

Instructions for use



CE
0297

Air motors

AM-25 L RM, AM-25 A BC/RM, AM-25 E BC/RM
AM-25 BC/RM/RQ, AM-20 E BC/RM, AP-20 RM/RQ
AM-16 RQ, AM-20 MW RM/ MW RQ/ MW, AM-05 MW RM/ MW RQ/ MW
AM-20 BC/RM/RQ, AM-20 SD RM/ SD RQ/ SD, AM-05 SD RM/ SD RQ/ SD

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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



Medical Device



Gebrauchsanweisung
beachten


AM-25 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)

 HIBC Data structure in
accordance with
Health Industry Bar Code


 REF Catalogue number


 Thermo washer
disinfectable


 135°C
Sterilizable up to the
stated temperature

 SN Serial number

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

 Date of manufacture

 Manufacturer

 Rx_{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.

 Forward-/Reverse drive

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 air motor is intended for the following applications: Drive for dental transmission instruments for dental restoration and prophylaxis. Supply of dental transmission instruments with cooling air, chip air, spray water and light.



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 (O-rings, LED-ring).
- > 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 Volt DC.

Safety notes



- > Never touch the patient and the electrical contacts on the medical device simultaneously.
- > 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 filtered, oil-free and cooled air supplied by dental compressors to operate the medical device.
- > Replace damaged or leaking O-rings immediately.
- > Check the medical device for damage and loose parts each time before using (e.g. O-ring).
- > Do not operate the medical device if it is damaged.
- > Perform a test run each time before using.
- > 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.
- > Always follow recommendations made by the manufacturer of the transmission instrument and the rotary instrument.
- > Do not look directly into the light source.

Safety notes



Risks due to electromagnetic fields

AM-25 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 an active implantable medical device (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

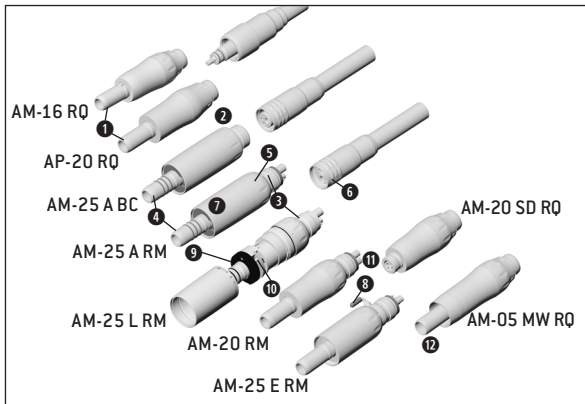


- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



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

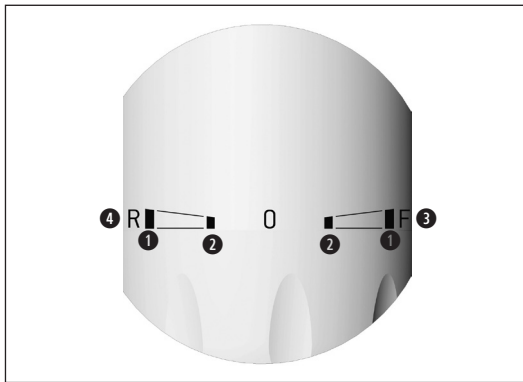
3. Product description



AM-25 L RM, AM-25 A BC/RM, AM-25 E BC/RM,
AM-25 BC/RM/RQ, AM-20 E BC/RM, AM-20 BC/RM/RQ,
AM-20 SD RM/ SD RQ/ SD, AM-05 SD RM/ SD RQ/ SD, AM-16 RQ
AM-20 MW RM/ MW RQ/ MW, AM-05 MW RM/ MW RQ/ MW

- ① ISO 3964 connection
- ② Borden 2/3-hole
- ③ Standard 4-hole
- ④ O-ring
- ⑤ Speed control ring
- ⑥ Union nut
- ⑦ Motor sheath
- ⑧ External coolant tube with protection cap
- ⑨ LED-ring
- ⑩ Electrical contacts
- ⑪ Star Dental connection
- ⑫ Midwest connection

Product description



Speed control (exception: AP-20 RM/RQ)

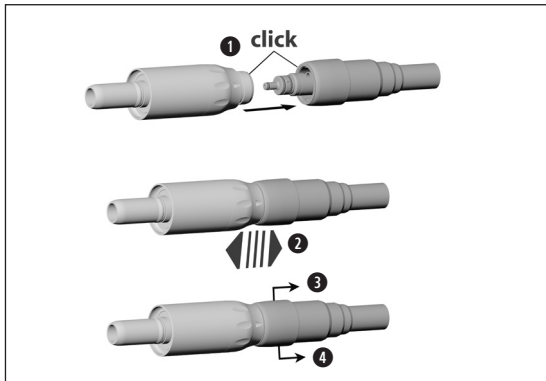
- ① Maximum speed
- ② 50 % of the maximum speed
- ③ Forward drive (F)
- ④ Reverse drive (R)



The air motor is set to »F« (forward) when delivered.

