Instructions for use

CE
0297

Electric motor
EM-11 L / EM-12 L

Supply hose
VE-10 / VE-11

Contents

Symbols

in the Instructions for use

WARNING!
(risk of injury)

ATTENTION!
(to prevent
damage occurring)

General explanations,
without risk to
persons or objects

Do not dispose of
with domestic waste

Caution!
Federal law restricts this device to sale by or on the order of a dentist, physician, 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.

Symbols

on the motor / packaging

CE XXXX — CE marking with identification number of the Notified Body

Consult Instructions for Use

REF — Catalogue number

SN — Serial number

80 % / % / 8 % — Humidity limitation

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

135°C — Sterilizable up to the stated temperature

Permitted temperature range

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

HIBC — Data structure in accordance with Health Industry Bar Code

Date of manufacture

MD — Medical Device

Manufacturer

Symbols

on the supply hose

CE XXXX — CE marking with identification number of the Notified Body

 — Type B applied part (not suitable for intracardiac application)

MD — Medical Device

REF — Catalogue number

SN — Serial number

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients
Prior to initial use please read the Instructions for use. These explain how to use your medical device and guarantee a smooth and efficient operation.


Observe the safety notes.

Intended use
Electrical drive, including the supply of cooling media, for dental transmission instruments used in the field of preventive dentistry, restorative dentistry such as cavity preparation and prosthodontics such as crown preparation.


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 dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

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.
> The medical device has no components that can be repaired by the user.
Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 48).

Skilled application
The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for Use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), 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. Safety notes

- Before using the medical device for the first time, store it at room temperature for 24 hours.
- Always ensure the correct operating conditions and cooling function.
- Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- In case of coolant supply failure, the medical device must be stopped immediately.
- Check the medical device for damage and loose parts each time before using.
- Do not operate the medical device if it is damaged.
- Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air.
- Perform a test run each time before using.
- Do not look directly into the light source.
- Never touch the patient and the electrical contacts on the medical device simultaneously.

> The medical device is not approved for operation in potentially explosive atmospheres.
> The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

> Moisture in the medical device may cause a malfunction. (Risk of short circuit)
> The medical product is lubricated for life and therefore should not be lubricated.
> Do not twist, kink or squeeze the supply hose (risk of damage).
> Replace damaged or leaking O-rings immediately.
> The medical device is tailored to the W&H supply hose and the W&H control electronics and must therefore only be used with W&H products. Using other components could lead to deviating parameters or even the destruction of the system.

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.

> Find out if patient and user have implanted systems before using the medical device and consider the application.
> Weigh the risks and benefits.
> Keep the medical device away from implanted systems.
> Do not place the motor on the patient's body.
> Make appropriate emergency provisions 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.

Rotational energy
Fast deceleration of the bur can, at times, cause the selected torque to be temporarily exceeded, compared to the value set, as a result of the rotational energy stored in the drive system.

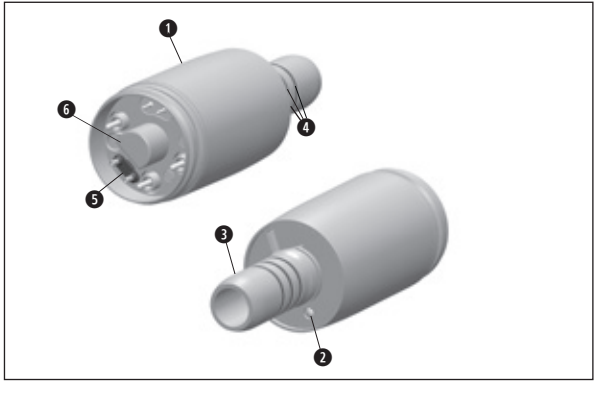
Transmission instruments

> Follow the directions and safety notes in the Instructions for Use of the transmission handpieces.
> Only use transmission instruments with an ISO 3964 (DIN 13940) compatible coupling system and manufacturer approved transmission instruments.
> Follow the directions of the manufacturer of transmission handpieces with reference to transmission ratio, maximum speed and maximum torque.

