

PEOPLE HAVE PRIORITY



## Instructions for use



proxeo

**Scaler**  
ZE-55 BC / ZE-55 RM

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## Symbols in the instruction for use

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**WARNING!**  
(risk of injury)



**ATTENTION!**  
(to prevent damage  
occurring)



General explanations,  
without risk to persons or  
objects



Suitable for use in an  
ultrasonic bath



Thermo washer  
disinfectable



Do not dispose of with  
domestic waste

## Symbols on the instrument / 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



Sterilizable up to the  
stated temperature



Serial number



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



Date of manufacture

## **1. Introduction**

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The W&H quality policy gives customer satisfaction top priority. This W&H product has been designed, manufactured and tested in accordance with the requirements of current laws and standards.

### **For your safety and the safety of your patients**

Please read the Instructions for use before using the device for the first time. They explain how to use the product and guarantee smooth, economical and safe operation.

### **Intended use**

This medical device is an air-powered ultrasonic unit for use in dental treatments. It may be used in combination with the tips approved by the manufacturer for the removal of supragingival and subgingival calculus, tooth cleaning, root planing, root canal preparation and processing hard tooth and bone substance.

Misuse may damage the scaler and hence cause risks and hazards for patients, users and third parties.

## Qualifications of the user

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



### Production according to EU Directive

The scaler is a medical device as defined by EU Directive 93/42/EEC.



### Responsibility of the manufacturer

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

- > The scaler must be used in accordance with these Instructions for use.
- > The scaler has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 37).

### **Qualified use**

The scaler is only intended for qualified use in dental medicine according to the applicable health and safety regulations, accident prevention measures and in observance of these Instructions for use. The scaler must only be prepared and maintained by persons who have been instructed in infection prevention, self-protection and patient safety. Improper use (e.g., due to lack of hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which have not been approved by W&H will invalidate all claims made under warranty or otherwise.

### **Service**

In case of malfunction, contact an authorized W&H service partner immediately (see page 37). Repair and maintenance work must be performed exclusively by authorized W&H service partners.

## 2. Safety notes

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- > Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- > Always provide sufficient coolant and ensure the appropriate suction. Turn off the scaler immediately in the event of failure in the coolant supply.
- > As drive air for the scaler, use only filtered, oil-free and cooled air supplied by dental compressors.
- > Check the scaler for damage and loose parts (e.g., scaler tip, seal) before every use.
- > Do not operate the scaler if it is damaged.
- > Perform a test run prior to each treatment.
- > Do not use the scaler where soft tissue injuries exist in the oral cavity (the air pressure may cause septic substances to infiltrate the tissue or trigger embolisms).
- > Run the rinsing function of the dental unit once a day.



## Tips



> Only use W&H tips, the W&H open-ended spanner respectively W&H tip changer.  
Tips/tip changers from another manufacturer which are approved for the W&H scaler may also be used.



- > Ensure that the original shape of the tip is not changed (e.g., by dropping).
- > Tips must not be bent back to shape or reground.
- > Only insert the tip when the scaler is idle.
- > Never touch the vibrating tip.
- > Place the tip changer on the inserted tip of the idle scaler immediately after every treatment (protects against injuries and infections, protects the tip).
- > Use the tip card supplied to check the wear to the tips (1AU, 2AU, 3AU, 1AP, 2APr, 2API).  
The wear of the tips must not amount to more than 2 mm.

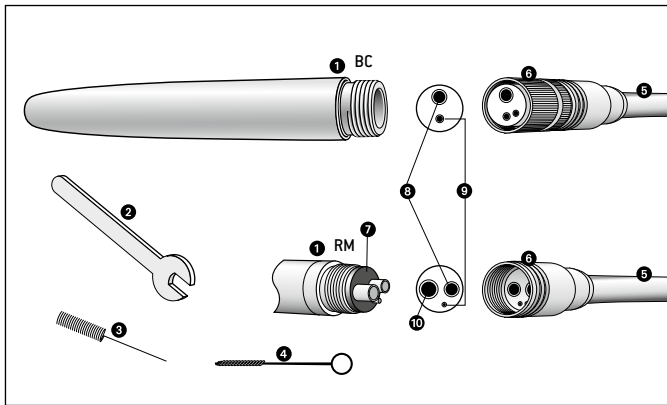
## Hygiene and maintenance before using for the first time



The scaler is supplied in a clean condition sealed in PE foil.

