System failure**
A total system failure does not constitute a critical fault.
Simply switch the unit off and then on again.



Handpiece drive

Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillator (ICD) can be affected by electric, magnetic and electromagnetic fields. This medical device is suitable for use on patients with unipolar and bipolar pacemakers or ICD, if a safety distance between the medical device and the cardiac pacemaker or ICD of at least 7 cm (2,76 inch) is maintained.

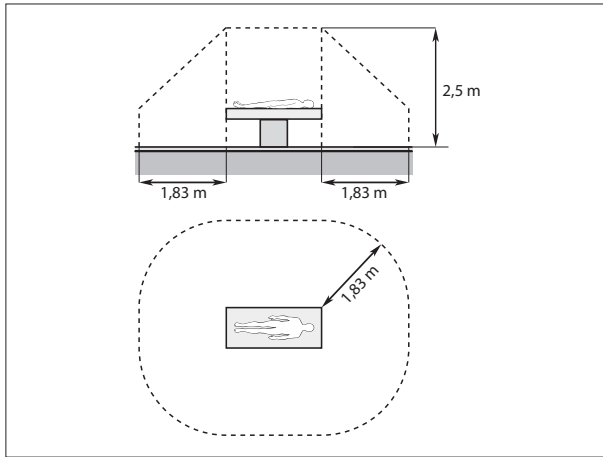
- > Find out if patient or user have implanted systems before using the medical device and consider the application.
- > Weigh the risks and benefits.
- > Make appropriate emergency precautions and take immediate action on any signs of ill-health.
- > Symptoms such as raised heartbeat, irregular pulse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

Foot control

- > Keep the foot control away from implanted systems.

Safety notes

Handpiece drive / Foot control



The patient environment (see diagram) encompasses the area up to 2.50 m above the patient and 1.83 m in all horizontal directions.



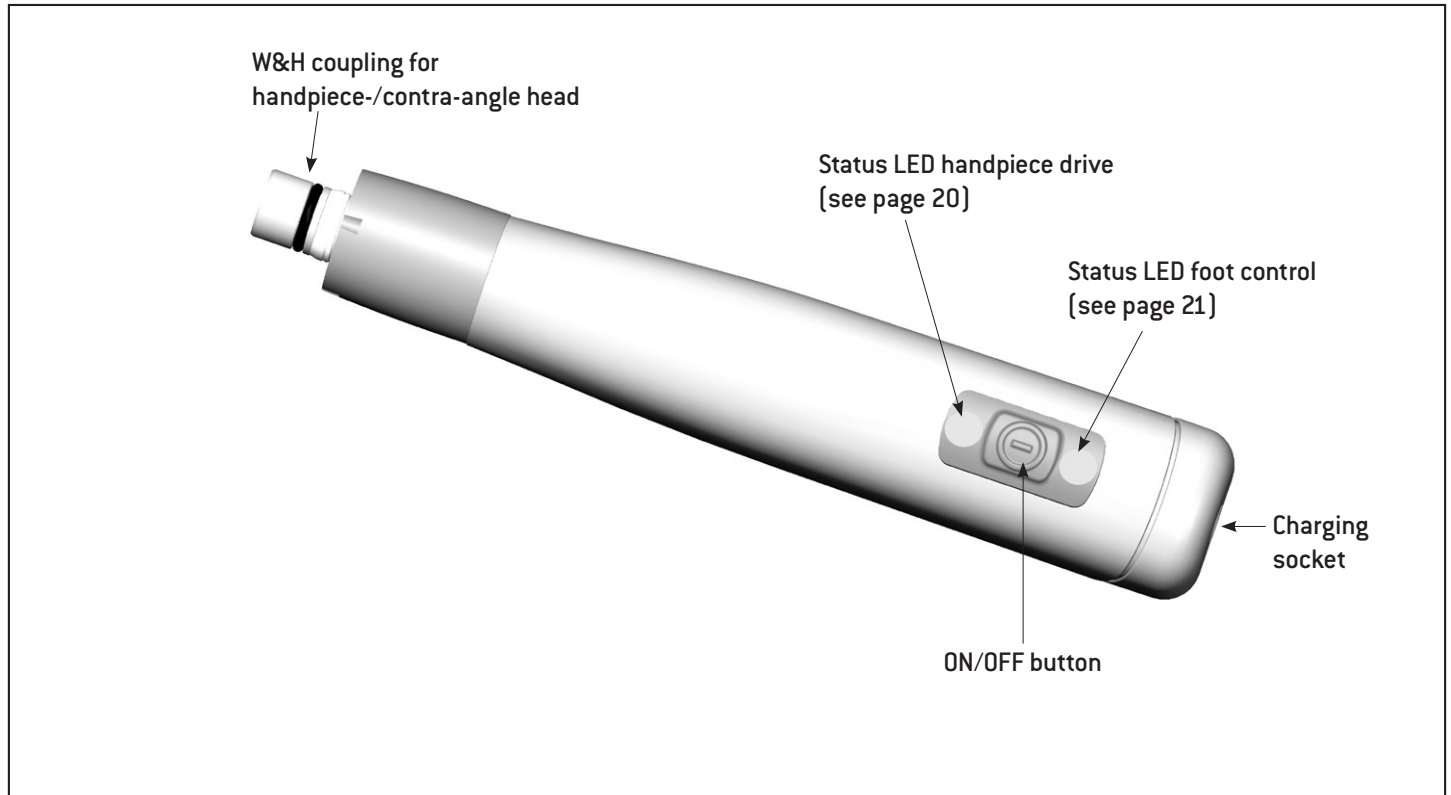
The charger must not be used within the patient environment.