4. Operation

Assembly/Removal - Roto Quick coupling



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

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

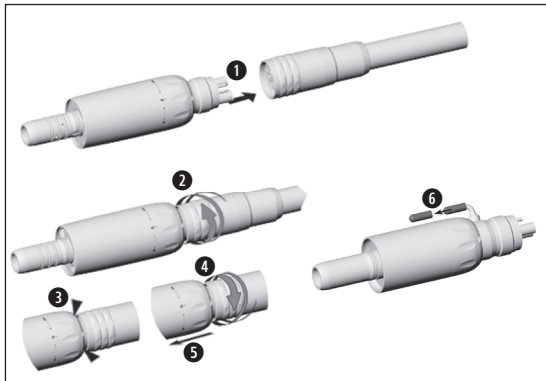


- 2** Verify full engagement

or

- 3** Pull back the sleeve of the Roto Quick coupling
- 4** Remove the air motor by pulling it axially

Operation



Assembly/Removal - Air motor with fixed connection



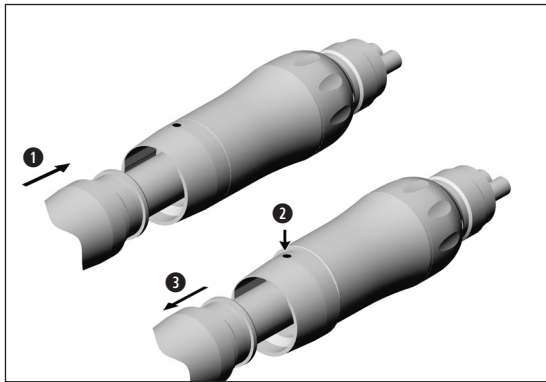
Do not assemble or remove the medical device during the operation!

- 1 Push the air motor with BC/RM connection into the supply hose apertures.
- 2 Screw the union nut on.



Verify full engagement.

- 3 Check leak tightness. (not possible with BC connection, because the return air is expelled through the outer sheath)
- 4 Unscrew the union nut and 5 remove the medical device from the supply hose.
- 6 Remove the protection cap from the external coolant tube



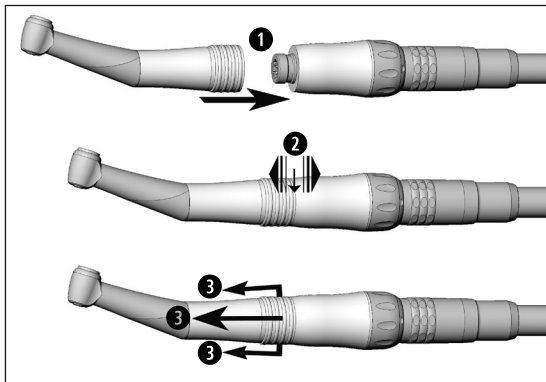
Do not assemble or remove the medical device during operation!

- 1 Push the handpiece onto the motor.



Verify full engagement.

- 2 Press the locking sheath.
- 3 Pull the handpiece to remove it from the motor.



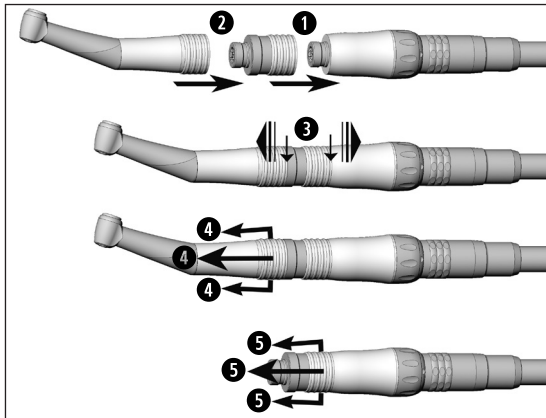
Do not assemble or remove the medical device during operation!

❶ Push the medical device onto the motor.



❷ Verify full engagement.

❸ Pull the retention sleeve of the handpiece back to remove the medical device from the motor.



StarDental® connection

When using the torque multiplier

- 1 Push the torque multiplier onto the motor.
- 2 Push the handpiece onto the torque multiplier.



- 3 Verify full engagement.