- > Lubricate the scaler before using it for the first time.
  - > Sterilize the scaler, tips, open-ended spanner/tip changer and the nozzle cleaner.
- 
- > Oil service      page 27 – 28
  - > Sterilization    page 29 – 30

### 3. Product description – Scaler



#### Scaler ZE-55 BC / ZE-55 RM

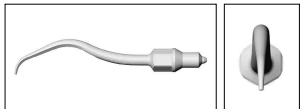
- ① BC/RM Connection
- ② Open-ended spanner
- ③ Nozzle cleaner
- ④ Small cleaning brush
- ⑤ Turbine hose
- ⑥ Union nut
- ⑦ Seal

#### Connections:

- ⑧ Drive air
- ⑨ Spray water
- ⑩ Return air

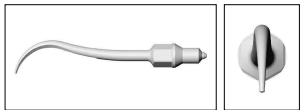
## Product description – Tips

### Application areas of approved W&H tips

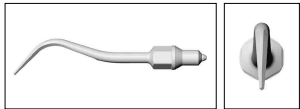


#### Prophylaxis tips

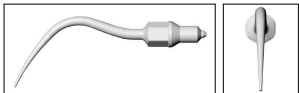
**1AU:** Universally applicable, also for cambered molar surfaces inclined towards lingual.



**2AU:** For anterior teeth of the lower jaw, lingual surfaces and in cases of stubborn adhesion of thick, hard collars of dental calculus.

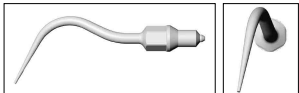


**3AU:** For removing plaque from the neck of the tooth and removing nicotine stains.



### Periodontology tips

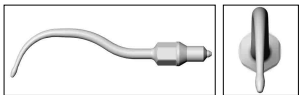
**1AP:** Removal of subgingival deposits, especially suitable for deep periodontal pockets.



**2APr:** Right-curved tip for removal of subgingival deposits.



**2API:** Left-curved tip for removal of subgingival deposits.

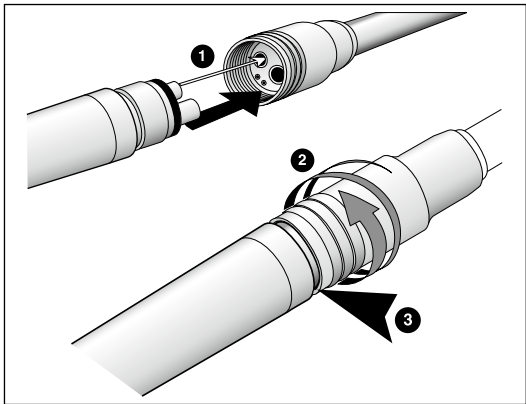


**3AP:** With a diamond coating on the instrument tip for periodontal debridement of furcations and concavities.



Use the diamond-coated 3AP periodontology tip, applying very light pressure (0.3 N) to avoid any type of overinstrumentation.

## 4. Starting operation



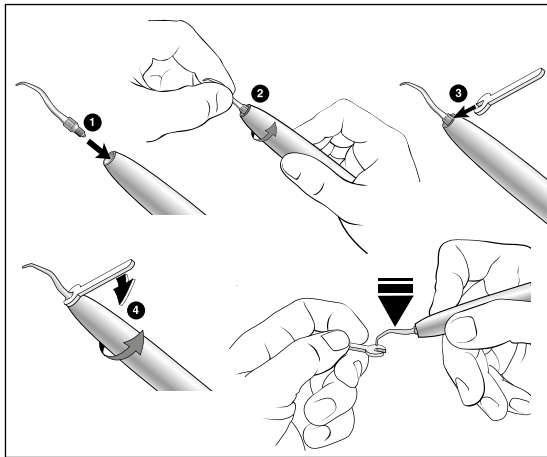
### Attachment and detachment



**Do not attach or detach while in operation!**



- 1** Insert the scaler with BC/RM connection into the openings of the turbine hose.
  - 2** Screw the union nut on.
  - 3** Check for leak tightness in the scaler with RM connection (not possible with BC connection as exhaust air escapes from the sheath).
- > Unscrew the union nut and detach the scaler from the turbine hose.