- > Use only the handpiece drive with the handpiece-/contra-angle head PL-44, PL-66 W, PL-64.
- > Follow the directions and safety notes in the Instructions for Use of the handpiece-/contra-angle head.

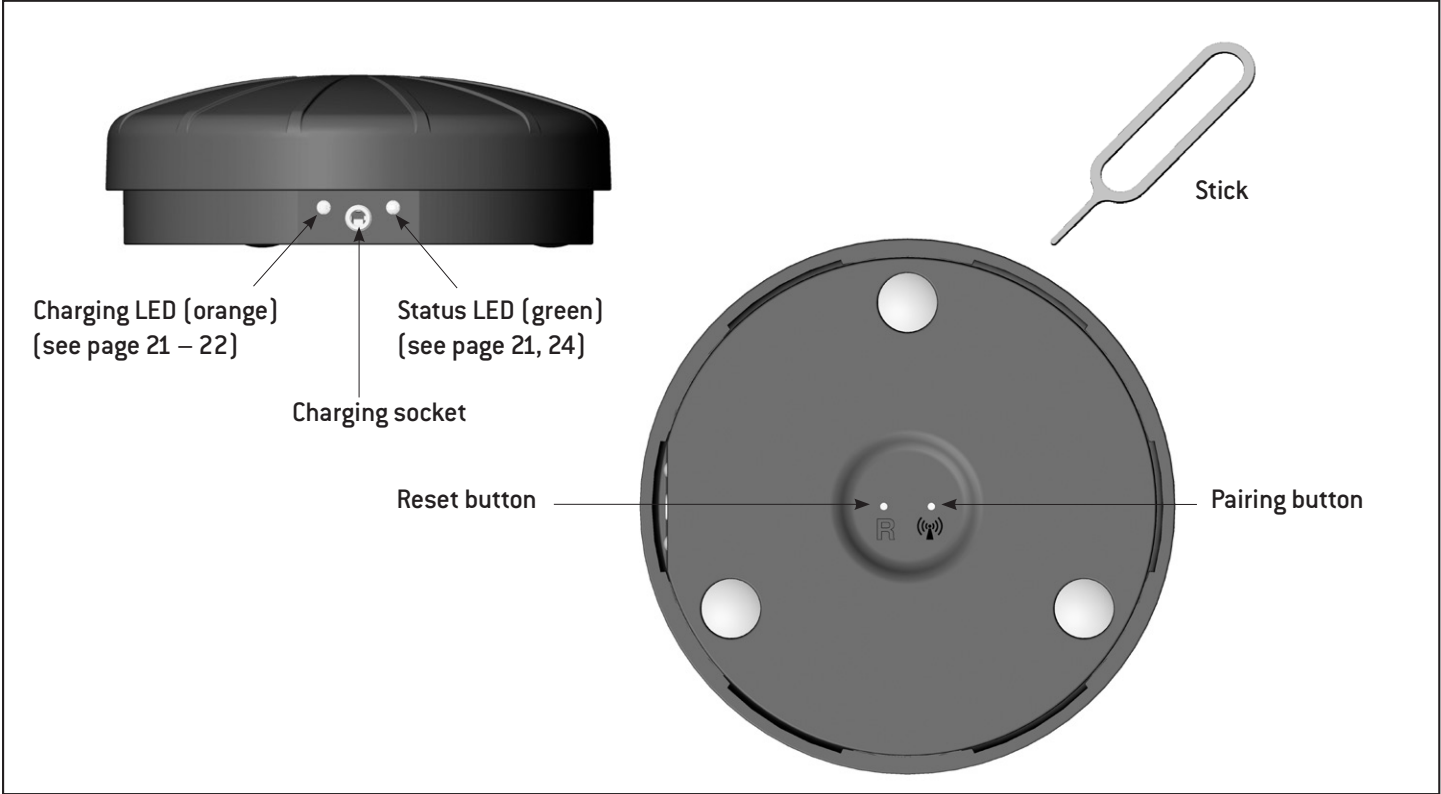
5. Description

Handpiece drive



Description

Foot control





Description

Status LED handpiece drive





Standby mode

- > The handpiece can be activated with the ON/OFF button.
- > If the handpiece drive is not used for longer than 4 minutes, it returns to standby mode automatically.

LED	steady	flashes	flashes intermittently
			
GREEN	<ul style="list-style-type: none"> → Battery is 25–100 % charged → Pairing successful > Handpiece drive is ready for operation (charging cable must be disconnected) 	<ul style="list-style-type: none"> → Pairing active 	
ORANGE	<ul style="list-style-type: none"> → Battery is charging > Not ready for operation 	<ul style="list-style-type: none"> → Battery is 2–25 % charged > Complete the treatment > Do not start any further treatment > Charge the battery 	<ul style="list-style-type: none"> → Battery is 1 % charged > Charge the battery
