

Instructions for use



CE
0297

syneca^{FUSION}

Turbine handpieces with light

TG-98 L / TG-97 L / TG-98 LM / TG-97 LM / TG-98 LW / TG-97 LW

TG-98 L N / TG-97 L N / TG-98 L RM / TG-97 L RM

Turbine handpieces without light

TG-98 / TG-97

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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



Do not dispose of with
domestic waste

on the medical device/packaging

MD

Medical Device



Consult Instructions for use












TG-97 L RM / TG-98 L RM



Type B applied part
(not suitable for intracardiac
application)

Symbols

on the medical device/packaging

	CE marking with identification number of the Notified Body		DataMatrix Code for product information including UDI (Unique Device Identification)		Data structure in accordance with Health Industry Bar Code
	Catalogue number		Thermo washer disinfectable		Sterilizable up to the stated temperature
	Serial number		UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements		
	Date of manufacture		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.		
	Manufacturer				

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

The dental turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.



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 (seal and water filter).
- > Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 55).



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.
- > 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).

The power supply unit for the dental unit must satisfy the following requirements to be guaranteed by the system assembler (Relates to medical device with LED):

- > 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 the applied part must be kept.
- > The secondary voltage in operation must be limited to a maximum of 4.2 V AC or 6 V DC.



- > Use only the supply hoses as specified by EN ISO 9168.
- > 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.
- > Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air.
- > Check the medical device for damage and loose parts before each use (e.g. push-button).
- > Do not operate the medical device if it is damaged.
- > Perform a test run before each use.
- > Avoid overheating at the treatment site.
- > Do not use the medical device if there are soft tissue wounds in the mouth. The air pressure can cause septic substances to enter the tissue or trigger embolisms.
- > Do not lift the cheek or tongue with the medical device. Risk of burning due to the push-button heating up!



- > 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.
- > Do not use the medical device as a light probe.
- > Do not look directly into the light source.



Risks due to electromagnetic fields

TG-98 L, TG-98 L RM, TG-97 L, TG-97 L RM

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



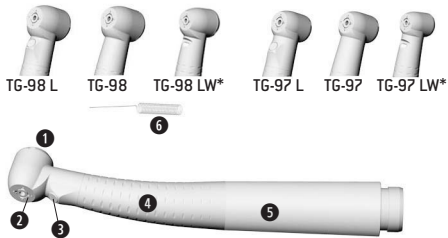
- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device and the nozzle cleaner.

3. Product description

Quick coupling

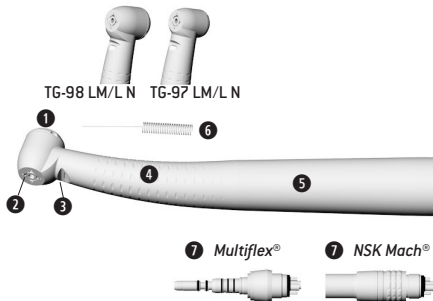


- ① Push-button
- ② Spray nozzles
- ③ LED / Compact glass rod
(TG-98 LW, TG-97 LW)
- ④ Grip profile
- ⑤ Sheath
- ⑥ Nozzle cleaner

