

Instructions for use



CE
0297

a dec 

synea
400 series

Highspeed Air Handpieces

valid since serial no. 01001

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A-dec|W&H symbols instructions for use



CAUTION!
(to prevent damage
occurring)




WARNING!
(Risk of injury)




General explanations,
without risk to
persons or objects




Do not dispose of
with domestic waste

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


A-dec|W&H symbols handpiece


 CE 0297
0297 from the manufacturer

REF Catalog number

 Thermal washer disinfectable

SN Serial number

 135°C
Sterilizable up to the
stated temperature

 Date of manufacture

1. Introduction


Creating customer success is a key foundation to the A-dec|W&H quality policy. In support of that effort, this A-dec|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 completely; they explain how to use your A-dec|W&H product and ensure proper, efficient and safe operation.

Intended use

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

 Always follow the manufacturer's recommendations for the handpiece.
Misuse may damage the handpiece, create risks, and pose hazards for patients, users, and others.

Qualifications of the user

We have based our development and design of the handpiece on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.



Production according to EU Directive

The handpiece is a medical product according to the EU Directive 93/42/ECC.



Device labeling statement

U.S. Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.



Responsibility of the manufacturer

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

- > The handpiece must be used in accordance with these Instructions for use.
- > The handpiece has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by authorized A-dec|W&H repair locations.

Skilled application

The handpiece is intended for use only by trained dental or medical practitioners for the purposes listed under the Indications for Use, in accordance with this document, the applicable health and safety regulations and the valid accident prevention regulations.

The handpiece should be prepared for use and maintained by staff who are 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 that are not approved by A-dec|W&H invalidates all claims under warranty and any other claims.

Service

In the event of malfunctions contact your local retail A-dec dealer or A-dec customer service.

Service and maintenance work must only be carried out by authorized A-dec|W&H repair locations.

2. Safety notes



- > The operation of the handpiece with light is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

The power supply unit for the dental unit must satisfy the following requirements to be guaranteed by the system assembler:

- > 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 (max. 700mA).
- > The leakage currents of the applied part must be kept.
- > The secondary voltage must be limited to a maximum of 5 V AC / DC.



- > 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 handpiece must be stopped immediately.
- > Use only non-contaminated, filtered, oil-free, and dry compressed drive air to operate the handpiece.
- > Check the handpiece for damage and loose parts each time before using (e.g., push-button chuck).
- > Do not operate the handpiece if it is damaged.
- > Perform a test run each time before using.
- > Do not use the handpiece at soft tissue wounds in the mouth (the air pressure can cause septic substances to penetrate the tissue, respective can cause embolism).
- > Avoid contact between the instrument head and soft tissue (risk of burning due to the push-button chuck heating up).
- > Run the rinse function for the dental unit once per day.
- > Do not use the handpiece as light sensor.
- > Do not look directly into the optic outlet.



Danger zones M and G

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



The handpiece 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 ICD (implantable cardioverter defibrillator) 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 the product away from implanted systems.
- > Make appropriate emergency provisions and take immediate action on any signs of ill-health.
- > Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).

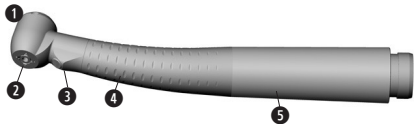
Cleaning and maintenance prior to initial use



Ensure that the handpiece is in clean condition and sealed in polyethylene (PE) film when the product is first delivered.