- 4 Pull the retention sleeve of the handpiece back and remove the handpiece from the torque multiplier.
- 5 Pull the retention sleeve of the torque multiplier back and remove it from the motor.

Test run





Do not hold the air motor at eye level.


- > Start the medical device idle for 5 seconds.
- > Turn the speed control ring to »F« forward or »R« reverse. (if available)
- > Vary the speed from minimum to maximum. (if available)




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 methods serves as an example for an ISO 17664 compliant reprocessing of the medical device.

- 
 - > Wear protective clothing, safety glasses, face mask and gloves.
 - > Remove the transmission instrument from the medical device.
 - > Set the speed control ring to F or R.
 - > Remove the air motor from the supply hose.

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



- > The use of the medical device is guaranteed until at least 1,000 reprocessing cycles.
- > If a washer-disinfector (WD) is not used
 - > the use of the medical device is guaranteed until at least 4,000 reprocessing cycles.
 - > the use of the LED-ring is guaranteed until at least 1,500 reprocessing cycles.



Clean the medical device immediately after every treatment, to flush out any 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 coolant outlets are rinsed out.



- > Wipe the entire surface of the medical device with disinfectant.
- > Remove the motor from the supply hose.

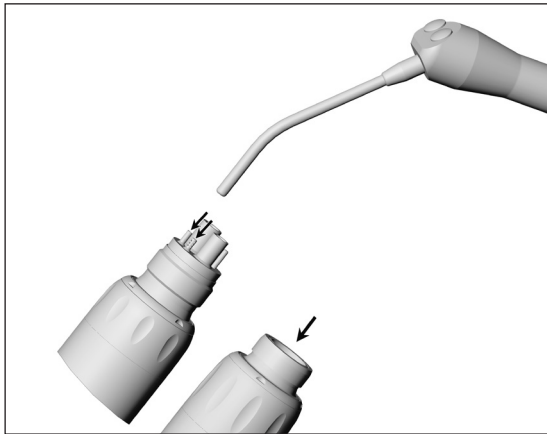


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.



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.
- > Move moving parts back and forth several times.
- > Remove any liquid residues using compressed air.





Cleaning the coolant tubes

Blow through the coolant tube using compressed air.



If it proves impossible to correct the malfunction, please 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).



W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).
(except AM-20 E BC/RM, AM-20 BC/RM/RQ, AM-20 SD RM/ SD RQ/ SD/ MW RM/ MW RQ/ MW,
AM-05 SD RM/ SD RQ/ SD/ MW RM/ MW RQ/ MW, AP-20 RM/RQ)

- > 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 "Steelco DS 50" (Steelco) washer-disinfector and the "Dr. Weigert neodisher® MediClean forte" cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

- > Cleaning at 60 °C (140 °F) – 3 minutes
- > Disinfection at 90 °C (194 °F) – 1 minutes

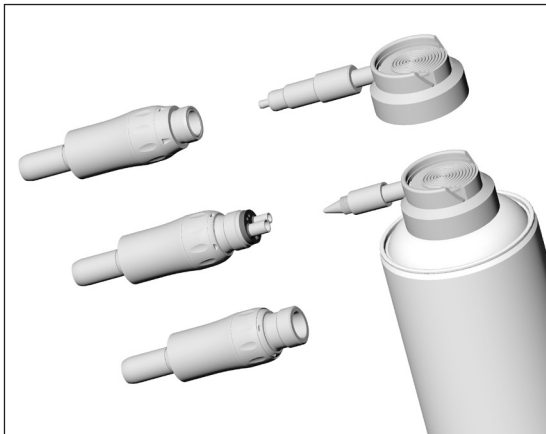


- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove any liquid residues using compressed air.

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

- > Set the speed control ring to F or R. (if available)



- > Lubricate the dry medical device at least once a week or after 90 minutes of use or after every internal cleaning (WD).
- > Direct the medical device downwards

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.

Test after lubrication



- > Set the speed control ring to F or R. (if available)
- > Direct the medical device downwards.
- > Operate the medical device so that excess oil can escape.