* only for RA-24, RA-25

3. Product description

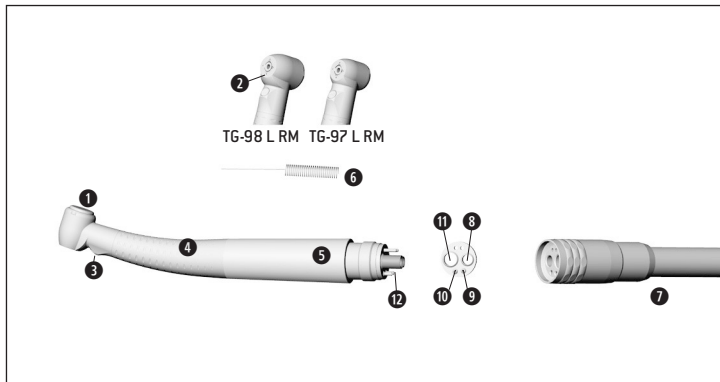
Multiflex[®], NSK[®] connection



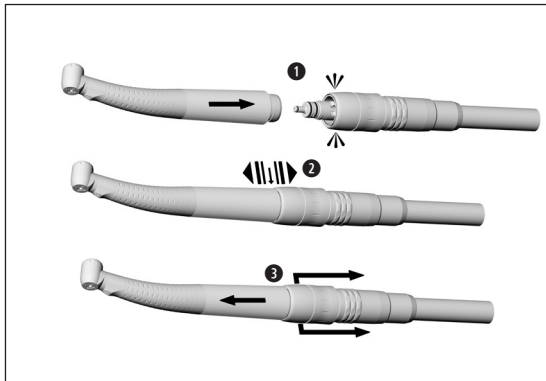
- 1 Push-button
- 2 Spray nozzles
- 3 Compact glass rod
- 4 Grip profile
- 5 Sheath
- 6 Nozzle cleaner
- 7 Connections

3. Product description

Turbine with RM connection



- 1 Push-button
- 2 Spray nozzles
- 3 LED
- 4 Grip profile
- 5 Sheath
- 6 Nozzle cleaner
- 7 Supply hose
- 8 Drive air
- 9 Coolant
- 10 Spray air
- 11 Exhaust air
- 12 Water filter with resuction stop



Quick coupling



Do not assemble or remove the medical device during operation.

- 1** Push the medical device onto the Quick coupling.



2 Verify full engagement.

or

- 3** Pull the retention sleeve of the Quick coupling back and remove the medical device by pulling in an axial direction.

Multiflex[®], NSK Mach[®] connection



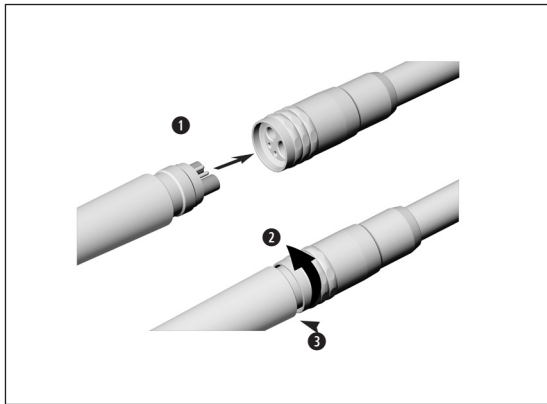
Do not assemble or remove the medical device during operation!

- > Attach the medical device to the Multiflex[®], NSK Mach[®] coupling as described by the coupling manufacturer.



> Verify full engagement.

- > Remove the medical device from the *Multiflex[®], NSK Mach[®]* coupling as described by the coupling manufacturer.



RM connection



Do not assemble or remove the medical device during operation!

- 1** Insert the medical device with RM connection into the apertures of the supply hose.
- 2** Firmly screw the union nut on.



3 Verify full engagement.

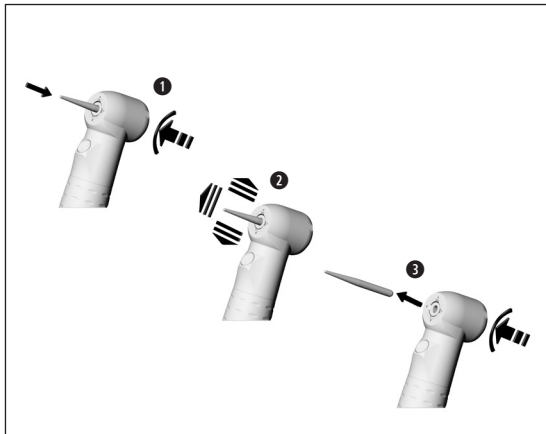
> Check leak tightness.

