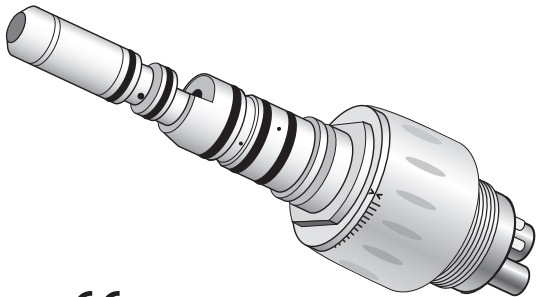
Instructions for use



CE
0297

Quick coupling
RM-34 LED

Contents

W&H 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

W&H Symbols

on the medical device/packaging

Medical Device

Type B applied part
(not suitable for intracardiac application)

W&H Symbols

on the medical device/packaging

CE
XXXX
CE marking
with identification number
of the Notified Body

REF
Catalogue number

SN
Serial number


Date of manufacture


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

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

℞ only
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.

HIBC
Data structure in accordance
with Health Industry Bar Code

1. Introduction

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

For your safety and for 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

Connector for media transfer (air, water, electricity and/or light) between the supply hose of the dental unit and air driven handpieces.

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.
> Only the components approved by the manufacturer may be replaced (e.g. o-rings).
> Modifications or repairs must only be undertaken by an authorized W&H service partner. (see page 45)
> Correct the malfunction as described in the Instructions for use.

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!

> Before using the medical device for the first time, store it at room temperature for 24 hours.
> The operation of the medical device is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

The power supply unit for the dental unit must satisfy the following requirements to be guaranteed by the system assembler (Relates to externally electrically supplied couplings and applied parts):

> Double insulation for the highest expected supply voltage must be provided between the primary and secondary power circuits.
> Double insulation for the highest expected secondary voltage must be provided between the secondary voltage and protective earth (PE).

> The secondary circuits must be galvanically isolated from each other.
> The secondary circuits must be protected against short-circuiting and overloading.
> The leakage currents of and between the applied parts must be kept.
> The secondary voltage to supply this medical device must must be limited to a maximum of 3 V AC or 5 V DC.

> Use only the supply hoses as specified by EN ISO 9168.
> Always ensure the correct operating conditions and cooling function.
> Check the medical device for damage and loose parts before using.
> Do not operate the medical device if it is damaged.
> Perform a test run each time before using.
> Do not look directly into the light source.
> Do not use the medical device as a light probe.

> The Quick coupling is a functional part of the supply hose and should therefore also be seen as an extension to it during reprocessing. It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the treatment water decontamination system, as well as its handling.

If the Quick coupling is processed separately from the supply hose, you can refer to the information in the chapter “Hygiene and maintenance” as per ISO 17664 from the manufacturer of the Quick coupling.

Risks due to magnetic fields

The functionality of active implantable medical devices (AIMD) (e.g. cardiac pacemaker, ICD) can be affected by electric, magnetic and electromagnetic fields.

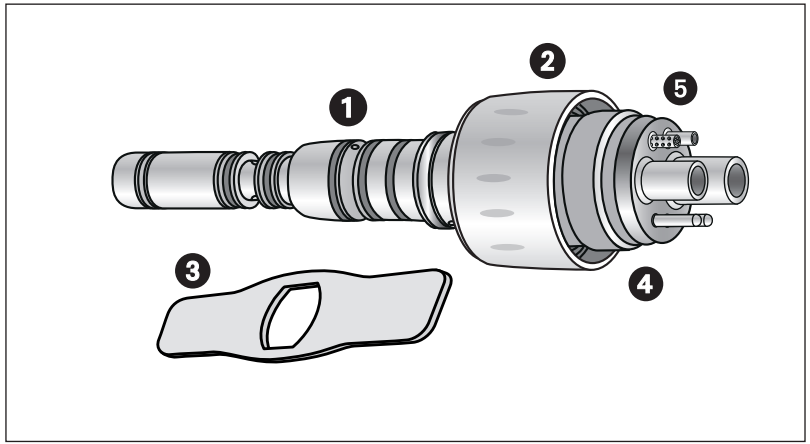
> Find out if the patient has active implantable medical devices (AIMD) before using the medical device and inform about the risks.
> Do not place the applied part on the patient's body.

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.