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 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 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:

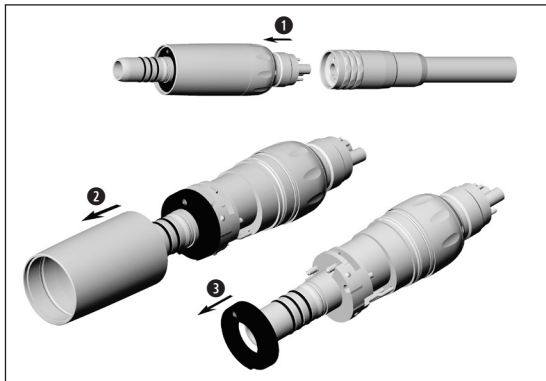
“Dynamic-air-removal prevacuum cycle” (type B): 132°C (270°F) – 30 minutes**
“Steam-flush pressure-pulse cycle” (type S): 132°C (270°F) – 30 minutes**
“Gravity-displacement cycle” (type N): 121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665

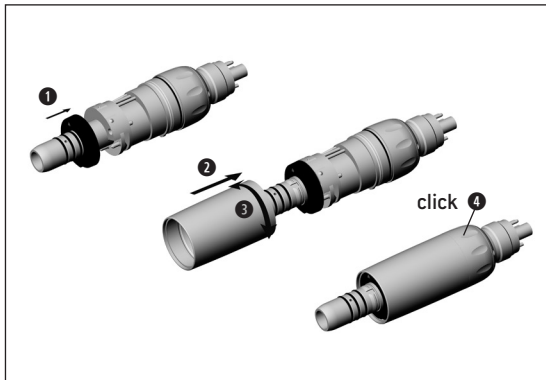
** ANSI/AAMI ST55, ANSI/AAMI ST79



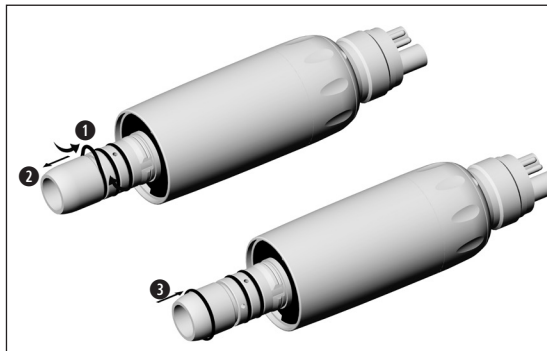
- > Store sterile goods dust-free and dry.
- > The shelf life of the sterile goods depends on the storage conditions and type of packaging.



- ➊ Remove the air motor from the supply hose.
- ➋ Remove motor sheath.
- ➌ Remove LED-ring.



- 1** Slide on LED-ring.
- 2** Push on the motor sheath.
- 3** Turn the motor sheath until it engages.
- 4** Push the motor sheath firmly into place.



- > Replacing the O-ring
- > Do not use sharp tools!

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



Repeat the complete hygiene and maintenance process.

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

000301xx	W&H Assistina
30310000	W&H Assistina Twin
10940021	W&H Service Oil F1, MD-400 (6 pcs)
02229200	Spray cap for Roto Quick System
02036100	Spray cap for fixed connection
02690400	Assistina adapter for Roto Quick System
01862300	O-ring (AM-25 L RM, AM-25 A BC/RM)
07389100	LED-ring (AM-25 L RM)
30015000	Torque multiplier (4:1 reduction)

Roto Quick couplings for air motors without light:

- RQ-03 W&H Roto Quick coupling with Borden 2(3)-hole-fixed connection, back-suction stop
- RQ-04 W&H Roto Quick coupling with Standard 4-hole connection, back-suction stop
- RQ-14 W&H Roto Quick coupling with Standard 4-hole connection, spray regulation, back-suction stop

Roto Quick couplings for air motors with light:

- RQ-24 W&H Roto Quick coupling with Standard 6-hole connection, electrical contacts, back-suction stop
- RQ-34 W&H Roto Quick coupling with Standard 6-hole connection, electrical contacts, spray regulation, back-suction stop

9. Technical data

	AM-25 RQ	AM-25 RM	AM-25 BC	AM-25 E BC/ RM	AM-25 A BC/ RM	AM-25 L RM
Coupling hose-side according to standard Motor/transmission instrument connection according to standard Outer diameter of the motor sheath (mm)	W&H RQ ISO 3964 20			ISO 9168 ISO 3964 20		
Operating pressure range (bar/psi)	2.2 – 3.5 bar 32 – 50.8 psi			2.2 – 3.3 bar / 32 - 47.9 psi		
Recommended operating pressure:	3.2 bar 46.4 psi			3.0 bar / 43.5 psi		
Speed range (rpm) at an operating pressure up to: (at resultant exhaust air pressure of maximum 0.25 bar/3.6psi)				25,000 +/- 10%		
Speed control				yes		
Maximum torque up to (Ncm)				4		
Maximum power up to (W)				30		
max. air consumption (l/min) at recommended operating pressure				< 60		
Spray water flow acc. to ISO 14457 (ml/min)		–			> 50	
Water pressure (bar)		–			1.5 – 2.5*	
Chip air pressure (bar)		–			2 – 3*	
Supply voltage V AC			–			2.2 – 4.2
Supply voltage V DC			–			2.2 – 6
Recommended voltage range V AC/DC			–			3.2 ± 0.1