- 4** Unscrew the union nut and remove the medical device from the supply hose.

Rotary instruments



- > Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when medical device is stationary.
- > Never touch the rotary instrument while it is still rotating.
- > Do not activate the push-button of the medical device during operation. This leads to detachment of the rotary instrument, damage to the chucking system and/or heating up of the medical device. Risk of burning!
- > Only use rotary instruments up to the maximum operating speed stipulated by the manufacturer.



To change rotary instrument

- 1** Insert the rotary instrument.
Activate push-button, at the same time insert the rotary instrument until back stop.



- 2** Verify full engagement.

or

- 3** Remove the rotary instrument by pushing the push-button.

Test run



Do not hold the medical device at eye level!

- > Insert the rotary instrument.
- > Operate the medical device.



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.



> 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.
- > 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, for example: 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) or 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 1,000 processing cycles or one year.



Clean the medical device immediately after every treatment, to flush out liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

- > Operate the medical device for at least 10 seconds at idle speed.
- > Ensure that all outlets are rinsed out.



- > Wipe the entire surface of the instrument with disinfectant.
- > Remove the rotary instrument.
- > Remove the medical device.

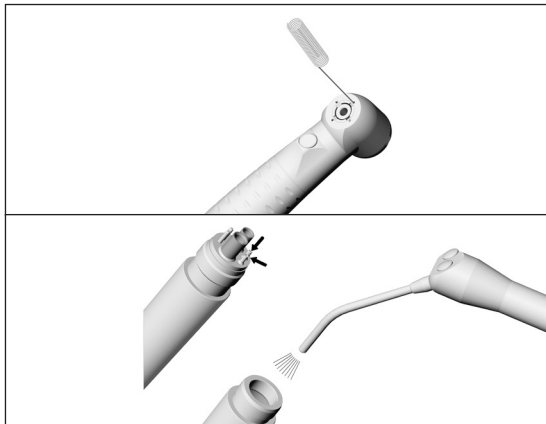


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.



Do not place the 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.
- > Move moving parts back and forth several times.
- > Remove any liquid residues using compressed air.



Cleaning of the spray nozzles

- > Clean coolant outlets carefully with the nozzle cleaner to remove dirt and deposits.



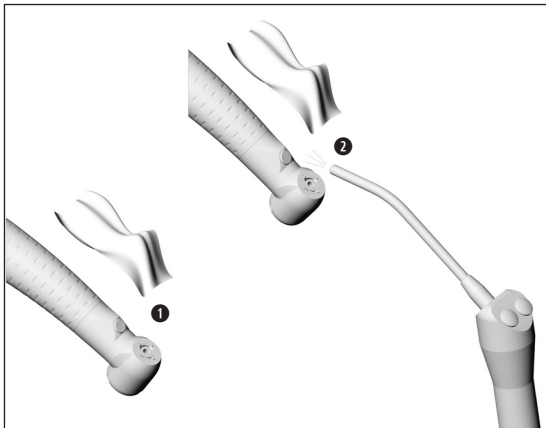
Clean and disinfect the nozzle cleaner in an ultrasonic bath / disinfection bath.

Cleaning of the coolant tubes

- > Blow through the coolant tube using compressed air.



In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner.



Cleaning of the light source

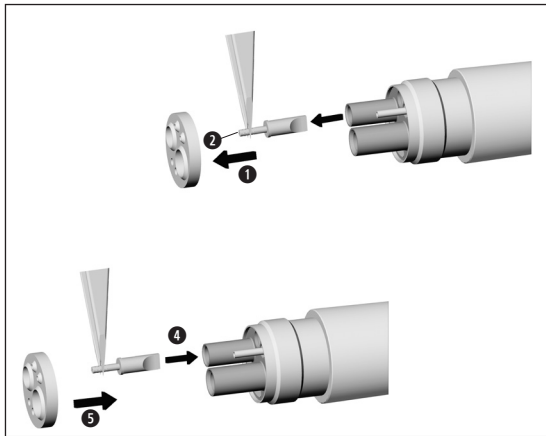


Avoid scratching of the light source!