RED		<ul style="list-style-type: none"> → Error message > Contact an authorised W&H service partner 	

Description





Status LED foot control

LED	flashes	flashes alternately
		
ORANGE	<ul style="list-style-type: none"> → Battery of foot control is flat > Complete the treatment > Charge the battery of the foot control 	<ul style="list-style-type: none"> → Pairing unsuccessful > Troubleshooting with pairing problems (see page 24)



Standby mode


> The foot control can be activated by pressing.

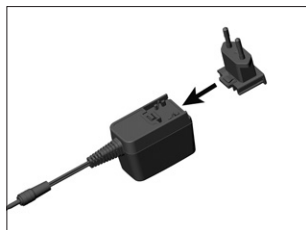
LED	steady	steady	flashes	flashes intermittently*
				
GREEN	<ul style="list-style-type: none"> → Connection to paired medical device established 		<ul style="list-style-type: none"> → Foot control is attempting to establish a connection to the paired medical device 	<ul style="list-style-type: none"> → Battery is flat > Charge the battery
ORANGE		<ul style="list-style-type: none"> → Battery is charging 		

* The LED flashes for 40 milliseconds every 4 seconds

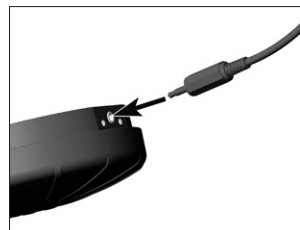
6. Start-up

Charging the battery

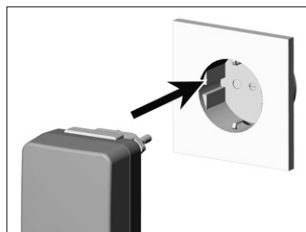
 Charge the medical device fully before you use them for the first time.