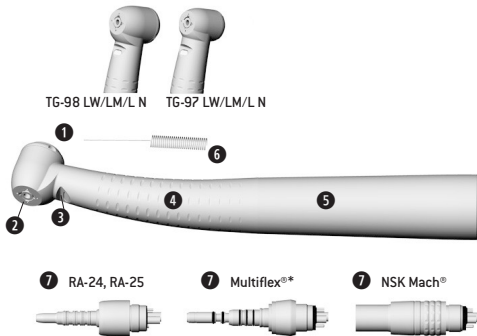
- > Lubricate the handpiece prior to initial use.
- > Sterilize the handpiece and the cleaning wire prior to initial use.
- > See lubrication instructions on page 25
- > See sterilization instructions on page 29

3. Product description for Roto Quick coupling handpieces



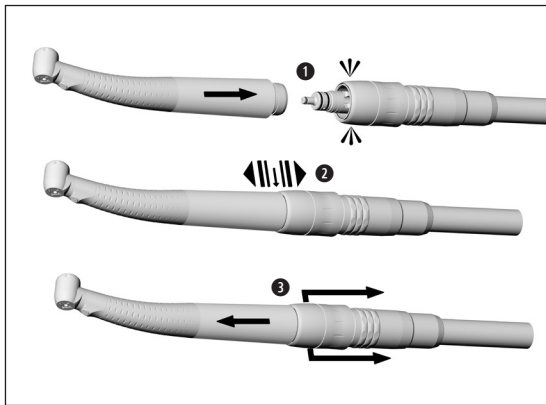
- 1 Push-button chuck
- 2 Spray ports
- 3 Optic outlet (LED)
- 4 Grip
- 5 Sheath
- 6 Cleaning wire

Product description for Multiflex[®]*, NSK[®]* coupling handpieces



- ① Push-button chuck
- ② Spray ports
- ③ Optic outlet (glass rod)
- ④ Grip
- ⑤ Sheath
- ⑥ Cleaning wire
- ⑦ Connections

4. Operation – assembly/removal: Roto Quick coupling



Do not assemble/remove during operation!

- 1** Push the handpiece onto the Roto Quick coupling.
- 2** Verify that the connection is secure.
- 3** Pull the retention sleeve of the Roto Quick coupling back and remove the handpiece by pulling in an axial direction.

Operation – assembly/removal: Multiflex[®], NSK Mach[®] connection



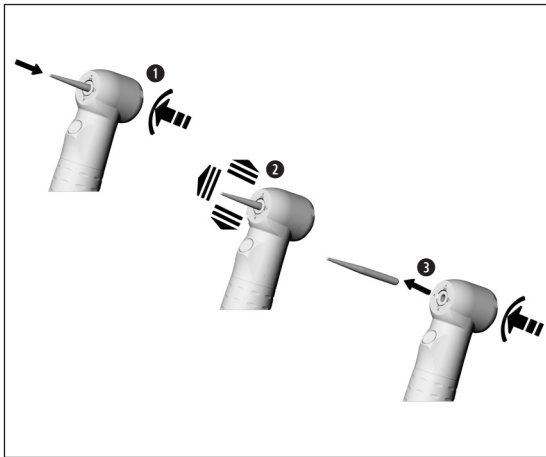
Do not assemble/remove during operation!

- > Attach the handpiece to the Multiflex[®], NSK Mach[®] coupling as described by the coupling manufacturer.
- > Check that the connection to the coupling is secure.
- > Remove the Multiflex[®], NSK Mach[®] coupling as described by the coupling manufacturer.

Dental burs



- > Use only dental burs in good condition with shanks that meet the requirements of the ISO 1797-1 standard. Follow the manufacturer's operating instructions.
- > Insert the dental bur only when the handpiece is stationary.
- > Do not touch the dental bur when it is in motion.
- > Do not activate the push-button chuck when the handpiece is in operation. This leads to dental bur detachment and/or may cause the push-button chuck to overheat (risk of injury).



Insert and remove the dental bur with push-button chuck

- 1 Insert the dental bur.
Activate push-button chuck, at the same time insert the dental bur until limit stop.
- 2 Pull slightly on the dental bur to verify a secure connection.
- 3 Press the push-button chuck to remove the dental bur.

Test



Do not hold the handpiece at eye level when testing to avoid possible injury.

- > Insert the dental bur.
- > Start the handpiece.

