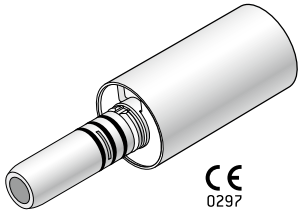


Instructions for use



CE
0297

PEOPLE HAVE PRIORITY



Electric motor

EM-E6

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W&H Symbols

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

Symbols on the motor


 CE 0297
from the manufacturer



Data Matrix Code for
product identification, e.g.
in hygiene / maintenance process

 135°C
Sterilizable up to the
stated temperature

REF Catalogue number

 Date of manufacture

SN Serial number

1. Introduction

Customer satisfaction is the main priority under the W&H quality policy. This W&H product has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms 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 W&H product and guarantee a smooth and efficient operation.

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 motor and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user

We have based our development and design of the electric motor system (includes tubing, electric motor and control unit) on the »dentists, dental hygienists, dental employees (prophylaxis) and dental assistants« target group.



Production according to EU Directive

The electric motor system is a medical product according to the EU-directive 93/42/EEC.



Responsibility of the manufacturer

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

- > The motor must be used in accordance with these Instructions for use.
- > The motor has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 31).



HF communication equipment

Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.

Skilled application

The motor is intended only for informed use in the dental or medical field according to its purpose of use in compliance with the valid health and safety at work regulations and the valid accident prevention regulations as well as in compliance with these Instructions for use. The motor 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.

Service

In case of service or repair contact an authorized W&H service partner (see page 31). Service and maintenance work must only be carried out by an authorized W&H service partner.

2. Safety notes



- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction (except in endodontic applications).



- In case of coolant supply failure, the motor must be stopped immediately.
- > Check the motor for damage and loose parts prior to every use (e.g. O-ring). Do not operate the motor if it is damaged.
- > Use only non-contaminated, filtered, oil-free and dry compressed air to operate the motor.
- > Replace faulty or leaky O-rings immediately.
- > Perform a test run prior to each treatment.
- > Run the rinse function for the dental unit once per day.
- > Always follow recommendations made by the manufacturer of the transmission instrument and the rotary instrument.



- > The operation of the motor 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 comply with the following requirements:
 - > Double insulation for the highest expected supply voltage must be provided between the primary and secondary power circuits.
 - > The compliance with the leakage currents of the applied part must be guaranteed by the system assembler.
 - > Double insulation for the highest expected secondary voltage must be provided between the secondary voltage and earth (PE).
 - > The system configurator has to ensure a galvanic separation between all secondary voltages incl. light supplies.
 - > The secondary circuits must be protected against short-circuiting and overloading.
- > The control electronics must only be installed in the dental unit by qualified staff who have been authorized by the unit manufacturer.



The motor 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.



Danger zones M and G

In accordance with IEC 60601-1/ANSI/AAMI ES 60601-1, the motor is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



The motor is not suitable for use in oxygen-enriched atmospheres.



Zone M is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary.

Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.



Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and ICDs (implantable cardioverter defibrillators) can be affected by electric, magnetic and electromagnetic fields.

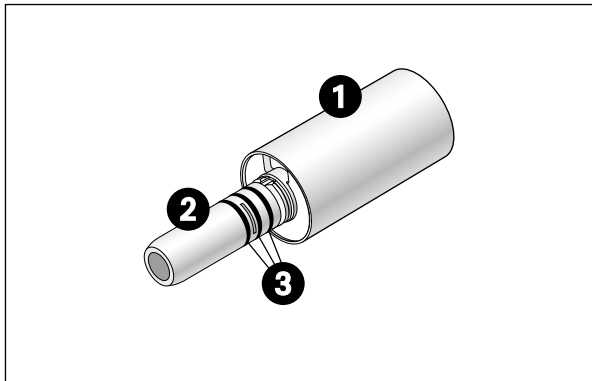
- > Find out if patient and user have implanted systems before using the product and consider the application.
- > Weigh the risks and benefits.
- > Keep this product away from implanted devices.
- > Make appropriate emergency provisions and take immediate action if patients become ill.
- > Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).

Hygiene and maintenance prior to initial use

The motor is in a clean condition and sealed in PE-film when delivered.

Sterilize the motor prior to initial use (see page 20).