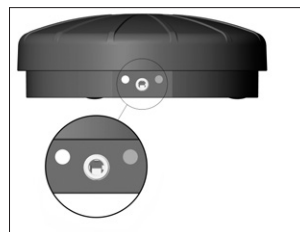
- ❶ Attach the adaptor to the power supply unit.





- ❷ Connect the charging cable into the foot control charging socket.

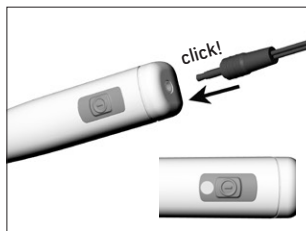


- ❸ Plug the charger into an power socket.





-  LED orange: Battery is charging.

-  LED off: Battery is charged.

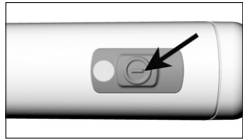


- ❹ Insert the charging cable into the handpiece drive charging socket until it audibly engages.


-  LED orange: Battery is charging.
LED green: Battery is charged.


-  The handpiece drive does not switch to standby mode and it is not ready for operation until it is connected to the charging cable.

 You can query the battery status when the handpiece drive is switched on and during the charging process.

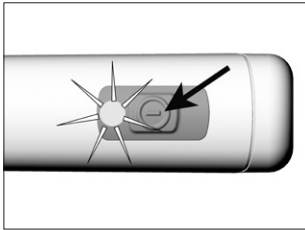


> Briefly press the ON/OFF button:


LED	flashes	Battery status
		
	3 x green	75–100 %
	2 x green	50–75 %
	1 x green	25–50 %
	orange	2–25 %

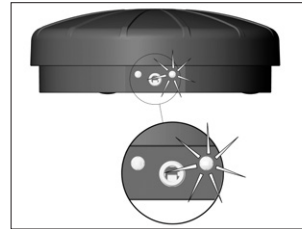
 The foot control and handpiece drive are already paired when delivered!
If pairing is active: Status LED (green) flashes on the foot control.


- > Both devices need to be in pairing mode for it to be possible to pair the handpiece drive and foot control.
- > To activate the handpiece drive's pairing mode, place it in the vicinity of the foot control.

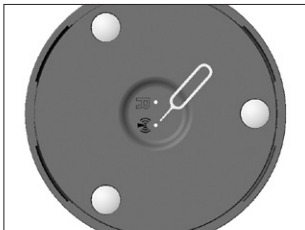


1 Press the ON/OFF button on the handpiece drive for 5 seconds.

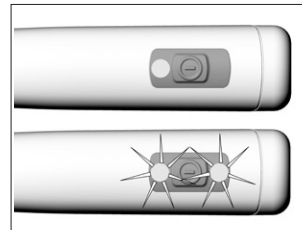
 LED flashing green: The handpiece drive is in pairing mode for 30 seconds.





 After 3 seconds the status LED switches from flickering to flashing. The foot control's pairing mode is now activated.



2 Use the stick to press the pairing button on the foot control for 3 seconds.



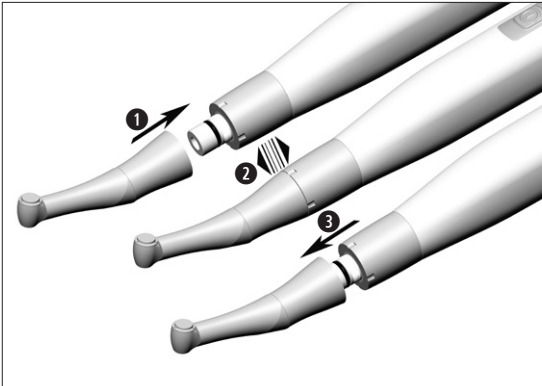
 Pairing successful. LED green.

 Pairing unsuccessful. LED flashing alternately orange. The LED goes out after 10 seconds.