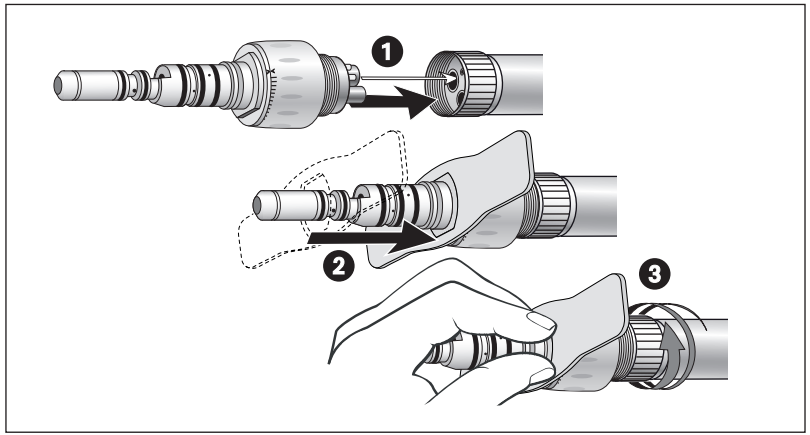
3. Product description



1. O-rings
2. Spray regulation ring
3. Key
4. RM seal
5. Water filter with resuction stop

All Quick couplings are equipped with a non-retraction valve which prevents contaminated cooling water from being sucked back into the turbine and the supply hose.
The non-retraction valve is integrated in the cooling water supply system.
In the event of blocked or incorrectly routed cooling water lines, please contact an authorized W&H service partner (see page 45).

The cooling water lines must not be cleaned with sharp objects!
(This could damage the sealing element and prevent the non-retraction valve from working.)

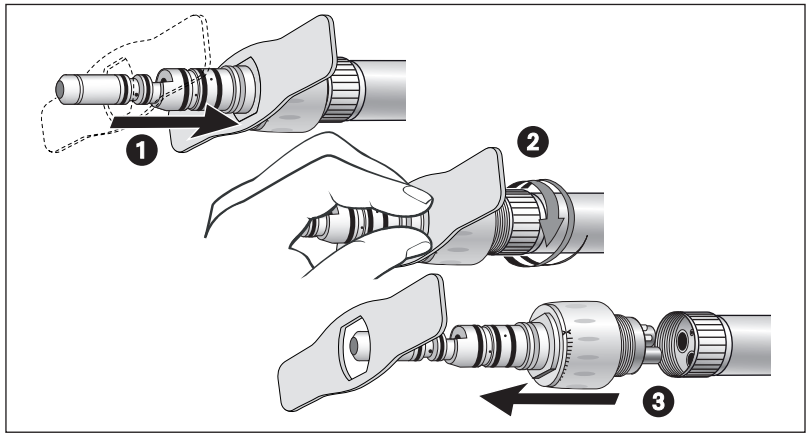


1. Connect the Quick coupling to the supply hose.
2. Firmly tighten the union nut of the supply hose by hand in a clockwise direction to ensure there are no leaks.

Verify full engagement.
Check the leak tightness.

This method of assembly provides a connection for drive air, chip air, return air, water and light.

Disconnecting the Quick coupling

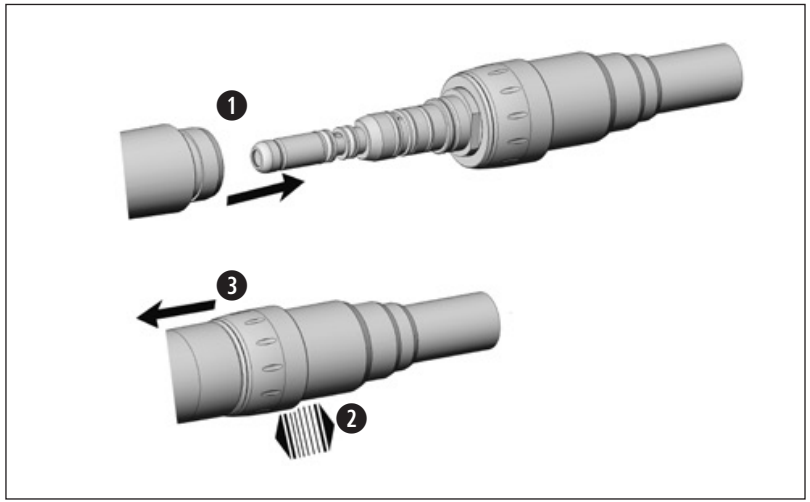


1. Slide the key as far as it will go onto the Quick coupling.
2. Hold the key and Quick coupling in a firm grip.
   Unscrew the union nut from the Quick coupling.
3. Pull off the Quick coupling from the supply hose.

Checking the Quick coupling for leaks

> Push an appropriate air driven product onto the Quick coupling.
> Activate the medical device, or if possible just activate the spray water only.
> No water should leak between the Quick coupling and the air driven product, and the Quick coupling and the supply hose.