- > If you observe problems, such as vibrations, unusual noise, overheating, smell, coolant supply failure, leakage, or discoloration of the LED, **stop the handpiece immediately** and contact your A-dec dealer or A-dec customer service.

5. Cleaning and maintenance



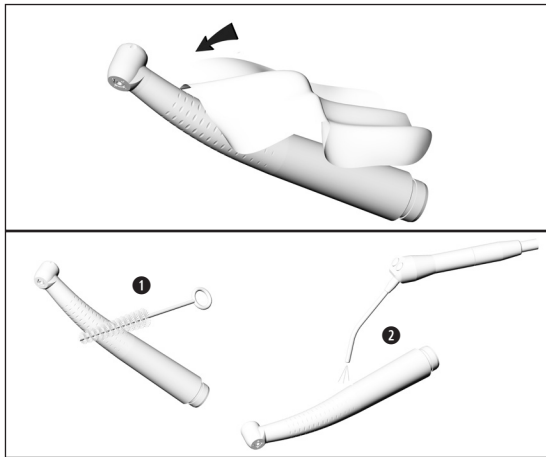
- Follow your local directives, standards, and guidelines for cleaning, disinfection, and sterilization.
- > You can process the handpiece manually or automatically.



- > Wear protective clothing and personal protective equipment (PPE).
- > Remove the handpiece from the Roto Quick coupling.
- > Remove the dental bur.

- > Clean and disinfect the handpiece **immediately after each patient** to flush out any liquid (such as blood, saliva, etc.) and to prevent debris from settling on the internal parts.

- > Sterilize the handpiece **after each patient**, following manual or automated cleaning, disinfection, and lubrication.
- > Sterilize the cleaning wire following manual cleaning and disinfection.



Pre-Cleaning

- > If heavily soiled, clean first with disinfectant cloths.



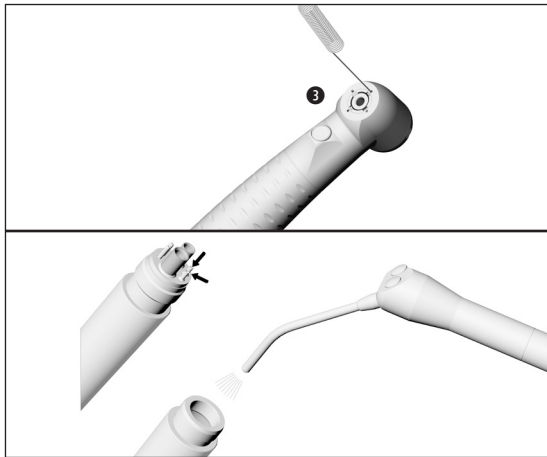
Do not use disinfectants that contain chlorine or protein fixatives. See manual disinfection on page 23.

Manual cleaning internal and external

- ① Rinse and brush off under demineralized water (< 100°F / < 38°C).
- ② Remove any liquid residues (absorbent cloth, blow dry with compressed air).



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



Clean spray ports

- 3 Use the cleaning wire to carefully remove dirt and deposits from the spray ports.



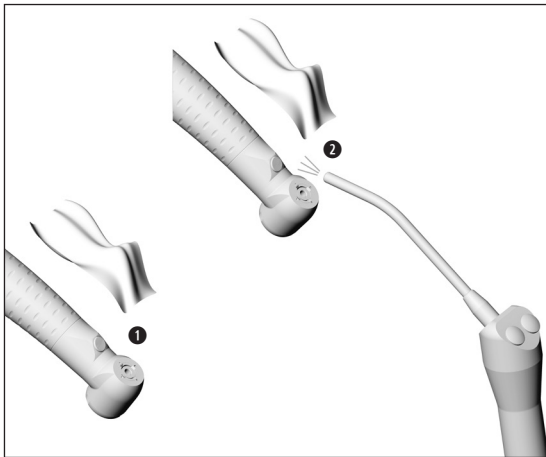
Clean and disinfect the cleaning wire in an ultrasonic bath/disinfection bath.