### Inserting the tip

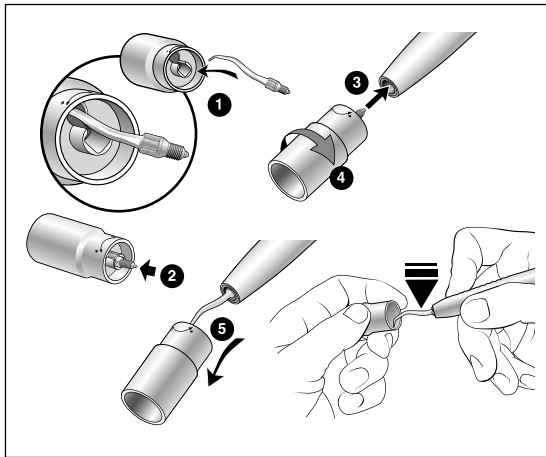
- 1 Insert the tip thread into the scaler opening.
- 2 Hold the tip tightly and turn the scaler anticlockwise until the tip is screwed in.
- 3 Position the open-ended spanner at the bottom part of the tip.
- 4 Screw the tip in tightly.



Check the secure attachment of the tip by pulling axially.



Press the tip against a hard, sterile surface (e.g., open-ended spanner) with approx. 10 N (=1 kg) to test the load-bearing capacity of the tip.



### Inserting the tip with the W&H tip changer (optional accessory)

- 1 Place the tip in the notch.
- 2 Push the tip into the tip changer.
- 3 Insert the thread of the tip into the opening on the scaler.
- 4 Screw the tip in tightly.
- 5 Pull the tip changer off carefully.

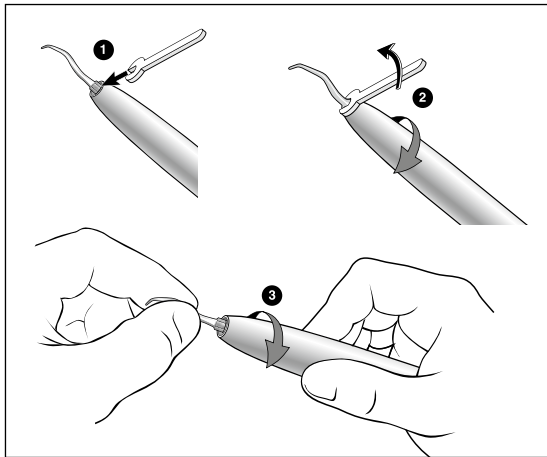


Check the secure attachment of the tip by pulling axially.



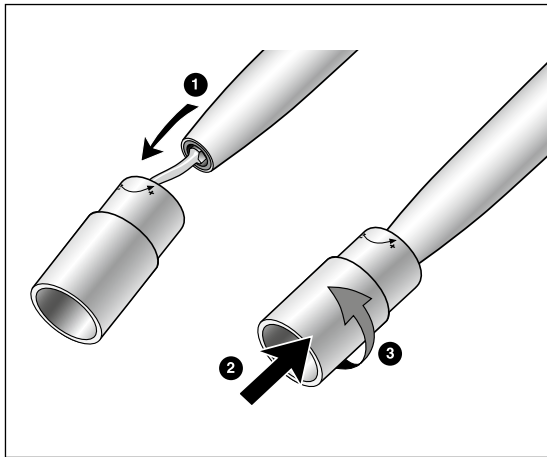
Press the tip against a hard, sterile surface [e.g., tip changer] with approx. 10 N [=1 kg] to test the load-bearing capacity of the tip.





## Removing the tip

- 1 Position the open-ended spanner at the bottom part of the tip.
- 2 Unscrew the tip anticlockwise with the open-ended spanner.
- 3 Hold the tip and turn the scaler clockwise until the tip is unscrewed.



## Removing the tip with the W&H tip changer (optional accessory)

- 1 Place the tip in the notch.
- 2 Press the tip changer onto the tip.
- 3 Unscrew the tip.



Leave the tip in the tip changer until the hygiene and maintenance process!

## Test run



Do not hold the scaler at eye level.

- > Insert the tip.
- > Start the scaler.
- > In the event of malfunctions (e.g., vibrations, unusual noises, overheating, coolant failure or leakage), **stop the scaler immediately** and contact an authorized W&H service partner (see page 37).

## 5. Hygiene and maintenance

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- > Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.
- > The scaler, the tips and the open-ended spanner/tip changer can be treated manually or mechanically.