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

Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Technical data

	AM-16 RQ	AM-20 RQ	AM-20 BC/RM	AM-20 E BC/RM
Coupling hose-side according to standard Motor/transmission instrument connection according to standard Outer diameter of the motor sheath [mm]	W&H RQ ISO 3964 16	W&H RQ ISO 3964 18	ISO 9168 ISO 3964 18	
Operating pressure range (bar/psi)	2.2 – 3.5 bar 32 – 50.8 psi		2.2 – 3.3 bar / 32 - 47.9psi	
Recommended operating pressure	3.2 bar / 46.4 psi		3.0 bar / 43.5psi	
Speed range [rpm] at an operating pressure up to: [at resultant exhaust air pressure of maximum 0.25 bar/3.6psi]	25,000 +/-10%			
Speed control	yes			
Maximum torque up to (Ncm)	4			
Maximum power up to (W)	30			
max. air consumption [NI/min] at recommended operating pressure	< 60			
Spray water flow acc. to ISO 14457 (ml/min)	–		> 50	
Water pressure (bar)	–		1.5 – 2.5*	
Chip air pressure (bar)	–		2 – 3*	

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

Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Technical data

	AM-20 MW RM AM-20 MW	AM-20 SD RM AM-20 SD	AP-20 RM	AP-20 RQ
Coupling hose-side according to standard Motor/transmission instrument connection according to standard Outer diameter of the motor sheath (mm)	ISO 9168 Midwest 16.9	ISO 9168 Star-Dental 16.5	ISO 9168 ISO 3964 18	W&H RQ ISO 3964 18
Operating pressure range	2.2 – 3.3 bar / 32 - 47.9 psi		2.2 – 3 bar 32 – 43.5 psi	2,2 – 3.5 bar 32 – 50.8 psi
Recommended operating pressure	3 bar / 43.5 psi		2.5 bar / 36.3 psi	3.2 bar / 46.6 psi
Speed range (rpm) at an operating pressure up to: (at resultant exhaust air pressure of maximum 0.25 bar/3.6psi)	25,000 +/- 10%			
Speed control	yes		no	
Maximum torque up to (Ncm)	4			
Maximum power up to (W)	30			
max. air consumption (NI/min) at recommended operating pressure	< 60			

Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Technical data

	AM-20 MW RQ	AM-20 SD RQ
Coupling	W&H RQ Midwest 16.9	W&H RQ Star-Dental 16.5
Motor/transmission instrument connection according to standard Outer diameter of the motor sheath (mm)	hose-side according to standard	
Operating pressure range	2.2 – 3.5 bar / 32 – 50.8 psi	
Recommended operating pressure	3.2 bar / 46.4 psi	
Speed range (rpm) at an operating pressure up to: (at resultant exhaust air pressure of maximum 0.25 bar/3.6psi)	25,000 +/-10%	
Speed control	yes	
Maximum torque up to (Ncm)	4	
Maximum power up to (W)	30	
max. air consumption (NI/min) at recommended operating pressure	< 60	

Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Technical data

	AM-05 MW RM AM-05 MW	AM-05 SD RM AM-05 SD	AM-05 MW RQ	AM-05 SD RQ	
Coupling	hose-side according to standard Motor/transmission instrument connection according to standard Outer diameter of the motor sheath (mm)	ISO 9168 Midwest 16.9	ISO 9168 Star-Dental 16.5	W&H RQ Midwest 16.9	W&H RQ Star-Dental 16.5
Operating pressure range	2.2 – 3.3 bar / 32 - 47.9 psi		2.2 – 3.5 bar / 32 - 50.8 psi		
Recommended operating pressure	3 bar / 43.5psi		3.2 bar / 46.4psi		
Speed range (rpm) at an operating pressure up to: (at resultant exhaust air pressure of maximum 0.25 bar/3.6psi)	5,600 +/-10%				
Speed control	yes				
Maximum torque up to (Ncm)	14.6				
Maximum power up to (W)	25				
max. air consumption (NI/min) at recommended operating pressure	< 60				

Power and speed are dependent on the quality of the supply hoses used and may 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)

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

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

AM-25 L RM



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.



HF 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		
HF-emission CISPR 11/EN 55011	Group 1 Class B	
Immunity to electromagnetic interference		
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	
Radiated RF electromagnetic field IEC/EN 61000-4-3	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 not 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

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.

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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