Clean coolant tubes

- > Use an air syringe to blow air through the coolant tube.



In the case of clogged spray ports or coolant tubes, contact your local A-dec dealer or A-dec customer service.



Clean the optic outlet

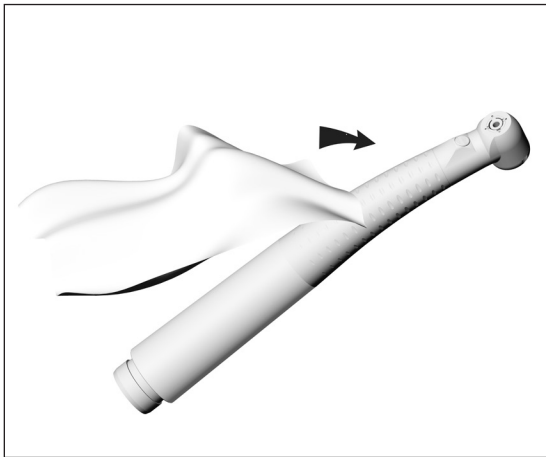


Clean the handpiece with care and avoid scratching the optic outlet.

- 1 Wash the optic outlet with cleaning/disinfectant fluid and a soft cloth.
- 2 Dry the optic outlet with an air syringe or soft cloth.



Inspect after each cleaning process.
If the optic outlet is damaged, do not use the handpiece and contact your local A-dec dealer or A-dec customer service.



Manual disinfection




A-dec|W&H recommends wiping the handpiece down with disinfectant.


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

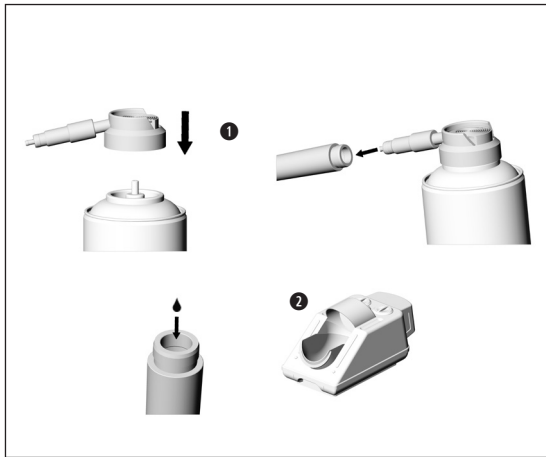


After manual cleaning, disinfection, and lubrication, you must sterilize the (wrapped) handpiece using a steam sterilizer.

Automated internal and external cleaning and disinfection

 The handpiece can be cleaned and disinfected in a thermal washer disinfectant.
> Note the manufacturer's specifications on equipment, cleaning agents and detergents.

 > Make sure that the handpiece is completely dry internally and externally after thermal washer disinfection. Remove any liquid residues with compressed air.
> Lubricate the dry handpiece immediately after thermal washer disinfection.



Lubrication

Recommended lubrication cycles

- > Essential after every internal cleaning
 - > before each sterilization,
- or
- > After 30 minutes of use or at least once daily.