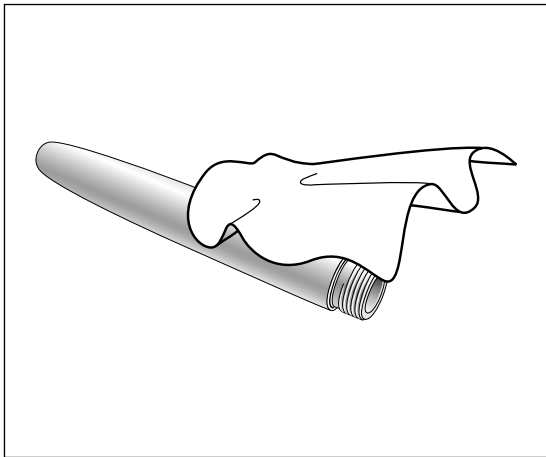
- > Wear protective clothing.
- > Remove the scaler from the turbine hose.
- > Remove the tip from the scaler.



- > Clean and disinfect the scaler, the tips and the open-ended spanner/tip changer **immediately after each treatment**, in order to rinse out any liquids (e.g., blood, saliva, etc.) that may have entered and to prevent inside parts from seizing up.



- > Sterilize the scaler after manual cleaning, disinfection and lubrication.
- > Sterilize the tips and the open-ended spanner/tip changer after manual or mechanical cleaning and disinfection.
- > Sterilize the nozzle cleaner after manual cleaning and disinfection.

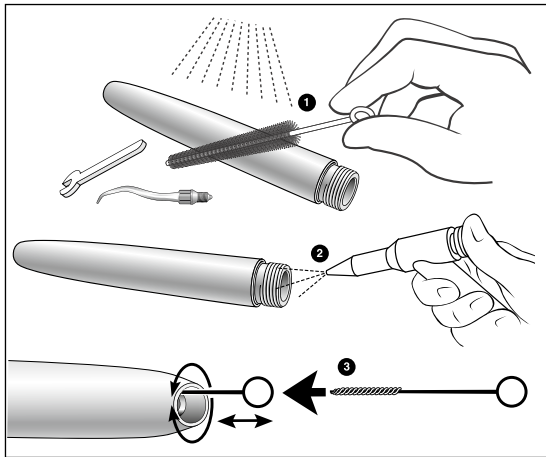


### **Pre-disinfection**

> If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants which have no protein-fixing effect.



## Manual cleaning inside and outside

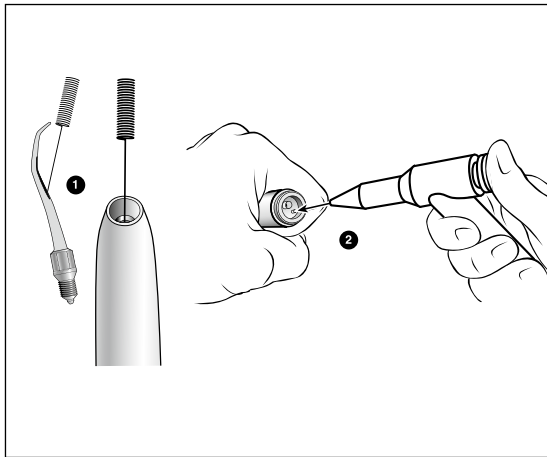
- 1 Rinse and brush off with demineralized water (< 38 °C / < 100 °F)
- 2 Remove any liquid residues (absorbent cloth, blow dry with compressed air).
- 3 Insert the small cleaning brush as far as it will go and clean the interior.



Do not place the scaler in disinfectant solution or in an ultrasonic bath!



You can clean and disinfect the tips and the open-ended spanner/tip changer in the drill bath or ultrasonic bath.



## Cleaning the spray outlets

- 1 Use the nozzle cleaner to remove dirt and deposits from the outlets.



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

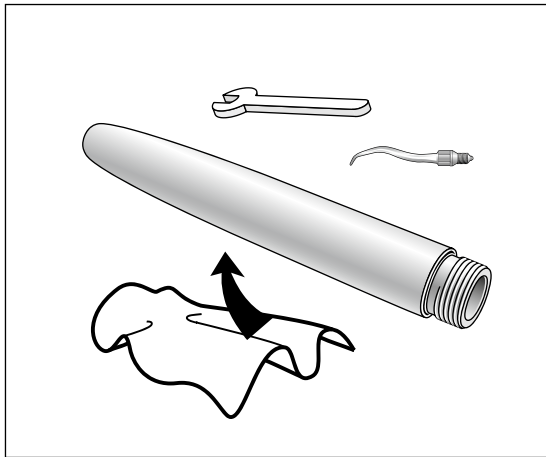
## Cleaning the coolant channel

- 2 Blow through the coolant channel with the air gun.