Troubleshooting with pairing problems

- > Remove any metallic objects located between the foot control and handpiece drive.
- > Change the position of the foot control.
- > Eliminate any sources of interference (e.g. brush motors, mobile telephones, radios, WLAN, ...)
- > Use the stick to press the reset button on the foot control and try pairing again.

If the pairing problem cannot be remedied using the steps described above, the unit will need to be inspected by an authorized W&H service partner.



Do not assemble or remove the handpiece-/contra-angle head during operation!

① Push the handpiece-/contra-angle head onto the handpiece drive.



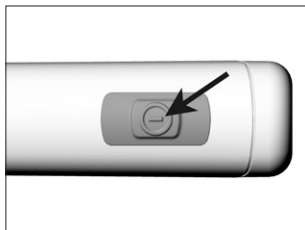
② Verify full engagement.

or

③ Remove the handpiece-/contra-angle head.

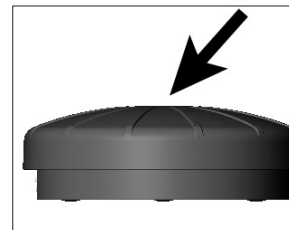
7. Handpiece drive

Operation




Switch on

- 1 Press the ON/OFF button.

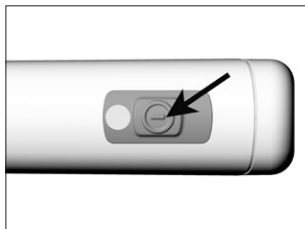


- 2 Press the foot control to variably control the speed of the rotary instrument.

 Press the foot control as far as it will go to attain the maximum speed of 3,000 rpm.

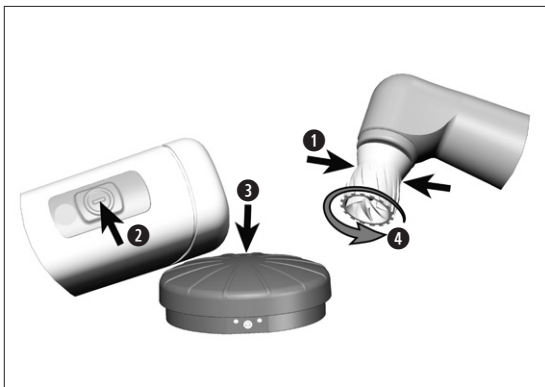
The following light signals are shown on the foot control:

Foot control pressed	
Status LED (green) flashes	Foot control is attempting to establish a connection to the paired medical device
Status LED (green) steady	Connection to paired medical device established



Switch off

- 1 Keep the ON/OFF button depressed for 2 seconds.



Reverse operation



For unscrewing the Screw-in Prophy Cups or Brushes.

- 1 Hold the Cup or Brush firmly.
- 2 Keep pressed the ON/OFF button of the handpiece drive.
- 3 And press the foot control.
- 4 The Cup or Brush is unscrewed.

Test run



Do not hold the handpiece drive at eye level!

- > Attach the handpiece-/contra-angle head to the handpiece drive.
- > Insert the rotary instrument.
- > Operate the handpiece drive with the foot control.



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



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



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



Cleaning agents and disinfectants

- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- > Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- > Use disinfectants which have been tested and found effective by the **Verbund für Angewandte Hygiene e.V.** (VAH = Association for Applied Hygiene), the **Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin** (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the **Food and Drug Administration (FDA)** and the **U.S. Environmental Protection Agency (EPA)**.
- > The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.



The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

- > Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.



- > Clean the medical device immediately after every treatment.
- > Wipe the entire handpiece drive, the handpiece holder and the foot control with disinfectant.




- > Ensure that no fluids enter the medical device.




- > Switch the handpiece drive off.
- > The charger must not be connected.



- > Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.

 > Do not place the handpiece drive, the handpiece holder and the foot control in liquid disinfectant or in an ultrasonic bath.

 > Do not immerse the handpiece drive and the foot control in water or clean them under running water.

Handpiece holder

- > Clean the handpiece holder under running tap water (< 35°C / < 95°F).
- > Rinse and brush off all internal and external surfaces.
- > Remove liquid residues using compressed air.



> W&H recommends wiping down with disinfectant.