- 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.

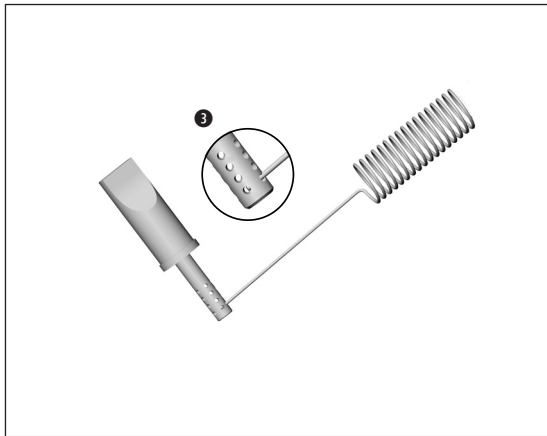


- > Carry out a visual inspection after each cleaning process.
- > Do not use the medical device if the light source is damaged and contact an authorized W&H service partner.



Changing the water filter (RM)

- 1 Remove the seal
- 2 Pull out the water filter with tweezers
- 3 Clean the water filter (see page 31)
- 4 Insert the water filter
- 5 Slide on the seal



Clean the water filter (RM)

- 3 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.

- > Perform a test run.



- > Repeat the complete hygiene and maintenance process.



> 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).



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, disinfection and lubrication.

Lubrication



- > Lubricate the dry medical device immediately after cleaning and/or disinfection.
- > Direct the medical device downwards.

Recommended lubrication cycles

- > Essential after every internal cleaning
 - > Before each sterilization
- or
- > After 30 minutes of use or at least once daily
 - > Chucking system once a week

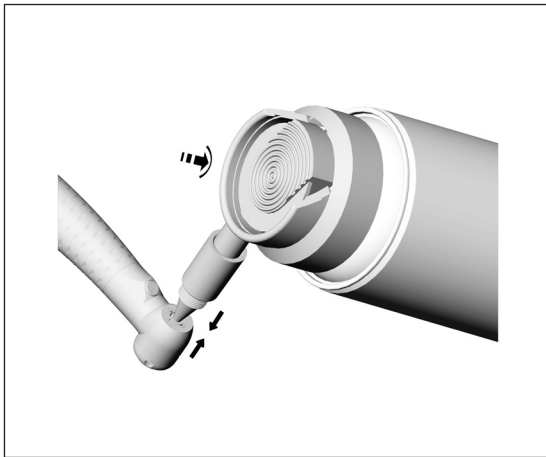
With W&H Service Oil F1, MD-400

- > Follow the instructions on the oil spray can and on the packaging.

or

With W&H Assistina

- > Follow the instructions in the Assistina Instructions for use.



Lubrication of the chucking system

With W&H Service Oil F1, MD-400

- > Fit the spray adaptor REF 02036100 onto the spray can.
- > Hold the medical device firmly.
- > Press the tip of the spray adaptor firmly into the chucking system
- > Spray for approx. 1 second.

or

With W&H Assistina

- > Follow the instructions in the Assistina Instructions for use.

Test after lubrication



- > Direct the medical device downwards.
- > Operate the medical device so that excess oil can escape.
- > Remove any oil that has escaped.



Pack the medical device and the accessories in 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 EN 13060, EN 285 oder 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 medical device.

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.

6. 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.