If the exit openings or coolant channels are blocked, contact an authorized W&H service partner (see page 37).





## Manual disinfection



W&H recommends wiping down with disinfection.

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



After manual cleaning, disinfection and an lubrication, you must carry out a thermal disinfection (unwrapped) or sterilization (wrapped) in a class B or S steam sterilizer (as per EN 13060).

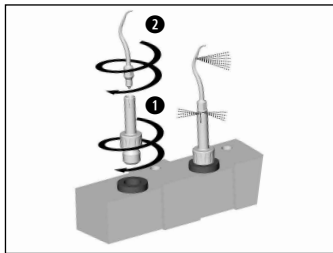
## Tips and open-ended spanner/tip changer

### Mechanical cleaning and disinfection (internal and external)

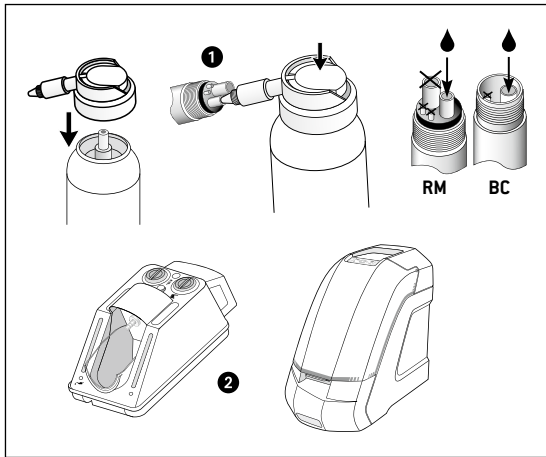


The tips and the open-ended spanner/tip changer can be cleaned and disinfected in the thermo washer disinfectant.

- > Follow the manufacturer's recommendations for devices and cleaning & rinsing agents.
- > Use the W&H adaptor set REF 07233500 for the thermo washer disinfectant for preparing the tips.



- 1 Screw the W&H adaptor into the injector rail adaptor.
- 2 Screw the tip onto the W&H adaptor.

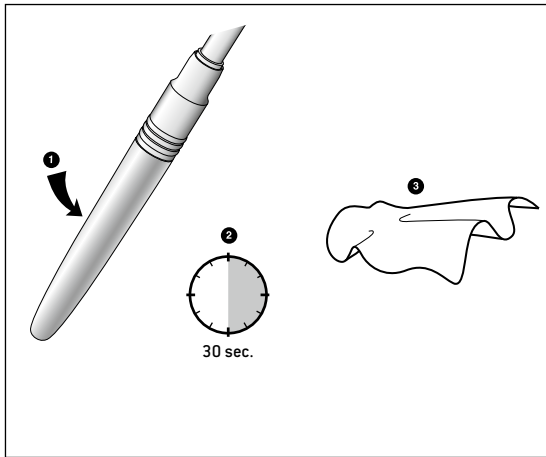


## Oil service

- ➊ With W&H Service Oil F1, MD-400
  - > Follow the instructions on the oil spray can and on the packaging.
- or
- ➋ With W&H Assistina
  - > See Assistina Instructions for Use.

## Recommended maintenance cycles

- > After every tenth internal cleaning process
- > Before every tenth sterilization process



### Test run after oil service

- ➊ Point the scaler downwards.
- ➋ Allow the scaler to run for 30 seconds in order to remove any excess oil.
  - > Repeat the entire hygiene and maintenance process if any dirt escapes.
- ➌ Wipe the scaler with a cellulose cloth or soft cloth.

## **Sterilization and storage**



W&H recommends sterilization according to EN 13060, class B

- > Note the manufacturer's specifications.
- > Clean, disinfect and lubricate prior to sterilization.
- > Wrap the scaler and accessories in sterile goods packaging according to EN 868-5.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods dust-free and dry.



The standard ISO 15606 stipulates a durability of at least 250 sterilization cycles.

In the case of the W&H scaler, we recommend you have a regular service carried out after 1000 sterilization cycles or one year.