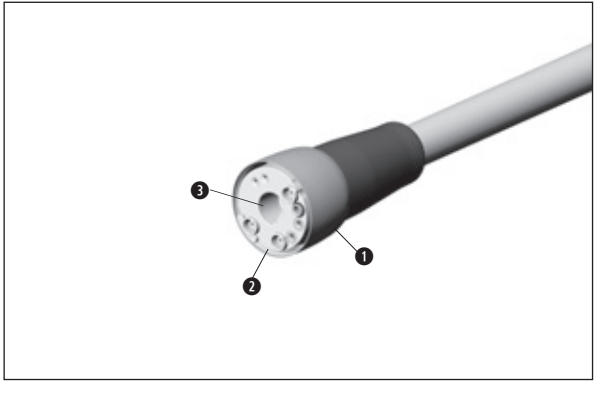
Hygiene and maintenance prior to initial use

> The medical device is sealed in PE film and not sterilized when delivered.
> The PE film and the packaging are non-sterilizable.

> Clean and disinfect the medical device.
> Sterilize the medical device.

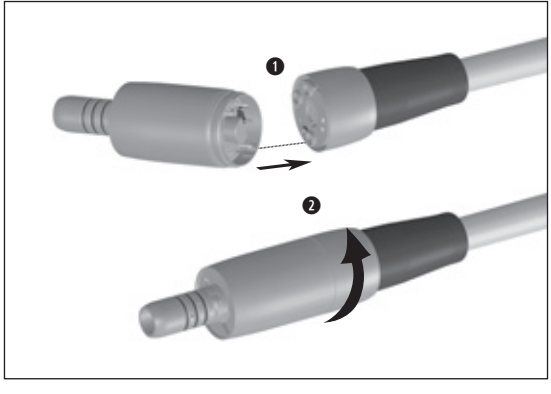


1. Motor shealt
2. LED
3. Connection for instruments as per ISO 3964
4. O-rings
5. Seal
6. Alignment pin (only for EM-11 L)



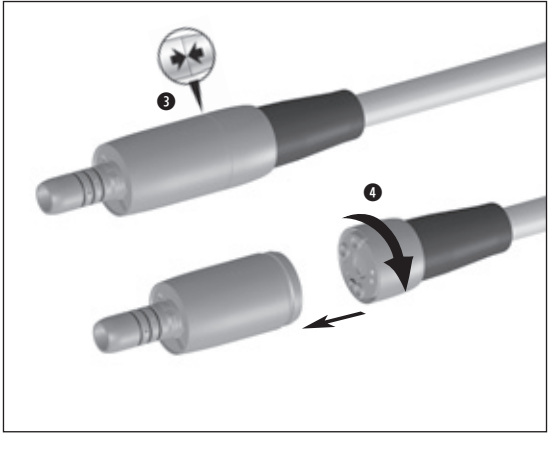
❶ Tubing sleeve
❷ Connection
❸ Alignment hole (only for EM-11 L)

Screw on the motor



Do not assemble or remove the medical device during operation!

1. Push the motor onto the supply hose.
   Note the alignment aids
2. Screw the tubing sleeve and the motor together.

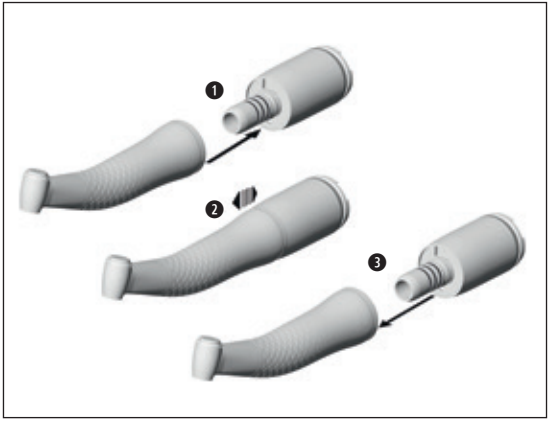


❸ Carry out a visual inspection. The motor and the tubing sleeve coupling must sit flush to one another.

Verify full engagement.

Unscrew the motor

❹ Unscrew the supply hose from the motor.



Assembly and removal of transmission instruments

Do not assemble or remove the medical device during operation!

❶ Push the transmission instrument onto the motor and turn it until it engages audibly.

❷ Verify full engagement.

❸ Remove the transmission instrument from the motor.

Test run

> Do not hold the medical device at eye level.

> Start the medical device using the attached transmission instrument.

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.

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

> Wear protective clothing, safety glasses, face mask and gloves.
> Remove the transmission instrument from the medical device.
> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

> The motor is not approved for automated processing in a washer-disinfector.
> Note the dental manufacturer´s reprocessing instructions for the supply hose.
> The supply hose is not approved for automated processing in a washer-disinfector and sterilization.