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

000301xx	W&H Assistina301 plus
30310000	W&H Assistina TWIN (MB-302)
02690400	Assistina adaptor for all W&H products with Roto Quick system
02693000	Assistina adaptor for chucking system
10940021	W&H Service Oil F1, MD-400 (6 pcs)
02036100	Spray adaptor for chucking system
02229200	Spray adaptor for all W&H products with Roto Quick system
03522500	Spray adaptor for LW connection
04396100	<i>Spray adaptor for Multiflex®* connection</i>
05773300	<i>Spray adaptor for NSK Mach®* connection</i>
02015101	Nozzle cleaner

8. Technical data

Synea Fusion with / without light		TG-98 L / TG-97 L TG-98 L RM / TG-97 L RM	TG-98 LM / TG-97 LM	TG-98 / TG-97 / TG-98 LW / TG-97 LW TG-98 LN / TG-97 LN
Coupling according to standard	EN ISO 9168:2009	W&H Roto Quick	Multiflex®*	W&H Roto Quick / NSK Mach®*
Rotary instruments	ISO 1797 (∅ mm)	1.6 – 0,01*	1.6 – 0.01	1.6 – 0.01
Max. Length approved by W&H**	(mm)	25 / 21	25 / 21	25 / 21
Minimum chucking length		until back stop	until back stop	until back stop
Max. operating part diameter	(mm)	2	2	2
Idle mode speed (± 30,000)	(min ⁻¹)	360,000 / 390,000	360,000 / 390,000	360,000 / 390,000
Operating pressure range	(bar/psi)	2.7 – 3.3 / 39 – 48	2.5 – 4 / 36 – 58	2.7 – 3.3 / 39 – 48
Recommended operating pressure	(bar/psi)	3 / 43.5	3 / 43.5	3 / 43.5
Exhaust air pressure	(bar/psi)	< 0.5 / < 7	< 0.5	< 0.5
Water setting range (Recommended water pressure)***	(bar/psi)	0.7 – 2 (1.5) / 10 – 29 (22)	0.7 – 2 (1.5) / 10 – 29 (22)	0.7 – 2 (1.5) / 10 – 29 (22)
Chip air setting range (Recommended chip air pressure)***	(bar/psi)	1.5 – 3 (2) / 22 – 43.5 (29)	1.5 – 3 (2) / 22 – 43.5 (29)	1.5 – 3 (2) / 22 – 43.5 (29)
Coolant supply volume	ISO 14457 (ml/min)	> 50	> 50	> 50
Chip air consumption at 2 bar / 29 psi	(NI/min)	> 1.5	> 1.5	> 1.5
Air consumption	(NI/min)	45	45	45
Allowed supply voltage Roto Quick connection nominal	(V DC oder V AC)	3.2	–	–
Allowed supply voltage range	V AC	2.2 – 4.2	–	–
Allowed supply voltage range	V DC	2.2 – 6	–	–
Current consumption	(A)	0.2	–	–

* *Multiflex® and NSK Mach® are trademarks of third parties not affiliated with W&H Dentalwerk Bürmoos GmbH.*



** When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

*** Chip air pressure / water pressure must be set at the same time
Chip air pressure / water pressure must be set at the same time

Power and speed data are largely dependent on the quality of the turbine hoses used and may therefore differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)



Temperature information

Temperature of the medical device on the operator side: maximum 55 °C (131 °F)

Temperature of the medical device on the patient side: maximum 50 °C (122 °F)

Temperature of the working part (rotary instrument): maximum 41 °C (105.8 °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

9. 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	<table> <tbody> <tr> <td>385 MHz</td> <td>27 V/m</td> </tr> <tr> <td>450 MHz</td> <td>28 V/m</td> </tr> <tr> <td>710/745/780 MHz</td> <td>9 V/m</td> </tr> <tr> <td>810/870/930 MHz</td> <td>28 V/m</td> </tr> <tr> <td>1720/1845/1970 MHz</td> <td>28 V/m</td> </tr> <tr> <td>2450 MHz</td> <td>28 V/m</td> </tr> <tr> <td>5240/5500/5785 MHz</td> <td>9 V/m</td> </tr> </tbody> </table>	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
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 or facilitations 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 12 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 partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 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.





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Form-Nr. 50743 AEN
Rev. 009 / 26.09.2023
Subject to alterations