## Approved sterilization procedures

- > Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060.  
Sterilization holding time a minimum of 3 minutes at 134°C (273.2 °F)
- or
- > Steam sterilization class S with sterilizers in accordance with EN 13060.  
The sterilizer manufacturer must give its express approval for the sterilization of the scaler.  
Sterilization holding time a minimum of 3 minutes at 134°C (273.2 °F)



### **Before resuming operation**

Wait until the scaler is completely dry.  
Moisture in the scaler can lead to a malfunction!

Wait until the scaler, the tip and the open-ended spanner/tip changer have cooled down completely.  
{Risk of burns}

## 6. W&H Accessories and spare parts

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Use only original W&H accessories and spare parts or accessories approved by W&H

Reference source: W&H Partner

301	Assistina
19922000	Assistina 3x2 (MB-200)
19923000	Assistina 3x3 (MB-300)
02083500	Intermediate adaptor from RM to Borden 2(3)-hole fixed connection
07014500	Assistina Borden adaptor
10940021	Service Oil F1, MD-400 (6 pcs)
02036100	Spray cap with nozzle
00636901	Nozzle cleaner
05452400	Small cleaning brush

04510700	Open-ended spanner
07308100	Tip changer
02207300	RM coupling seal
01000700	BC coupling seal
07233500	Adaptor set for the thermo washer disinfectant

07159700	Tip 1AU
07159800	Tip 2AU
07159900	Tip 3AU
07009100	Tip 1AP
05254400	Tip 2APr
05153300	Tip 2API
05280200	Tip 3AP



## 7. Technical data

Proxeo scaler		ZE-55 BC	ZE-55 RM
Coupling hose side acc. to standard EN 29168		Borden 2/3-hole	Standard 4-hole
Operating pressure	(bar)	2,5 ± 0,3*	2,5 ± 0,3*
Water pressure	(bar)	0.7 – 2	0.7 – 2
Coolant flow rate	ISO 15606 (ml/min)	30 – 60	30 – 60
Lowest permitted coolant flow rate	(ml/min)	30	30
Air consumption	(l/min)	34	34
Oscillating frequency	(kHz)	6	6
Oscillation amplitude	ISO 15606 (µm)	< 200	< 200

\* Adjust the operating pressure directly on the scaler using a manometer.

### **Temperature information**

Temperature of the scaler on the operator side:	max. 55°C (131 °F)
Temperature of the scaler on the patient side:	max. 50°C (122 °F)
Temperature of the working instrument (tip):	max. 41°C (105.8 °F)

### **Ambient conditions**

Temperature during storage and transport:	-40°C (-40 °F) to +70°C (+158 °F)
Air humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature in operation:	+10°C (+50 °F) to +35°C (+95 °F)
Humidity in operation:	15% to 80% (relative), non-condensing

## 8. Disposal

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Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for the disposal.

- > Medical device
- > Waste electrical equipment
- > Sales packaging

# Explanation of warranty terms

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees 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 the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase. Accessories and consumables (tips, open-ended spanner, tip changers, nozzle cleaners, cleaning brushes, coupling seals) are excluded from 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.

**12 months warranty**

## Authorized W&H service partners

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Find your nearest W&H service partner at <http://wh.com>

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

**W&H (UK) Limited**, Unit 6, Stroud Wood Business Centre, Park Street, St Albans, AL2 2NJ Hertfordshire  
t + 44 1727874990, f + 44 1727872254, E-Mail: [technical.uk@wh.com](mailto:technical.uk@wh.com)

**W&H IMPEX INC.**, 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada  
t + 1 519 9446739, f + 1 519 9746121, E-Mail: [service.ca@wh.com](mailto:service.ca@wh.com)

**W&H IMPEX INC.**, 14300 Henn Road, Dearborn, MI 48126, USA  
t + 1 519 9446739, f + 1 519 9746121, E-Mail: [service.us@wh.com](mailto:service.us@wh.com)

**W&H AUSTRIA GMBH**, Ignaz-Glaser-Straße 53, 5111 Bürmoos  
t + 43 62746236239, f + 43 62746236890, E-Mail: [office.at@wh.com](mailto:office.at@wh.com)

**A-DEC Australia**, *Office and showroom*, Unit 8, 5-9 Ricketty Street, 2020 Mascot NWS  
t + 61 283324000, f + 61 283324099, E-Mail: [a-dec@a-dec.com.au](mailto:a-dec@a-dec.com.au)

## **Manufacturer**

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