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.

Processing cycles

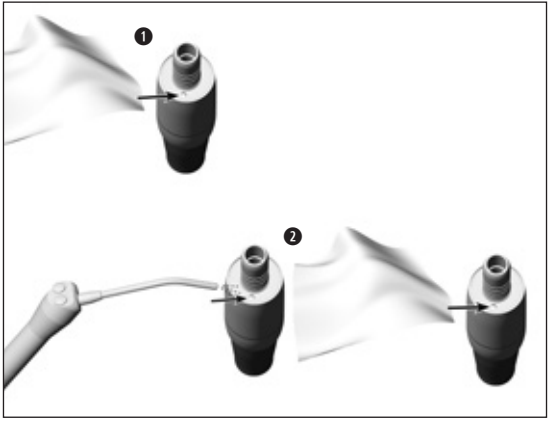
> We recommend a regular service for the W&H motor after 500 processing cycles or one year.

> Remove the motor from the supply hose.
> Clean the medical device immediately after every treatment.

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

Do not place the medical device in liquid disinfectant or in an ultrasonic bath.

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



Cleaning of the optic outlet

Avoid scratching the light source!

1. Wash the optic outlet with cleaning fluid and a soft cloth.
2. Blow the optic outlet dry with compressed air or dry it carefully with a soft cloth.

Carry out a visual inspection after each cleaning process. Do not use the medical device if the light source is damaged and contact an authorized W&H service partner.

> W&H recommends wiping down with disinfectant.

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

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

Inspection

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

Pack the medical device in sterilization packaging that meet the following requirements:

> The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
> The sterilization package must be large enough for the sterilization goods.
> The filled sterilization package must not be under tension.

W&H recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST55.

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
> The program selected must be suitable for the motor.

Recommended sterilization procedures

> "Dynamic-air-removal prevacuum cycle" (type B) / "Steam-flush pressure-pulse cycle" (type S)*/**
134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes
> "Gravity-displacement cycle" (type N)**
121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

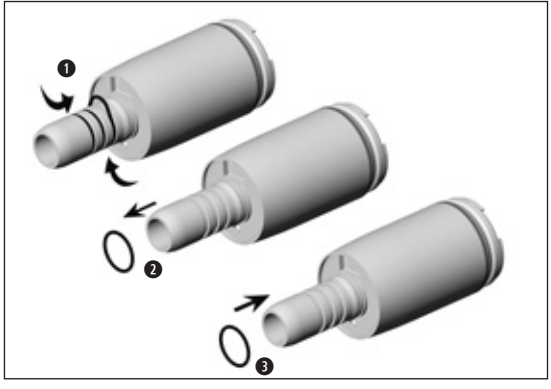
"Dynamic-air-removal prevacuum cycle" (type B):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Steam-flush pressure-pulse cycle" (type S):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

Drying times:

"Dynamic-air-removal prevacuum cycle" (type B):	132°C (270°F) – 30 minutes**
"Steam-flush pressure-pulse cycle" (type S):	132°C (270°F) – 30 minutes**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55 , ANSI/AAMI ST79

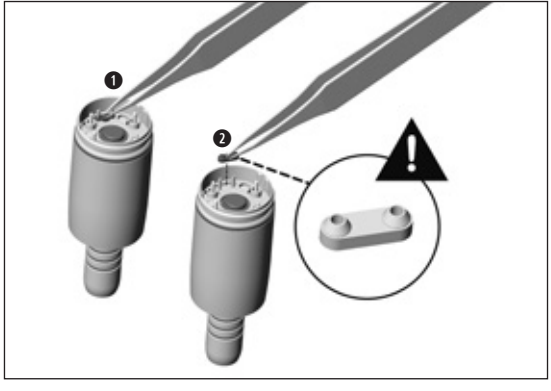
> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.



Replace damaged or leaking O-rings immediately. Do not use sharp tools!

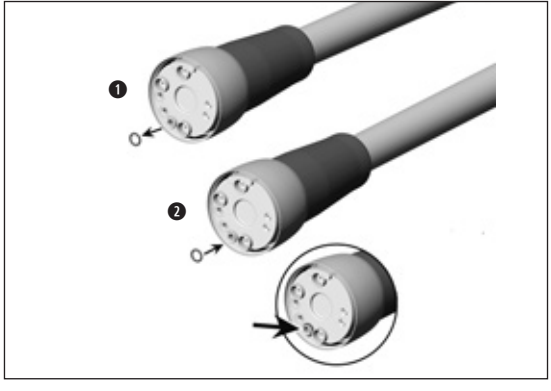
1. Squeeze the O-ring together between thumb and forefinger to form a loop.
2. Pull off the O-rings.
3. Slide on the new O-rings.