> Always follow recommendations made by the manufacturer of air driven products.
> Only connect air driven product with appropriate connection to the Quick coupling.
> The user accepts sole responsibility if other air driven products are used. We accept no liability in such cases.



Do not assemble or remove the medical device during the operation.

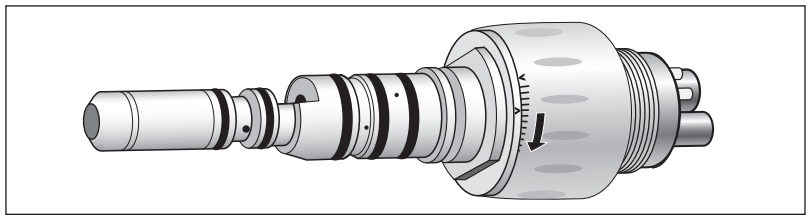
❶ Attach the air driven product onto the Quick coupling until it audibly engages.

❷ Verify full engagement

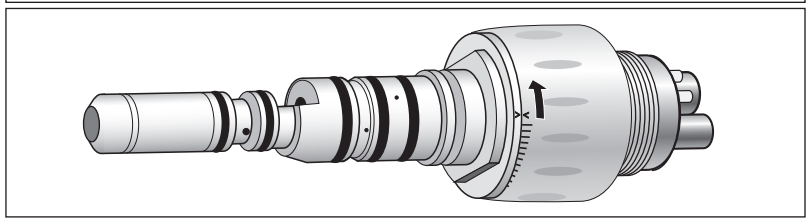
❸ To disconnect the air driven product, pull it off in axial direction.

Regulating the spray water

The water quantity is regulated directly via the spray control ring of the medical device or via the adjustable valves on the unit.



Maximum spray flow: Turn the spray control ring anti-clockwise.



Minimum spray flow: Turn the spray control ring clockwise.

Test run

Do not hold the medical device at eye level.

> Connect the Quick coupling to the supply hose.
> Attach the air driven product onto the Quick coupling until it audibly engages.
> Start the air driven product.

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.

5. Hygiene and maintenance

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

> The information on the validated reprocessing procedures serves as an example of an ISO 17664 compliant processing of the medical device.

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

> Couplings are considered an extension of the tubing. Clean and disinfect without disconnecting from the tubing using an intermediate, hospital grade disinfectant after each patient.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar (43.5 psi) for manual drying.

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 Österreichische 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

> In the case of wipe disinfection, the use of the medical device is guaranteed without restriction until a functional or material limitation is recognizable.

Clean the medical device immediately after every treatment.

> Wipe the entire surface of the instrument with disinfectant.

> If the Quick coupling remains on the supply hose, follow the instructions of the unit manufacturer.

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 liquid residues using compressed air.

> W&H recommends wipe-down disinfection.

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).

The medical device is not approved for automated cleaning and disinfection.

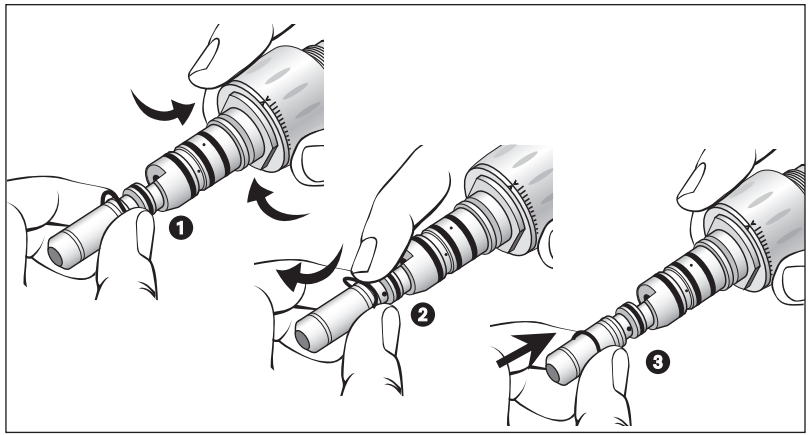
Inspection

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

> The medical device is not suitable for sterilization.

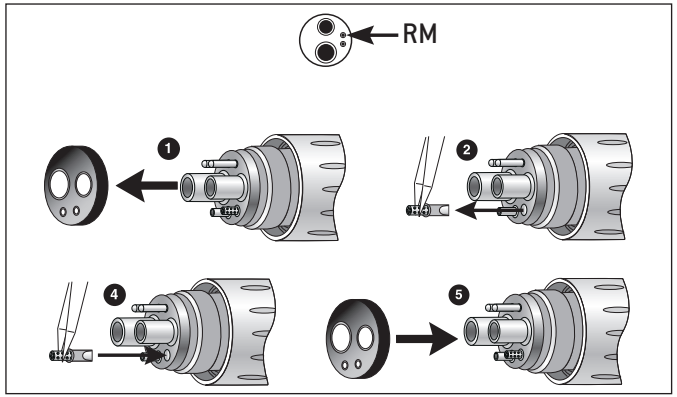
The Quick coupling may be stored on the supply hose.

