Instructions for use

Edition USA

Electric motor

EM-19 / EM-19 LC

Contents

Symbols

WARNING!
(risk of injury)

CE marking
with identification number
of the Notified Body

Catalogue number

ATTENTION!
(to prevent damage
occurring)

Consult Instructions for
Use

Serial number

General explanations,
without risk to persons or
objects

Sterilizable up to the
stated temperature

Thermo washer
disinfectable

Date of manufacture

Manufacturer

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

Symbols

Type B applied part (not suitable for intracardiac application)

Do not dispose of with domestic waste

HIBC

Data structure in accordance with Health Industry Bar Code

c UL us

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

Temperature limitation

Humidity limitation

MD

Medical device

℞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.

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.

Indication for use
Electrical drive for transmission instruments with ISO 3964 (DIN 13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF).

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

Qualifications of the user
Only suitably qualified medical, technical and specialist trained staff may use the medical device.
We have based our development and design of the medical device on the physician 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 40).

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.
> 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.
> Check the parameter settings every time you restart.
> Perform a test run each time before using.
> Ensure that it is possible to complete the operation safely should the units or instruments fail.
> The medical device is not approved for operation in potentially explosive atmospheres.
> The medical device is not approved for operation in oxygen rich Environment.

> Do not twist or kink the motor cable! Do not coil it too tightly!
> Moisture in the medical device may cause a malfunction! (Risk of short circuit)
> The medical device must not be disassembled.
> The medical product is lubricated for life and therefore should not be lubricated.

Risks due to electromagnetic 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

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

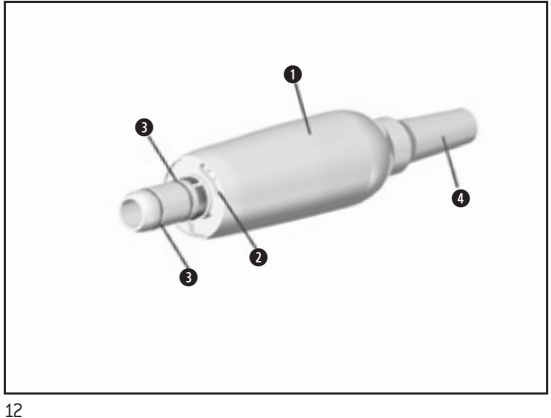
> Follow the directions and safety notes in the Instructions for Use of the transmission instruments.
> Only use transmission instruments with an ISO 3964 (DIN 13940) compatible coupling system and manufacturerapproved transmission instruments.
> Follow the directions of the manufacturer of transmission instruments 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.

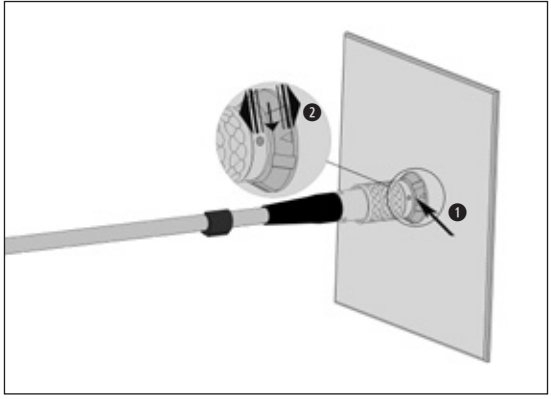
> Clean and disinfect the medical device.
> Sterilize the medical device.

3. Product description



1. Motor sheath
2. Electrical contacts*
3. O-Ring
4. Motor cable

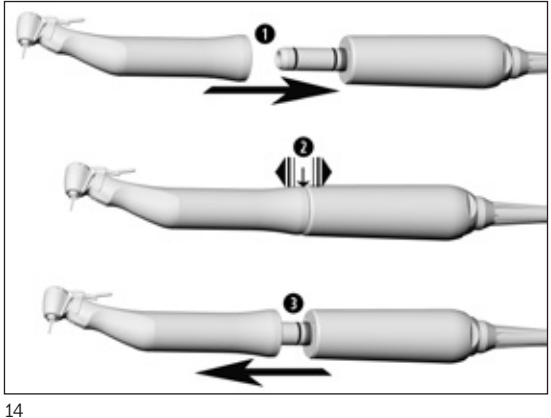
*only EM-19 LC



Do not assemble or remove the medical device during operation!

❶ Connect motor cable.
Pay attetion to the positioning.

❷ Verify full engagement.



Do not assemble or remove the medical device during operation!

1. Push the transmission instrument onto the medical device and turn it until it engages audibly.

2. Verify full engagement.

3. Remove the transmission instrument from the medical device by pulling in an axial direction.

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 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, 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.

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 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 medical device after 500 processing cycles or one year.

> Clean the medical device immediately after every treatment.
> Wipe the entire surface of the medical device with disinfectant.

1. Disconnect the medical device from the control unit. Check for any damage on the outer surface of each component.
2. Use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions for use supplied by the disinfectant manufacturer.

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

Do not immerse 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 wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant "CaviWipes™" (Metrex).

W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.

Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the "Miele PG 8582 CD" washer disinfector (Miele & Cie. KG, Gütersloh) and the "Dr. Weigert neodisher® MediClean forte" cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

> Cleaning at 55°C (131°F) – 5 minutes
> Disinfection at 93°C (200°F) – 5 minutes

> 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 medical device following cleaning and disinfection.

Pack the medical device in FDA cleared sterilization packages 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 ANSI/AAMI ST55 or ANSI/AAMI ST79.

> 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 medical device.

Recommended sterilization procedures

> "Dynamic-air-removal cycle" (type B, S)
  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)) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

"Dynamic-air-removal cycle": 132°C (270°F) – 4 minutes*/**
"Gravity-displacement cycle": 121°C (250°F) – 30 minutes**

Minimum drying times:
"Dynamic-air-removal cycle": 132°C (270°F) – 30 minutes**
"Gravity-displacement cycle": 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.

6. 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.

7. 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

04363600	Disposable irrigation tubing set 2.2 m (6 pcs)
06290600	Hose clips (5 pcs)

8. Technical data

Motor	EM-19 / EM-19 LC
Direction of rotation	forward / reverse
Speed range	200 – 40.000 rpm
Maximum torque at the motor	6,2 Ncm
Coolant volume flow at 100%	min. 90 ml/min
Maximum power output	80 W

Type B applied part (not suitable for intracardiac application)

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% (relativ), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relativ), non-condensing
Altitude:	up to 3,000 m above sea level

9. 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 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		
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	
Voltage fluctuations and flicker IEC/EN 61000-3-3	–	
Immunity to electromagnetic interference		
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±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	710 / 745 / 780 / 5240 / 5500 / 5785 MHz	9 V/m
	385 MHz	27 V/m
	450 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 MHz	28 V/m

Electrical fast transients / bursts IEC/EN 61000-4-4	Mains supply: ±2 kV Input and output ports: ±1 kV		
Surges IEC/EN 61000-4-5	±1 kV L – N	±2 kV L – PE	±2 kV L – PE
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 V 6 V in ISM bands and in amateur radio bands		
Power frequency magnetic fields IEC/EN 61000-4-8	30 A/m		
Voltage dips, short interruptions and voltage variations IEC/EN 61000-4-11	0% for 0.5 cycle at 45° steps from 0°-315° 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles		
Proximity magnetic fields IEC/EN 61000-4-39	30 kHz	8 A/m	
	134,2 kHz	65 A/m	
	13,56 MHz	7,5 A/m	

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

10. 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 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. Accessories and consumables are not covered by 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 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.

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