Evidence of the basic suitability of the handpiece drive and the handpiece holder for effective manual disinfection was provided by an independent test laboratory using the “mikrozid® AF wipes” disinfectant (Schülke & Mayr GmbH, Norderstedt) and “CaviWipes™” (Metrex).



- > The handpiece drive, the handpiece holder and the foot control are not approved for automated processing in a washer-disinfector and sterilization.



- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove liquid residues using compressed air.

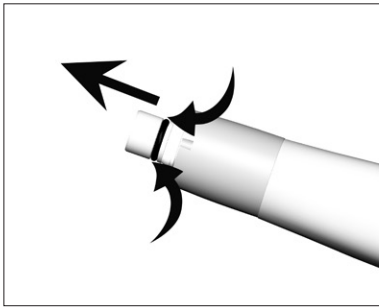


- > Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
- > Reprocess any medical devices that are still soiled.

9. Replacing the O-ring



Do not use sharp tools!



- ① Squeeze the O-ring between your thumb and index finger firmly so that it forms a loop.
- ② Pull the old O-ring off.
- ③ Push the new O-ring on in its place.

10. Servicing



Periodic inspection

Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The periodic inspection covers the complete medical device and must only be performed by an authorized service Partner.

Servicing

Repairs 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.



> Ensure that the medical device has been completely processed before returning it.



> Always return equipment in the original packaging!

11. W&H Accessories and spare parts



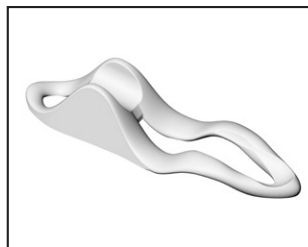
Use only original W&H accessories and spare parts or accessories approved by W&H.

Supplier: W&H partners



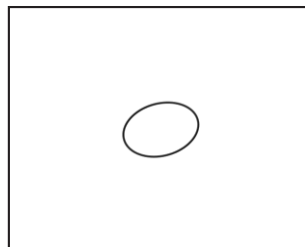
07947190

Handpiece drive



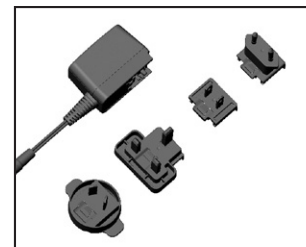
05882600

Handpiece holder



01225100

O-ring



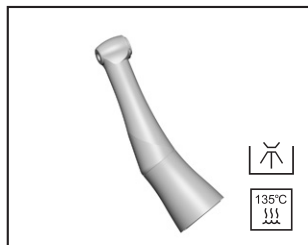
07969610

Charger incl. adaptor



30316000

Foot control C-NW
with Stick

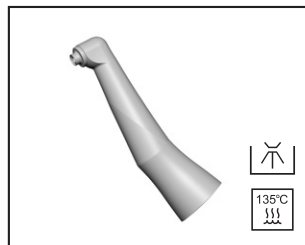


30096000

PL-66 W Contra-angle head
System LatchShort



135°C
!!!

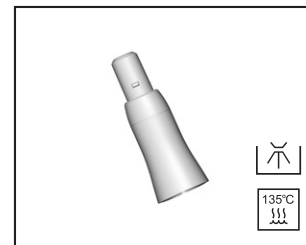


30097000

PL-64 Contra-angle head
System Screw-in Young



135°C
!!!



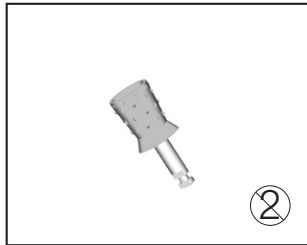
30098000

PL-44 Handpiece head
System Doriot



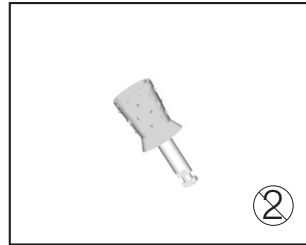
135°C
!!!