Exchanging o-rings



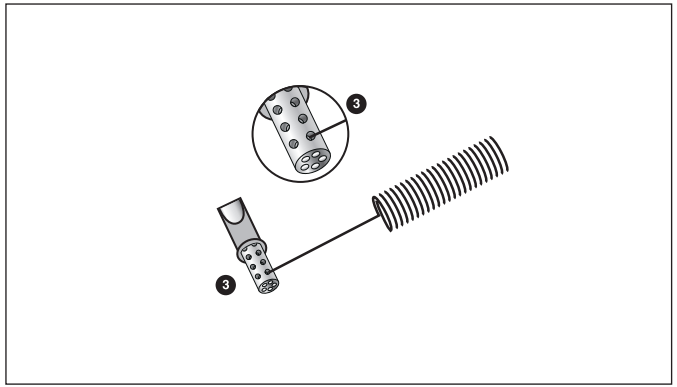
> Replace damaged or leaking o-rings immediately.
> Always replace all o-rings.
> Do not use sharp tools.

1. Press the o-ring firmly together with your thumb and index finger until it forms a loop.
2. Pull off the o-ring.
3. Slide the new o-ring back on.



Changing the water filter

1. Remove the seal.
2. Pull out the water filter with tweezers.
3. Clean the water filter (see page 34).
4. Carefully insert the water filter.
5. Slide on the seal.



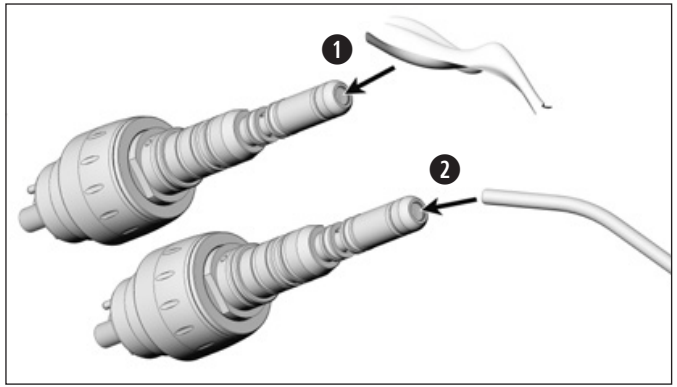
Clean the water filter

❸ Use the nozzle cleaner carefully to remove dirt and deposits from the water filter outlets.

The water filter can be cleaned in an ultrasonic bath.

If it proves impossible to correct the malfunction, please contact an authorized W&H service partner.

> Repeat the complete hygiene and maintenance process.



Cleaning of the light source

Avoid scratching the light source!

1. Wash the light source with cleaning fluid and a soft cloth.
2. Blow the light source dry using 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 optic outlet is damaged and contact an authorized W&H service partner.

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

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

8. Accessories, consumables, spare parts and other recommended medical devices by W&H

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

02207300	RM seal
02675810	O-ring, large
04198810	O-ring, small
06580700	Key
04697000	Back-pressure valve
04697100	Water tube

9. Technical data

Quick coupling		RM-34 LED
Connection according to standard	EN ISO 9168:2009	Type 3: “Ritter Midwest (6 hole)“
Connection medical device		Multiflex
Water quantity adjustable		yes
Light		LED
Electrical contacts (for power transmission to the medical device)		no
Recommended voltage range	V DC or V AC ±0.1	3.2
Voltage range	V AC	3 - 4
Voltage range	V DC	3 - 5
Current consumption at nominal/recommended voltage	A	< 0.3
Sterilizable		no

Temperature information

Temperature of the medical device on the operator side: maximum 55°C (131°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 +86 °F)
Humidity during operation:	15 % to 80 % (relative), non-condensing

10. Information 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 high-intensity 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. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

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.

RF communication equipment
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	
Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B
Immunity to electromagnetic interference	
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 15 kV
Radiated RF electromagnetic fields IEC/EN 61000-4-3 [80 MHz – 2,7 GHz]	10 V/m
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

*) There are no deviations of facilitations to IEC/EN 60601-1-2.

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

Letter of indemnity

This W&H 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 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 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

Authorized W&H service partner

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

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, **Austria**

t + 43 6274 6236-0, **f** + 43 6274 6236-55
office@wh.com **wh.com**

Form-Nr. 50726 AEN
Rev. 005 / 15.11.2022
Subject to alterations