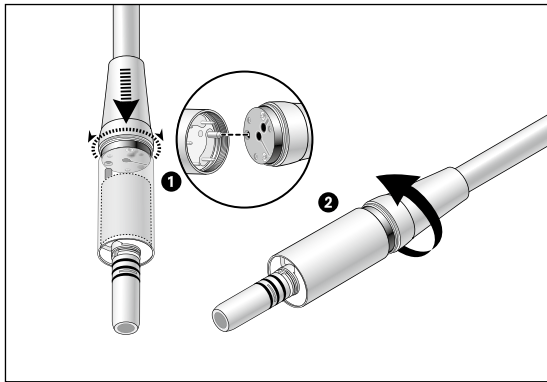
3. Product description



Motor EM-E6

- ① Motor sheath
- ② Connection ISO 3964
- ③ O-rings

4. Operation



Screw on the motor

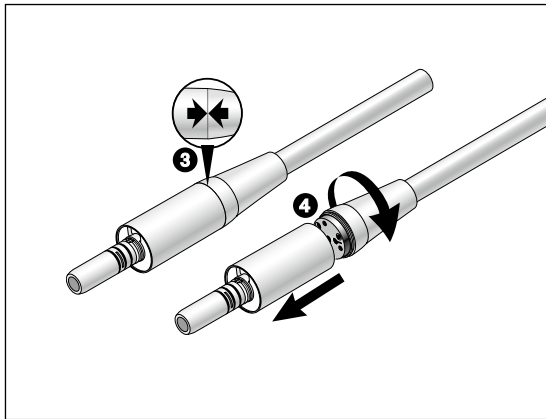


Do not twist, kink or squeeze the supply hose (risk of damage).



Do not screw on or unscrew the motor during operation.

- 1 Align the connection tubes of the motor with the connection openings of the hose.
- 2 Screw the motor and the hose together.

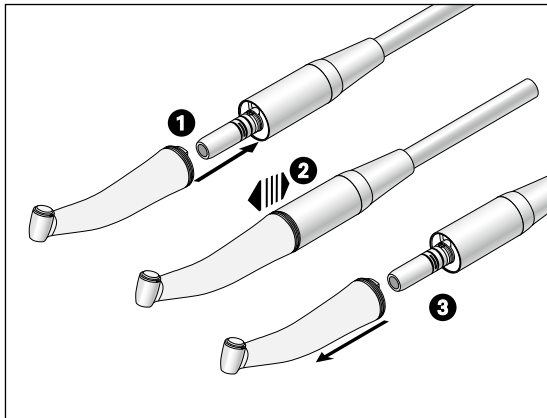


Check

- ③ Carry out a visual inspection. Check to ensure that the motor is securely connected to the hose. The motor and hose coupling must sit flush to one another.

Unscrew the motor

- ④ Unscrew the motor from the hose.



Assembly and removal of transmission instruments



Do not assemble / remove while the motor is running.



Only use transmission instruments that conform with ISO standard 3964.

> Follow the instructions for use of the respective transmission instrument manufacturer.

- ➊ Push the transmission instrument onto the motor and rotate until it engages audibly.
- ➋ Check for secure connection to the motor.
- ➌ Remove the transmission instrument from the motor by pulling in an axial direction.

Test run



Do not hold the motor with attached transmission instrument at eye level.

- > Start the motor using the attached transmission instrument.
- > If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage), **stop the motor immediately** and contact an authorized W&H service partner (see page 31).

5. Hygiene and maintenance



- > Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.

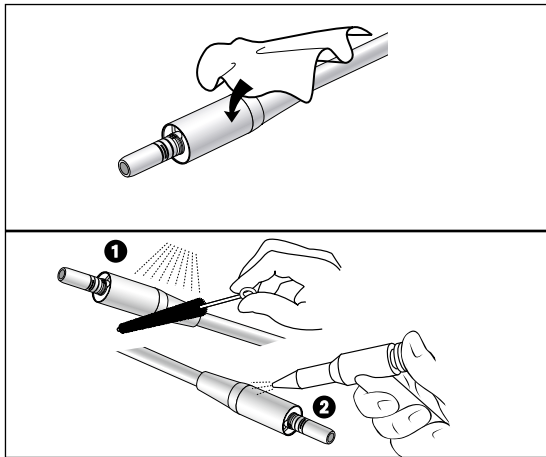


- > Wear protective clothing.
- > Remove the transmission instrument from the motor.
- > Do not remove the motor from the hose and make sure that no liquid can enter.
- > The motor is lubricated for life and therefore should not be lubricated!

- > Clean and disinfect the motor **immediately after every treatment.**

- > Sterilize the motor following manual cleaning and disinfection.

- > The motor is not approved for mechanical cleaning (thermo washer disinfectors).



Pre-disinfection

- > If heavily soiled: Clean first with disinfectant cloths.



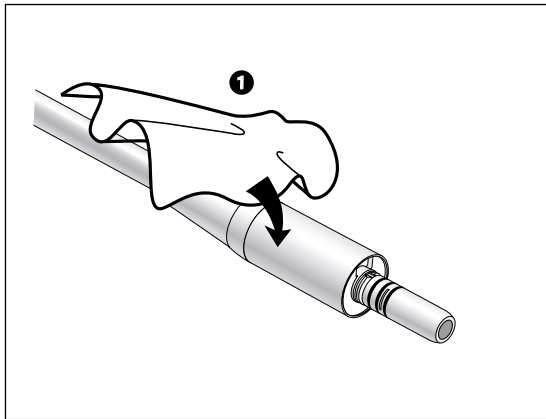
Only use disinfectants that have no protein-fixing effects.