Always change all three O-rings at the same time in order to ensure the tightness of the motor.



1. Lift up the seal with the tip of a pair of tweezers. Remove the seal.
2. Carefully insert the new seal.

Pay attention to the positioning of the seal.



Replace damaged or leaking O-rings immediately. Do not use sharp tools!

1. Pull off the O-ring.
2. Slide on the new O-ring.

7. 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.

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.

8. W&H Accessories and spare parts

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

01862300	Motor O-rings (3 pcs)
06893400	Seal (1 pcs)
07072400	Supply hose O-ring (1 pcs)

9. Technical data

Motor	EM-11 L	EM-12 L
Approved supply hose	VE-11	VE-10 / VE-11
Transmission instrument according to standard	ISO 3964	
Direction of rotation	forward/reverse	
Speed range	2,000 – 40,000 rpm	100 – 40,000 rpm
Maximum torque at the motor	3 Ncm	
Adjustment cooling air	6 – 8 Nl/min	
Air coolant pressure* The air coolant pressure has to be higher than the water coolant pressure	0.5 – 3.0 bar	
Water coolant volume at (0,5 bar)	> 60 ml/min	
Water coolant pressure*	0.5 - 3.0 bar	

* Adjust the actual pressure with an attachment in place.

Technical data

Supply hose	VE-10	VE-11
Approved electric motor	EM-12 L	EM-11 L / EM-12 L
Drive air respective cooling air at 250 kPa (2,5 bar)	> 8 Nl/min	
Spray air at 250 kPa (2,5 bar)	> 8 Nl/min	
Spray water at 200 kPa (2,0 bar)	> 200 ml/min	
Maximum pressure	400 kPa (4.0 bar)	

10. Data on electromagnetic compatibility according to IEC/EN 60601-1-2

Operating environment and EMC warning notes
This medical device is neither life-sustaining nor coupled to the patient. It is suitable for operation both in domestic healthcare and in facilities used for medical purposes except rooms/areas, in which EMC interference of highintensity may occur.
The customer and/or the user should assure that this medical device is set up and used in an environment of the specified type and/or in accordance with the specifications of the manufacturer. This medical device uses RF energy only for its internal functions.

No special precautions are necessary to maintain the basic safety and essential performance of this medical device.

Essential performance
This medical device has no critical functions and therefore does not have any essential performance features.

Portable RF communication devices

Portable RF 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.

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.

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.

Results of the electromagnetic tests

Requirement	Class / Test Level*
Electromagnetic emissions	
Mains terminal disturbance voltage (Conducted Emissions) CISPR 11/EN 55011 [150 kHz – 30 MHz]	Group 1 Class B
Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B
Harmonic distortion IEC/EN 61000-3-2	Class A
Immunity to electromagnetic interference	
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 2/4/8/15 kV
Radiated RF electromagnetic field IEC/EN 61000-4-3 [80 MHz – 2,7 GHz]	10 V/m

* There are no deviations or simplifications to IEC 60601-1-2.

Proximity fields from RF wireless communications equipment IEC/EN 61000-4-3	385 MHz	27 V/m
	450 MHz	28 V/m
	710 / 745 / 780 MHz	9 V/m
	810 / 870 / 930 MHz	28 V/m
	1720 / 1845 / 1970 MHz	28 V/m
	2450 MHz	28 V/m
	5240 / 5500 / 5785 MHz	9 V/m
Electrical fast transient/burst IEC/EN 61000-4-4 Electrical cables Input and output cables	 ±2 kV ±1 kV	
Conducted disturbances induced by RF fields IEC/ EN 61000-4-6	3 V 6 V in ISM bands 6 V in amateur radio bands	
Power frequency magnetic field EN 61000-4-8	30 A/m	

Temperature information
Temperature of the medical device on the operator side: maximum 56°C (133°F)

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°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
Altitude:	up to 3,000 m above sea level

11. 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 medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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 manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

24 months for the motor EM-11 L / EM-12 L

12 months for the supply hose VE-10 / VE-11

Accessories and consumables 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.

24/12 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

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