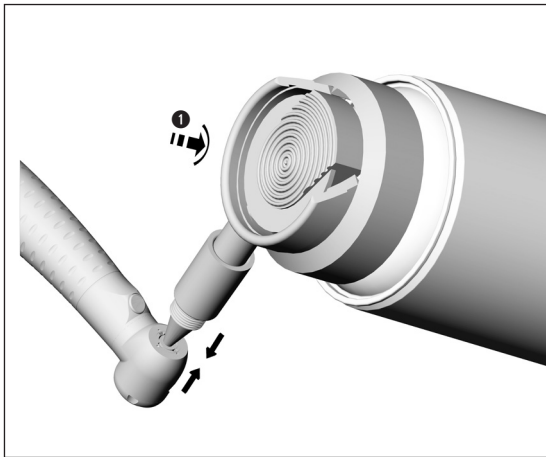
❶ With W&H Service Oil F1, MD-400

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

or

❷ With A-dec|W&H Assistina 301 plus

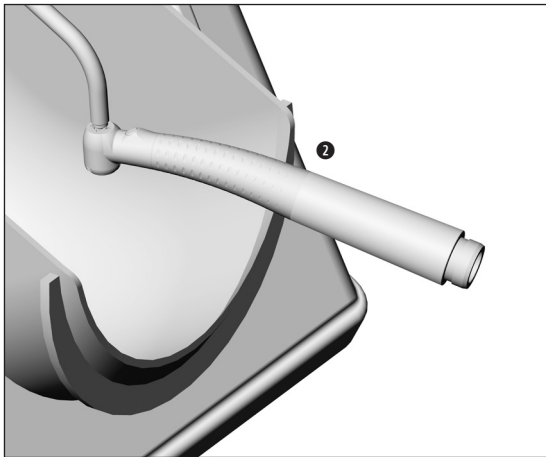
- > See instructions for use of Assistina.



Weekly lubrication of the chuck system

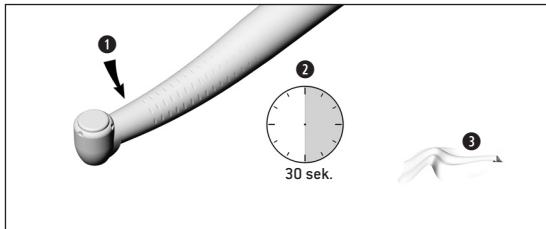
- ① With W&H Service Oil F1, MD-400
 - > Fit the spray cap REF 02036100 on the spray can.
 - > Hold the handpiece firmly.
 - > Press the tip of the spray nozzle firmly into the chuck system.
 - > Spray for approximately 1 second.

or



2 With the A-dec|W&H Assistina 301 plus

- > Fit the adaptor REF 02693000 onto the maintenance handpiece.
Position the exit nozzle downward.
- > Press the bur side of the handpiece onto the adaptor from below.
- > Start the Assistina.
- > Press the handpiece onto the adaptor for approximately 10 seconds.
- > Remove the handpiece from the adaptor.
- > Close the cover of the Assistina and allow it to run for the remainder of the maintenance cycle [approximately 25 seconds].



Test following lubrication

- 1 Place the handpiece with the head positioned downward.
- 2 Start the handpiece for 30 seconds to remove excessive oil.
 - > Repeat the complete cleaning and maintenance process with any sign of dirt or debris.
- 3 Wipe the handpiece with gauze or soft cloth.
 - > Sterilize the handpiece.

Sterilization and storage

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect, and lubricate prior to sterilization.
- > Place the handpiece in a standard handpiece sterilization pouch.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods dust-free and dry.



The standard ISO 14457 stipulates a durability of at least 250 sterilization cycles.

We recommend that you regularly service the A-dec|W&H handpieces after 1,000 sterilization cycles or one year of use.

Approved sterilization procedures



Follow your country-specific directives, standards, and guidelines.

- > Dynamic-air-removal sterilizers: 270°F (132°C) for 4 minutes or
- > Gravity displacement sterilizers: 270°F (132°C) for 15 minutes

- > All other sterilization methods are not approved and must not be used.



Do not exceed 277°F (136°C) during sterilization.

Allow the load to dry for approximately 20 to 30 minutes before removing from the sterilizer.

6. A-dec|W&H accessories and spare parts

Use only original A-dec|W&H accessories/spare parts or accessories approved by W&H.