W&H Accessories and spare parts



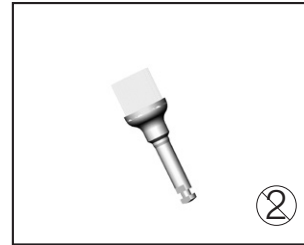
07597900

Prophy Cups, firm / dark green,
LatchShort (144 pcs)



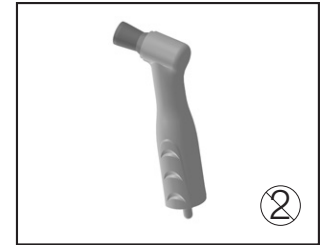
08003630

Prophy Cups, soft / apple green,
LatchShort (144 pcs)



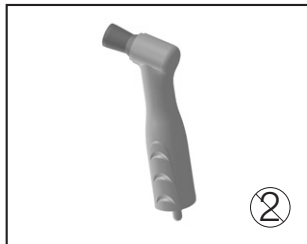
08003650

Prophy Brushes, cup-shaped,
soft / clear, LatchShort (144 pcs)



07979710

Prophy Angle Cup, 105°,
firm / dark green (100 pcs)



07994950

Prophy Angle Cup, 105°,
soft / apple green (100 pcs)

12. Technical data

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

Handpiece drive	PL-40 HW
Battery type:	Li-Ion
Runtime:	8 treatments with a polishing duration of 6 min.
Standby:	automatically after 4 min.
Charging time:	approx. 2 h
Rated voltage:	3.7 V
Rated capacity:	680 mAh
Max. speed:	12,000 rpm
Max. speed with rotary instrument:	3,000 rpm
Max. torque with rotary instrument:	2 Ncm
Dimensions (WxDxH):	141 x 25 x 28 mm
Weight:	105 g

Technical data

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

Charger	
Rated voltage:	100 - 240 V
Permissible voltage fluctuation:	$\pm 10\%$
Frequency:	50 – 60 Hz
Power:	7 VA

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 (protective earth conductor used for functional earth connection only!)

Handpiece drive: Internally powered



Type BF applied part (not suitable for intracardiac application)



The 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



Temperature information

Temperature of the handpiece at the operator side: max. 55°C (max. 131°F)

Temperature of the handpiece at the patient side: max. 50°C (max. 122°F)

13. 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

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 12 months from the date of purchase. Accessories and consumables (handpiece holder, stick) 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.

12 months warranty

Authorized W&H service partners

Find your nearest authorized W&H service partner at <http://wh.com>
Simply go to the menu option “Service” for full details.

Or simply scan the QR code.



Manufacturer's declaration

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
Power supply	1.8 m	Manufacturer: FRWDO Product: W&H REF: 07969810
Wireless foot controller C-NW	Wireless transmission	Manufacturer: W&H GmbH REF: 30316xxx

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 60601-1 Level (3rd Ed.)	IEC 60601-1 Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors 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 Burst repetition rates	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 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 variations on power supply input lines IEC61000-4-11	>95% dip in U ₁ for 0.5 cycle 40% U ₁ (60% dip in U ₁) for 5 cycles 70% U ₁ (30% dip in U ₁) for 25 cycles ~45% U ₁ (>95% dip in U ₁) for 5 sec	0% U ₁ 1 cycle and 70% U ₁ 25/30* cycles @ 0° 0% U ₁ ; 25/30* cycle	Complies to both 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	30A/m for 5 sec	30A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note: U₁ is the mains (AC) voltage before supply test levels
* 25/30 (25/30/300) means cycles at 50/60Hz

Manufacturer's declaration

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 60601-1-2 Level (3rd Ed.)	IEC 60601-1-2 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) and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, such as those used for mobile telephony site surveys [†] , should be less than the compliance level [†] in each frequency range



Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 900MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from

* 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.

† 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.

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

Manufacturer's declaration

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

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (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 kHz 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						
5500						
5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9

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.

Manufacturer's declaration

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 to 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 90 MHz $d = 1,2 \cdot \sqrt{P}$	90 MHz to 800 MHz $d = 1,2 \cdot \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \cdot \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	3,8	3,8	7,3
10	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 in 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

Manufacturer

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