Manual cleaning external

- ➊ Rinse and brush off under demineralized water (< 38 °C).
- ➋ Remove any liquid residues (absorbent cloth, blow dry with compressed air).



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



Manual disinfection



W&H recommends wiping down with disinfection.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



After manual cleaning and disinfection you must carry out a final sterilization (wrapped) in the class B or S steam sterilizer (according to EN 13060).

Sterilization and storage



W&H recommends sterilization according to EN 13060, class B
Other sterilization methods may reduce the life span of your motor.

- > Note the instructions of the unit manufacturer.
- > Clean and disinfect before sterilizing.
- > Wrap the motor and the accessory in sterile goods packing according to EN 868-5.
- > Make sure, that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060. Sterilization holding time a minimum of 3 minutes at 134 °C

or

- > Steam sterilization class S with sterilizers including drying program in accordance with EN 13060. The sterilizer manufacturer must give their express approval for the sterilization of electric motors. Sterilization holding time a minimum of 3 minutes at 134 °C

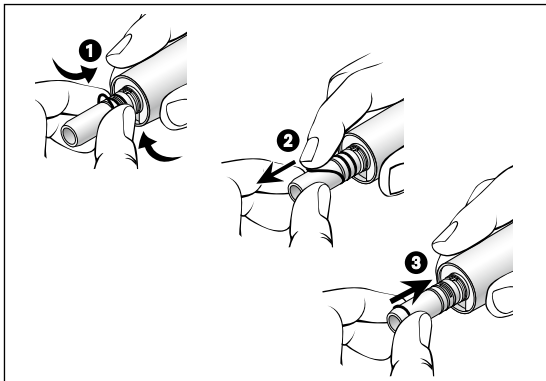


Before restart operation

Wait until the motor is completely dry.

Moisture in the motor can lead to a malfunction! (Risk of short circuit)

6. Exchanging the O-rings



Exchange damaged or leaking O-rings immediately. Do not use sharp instruments!

- 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.

7. W&H Accessories

Use only original W&H accessories and spare parts!

Suppliers: W&H partners

01862300 O-ring (3 pcs)

8. Servicing



Regular checking of motor and accessories

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 organization and must include the following procedures:

- > External visual inspection and a check on changes relevant to safety e. g. mechanical damage of the enclosure or indications of overheating.

We recommend that this checkup should be performed by an authorized W&H service partner (see page 31) or by the unit manufacturer only.

Returns

- > Refer all questions to an authorized W&H service partner (see page 31).
- > Always return equipment in the original packaging!

Motor

The standard ISO 11498 stipulates a durability of at least 250 sterilization cycles. In the case of the motor from W&H, we recommend you to have a regular service carried out after 500 sterilization cycles or one year.

9. Technical Data

	EM-E6
Coupling hose	VE-6
Transmission instrument acc. to standard	ISO 3964
Operation mode, optional	Links-/Rechtslauf
Speed range with control EM-C2 (LED)	2,000 – 40,000 min ⁻¹
Speed range with control EM-C3 (LED)	2,000 – 40,000 min ⁻¹
Max. torque on the motor	3 Ncm
Adjustment cooling air	6 – 8 l/min.
Air coolant pressure*	50 – 300 kPa (0.5 – 3.0 bar)
The air coolant pressure has to be higher than the water coolant pressure	
Water coolant volume at 50 kPa (0.5 bar)	> 60 ml/min.
Water coolant pressure*	50 – 300 kPa (0.5 – 3.0 bar)

* Adjust the actual pressure with an attachment in place.

Intermittet operation mode S6

The permissible relative load time is 2 minutes to 3 minutes idle time.



If the operating mode specified is observed no overheating of the motor and therefore no injury to the patient, user or third persons arises. The responsibility for the use and timely shutdown of the system lies with the user.

Temperature information

max. temperature at operator side of the dental handpiece (motor): 55 °C

Physical characteristics

Temperature during storage and transport:

-40 °C to +70 °C

Air humidity during storage and transport:

8 % to 80 % (relative), non-condensing

Temperature in operation:

+10 °C to +35 °C

Air humidity in operation:

15 % to 80 % (relative), non-condensing

Altitude:

up to 3,000 m above sea level

10. Recycling and disposal

Recycling

W&H considers that it has a special duty towards the environment. The motor along with its packaging has been designed to be as environmentally friendly as possible.



Disposal of the motor

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices. Ensure that the parts are not contaminated on disposal.

Disposal of the packaging material

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.

Explanation of warranty terms

This W&H product 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.

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 point. 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 W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

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