Suppliers: A-dec|W&H partners

301	Assistina
02693000	Assistina adaptor for chuck system
10940021	Service Oil F1, MD-400 (6 pcs)
02036100	Spray cap with spray nozzle for chuck system
02229200	Spray cap with spray nozzle for all W&H products with Roto Quick system
04396100	Spray cap with nozzle for Multiflex® connection
05773300	Spray cap with nozzle for NSK Mach® connection
03522500	Spray cap with nozzle for LW connection
02015101	Cleaning wire

7. Technical data

Synea Fusion with / without light		TG-98 L / TG-97 L	TG-98 LM / TG-97 LM	TG-98 / TG-97 TA-98 LW / TA-97 LW TG-98 L N / TG-97 L N
Connection according to standard	EN ISO 9168:2009	W&H Roto Quick	Multiflex®* (LM)	W&H Roto Quick (LW) / NSK Mach®*
Dental bur	ISO 1797-1 (Ø mm)	1.6 – 0.01	1.6 – 0.01	1.6 – 0.01
Maximum Length approved by W&H	(mm)	25** / 21**	25** / 21**	25** / 21**
Minimum chuck length		until limit stop	until limit stop	until limit stop
Maximum operating part diameter	(mm)	2	2	2
Idle mode speed (± 30,000)	(rpm)	360,000 / 390,000	360,000 / 390,000	360,000 / 390,000
Coolant supply volume	ISO 14457 (gal/min)	> 0.013	> 0.013	> 0.013
Water setting range (Recommended water pressure)	(psi)	10 – 29 (22)***	10 – 29 (22)***	10 – 29 (22)***
Chip air setting range (must be higher than water pressure) (Recommended chip air pressure)	(psi)	22 – 43,5 (29)***	22 – 43,5 (29)***	22 – 43,5 (29)***
Exhaust air pressure	(psi)	< 7	< 7	< 7
Operating pressure	(psi)	43.5 ± 4.5	36 – 58	43.5 ± 4.5
Recommended operating pressure	(psi)	–	43.5 + 3	–
Air consumption	(CFM)	1.59	1.59	1.59
Supply voltage	(V DC or V AC)	3.2 ± 0.1	–	–
Current consumption	(A)	0.2	–	–
Chip air consumption at 29 psi	(CFM)	> 0.053	> 0.053	> 0.053

* see page 33

- * Multiflex® is a registered trademark of Kaltenbach & Voigt GmbH, Germany
- * NSK Mach®, is a registered trademark of NSK NAKANISHI INC., Japan



** When using longer dental burs, 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 must be higher than water pressure

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

rpm = min⁻¹ (revolutions per minute)

Temperature information

Temperature of the handpiece at the operator side:

max. 131°F (55°C)

Temperature of the handpiece at the patient side:

max. 122°F (50°C)

Temperature of the working part (dental bur):

max. 105.8°F (41°C)

Physical characteristics

Temperature for storage and transport:

-40°F to +158°F (-40°C to +70°C)

Air humidity for storage and transport:

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

Ambient temperature during operation:

+50°F to +95°F (+10°C to +35°C)

Air humidity during operation:

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

8. Recycling and disposal

Recycling

A-dec|W&H considers that it has a special duty toward the environment. The handpiece along with its packaging has been designed to be as environmentally friendly as possible.



Disposal of the handpiece

Follow your local 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 reduction of waste.

Warranty

A-dec warrants all products in this document against defects in material or workmanship for one year from time of delivery. A-dec's sole obligation under the warranty is to provide parts for the repair, or at its option, to provide the replacement product (excluding labor). The buyer shall have no other remedy. All special, incidental, and coincidental damages are excluded.

Written notice of breach of warranty must be given to A-dec within the warranty period. The warranty does not cover damage resulting from improper installation or maintenance, accident or misuse. The warranty does not cover damage resulting from the use of cleaning, disinfecting or sterilization chemicals and processes. Failure to follow instructions provided in the A-dec|W&H instructions for use (operation and maintenance instructions) may void the warranty.

No other warranties as to merchantability or otherwise are made.

A-dec|W&H contacts

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