Instructions for use

CE
0297

proxeo

Scaler with light
ZA-55 LM / ZA-55 LS

Scaler without light
ZA-55 / ZA-55 M

Contents

Symbols

WARNING!
(risk of injury)

ATTENTION!
(to prevent damage occurring)

General explanations, without risk to persons or objects

Do not dispose of with domestic waste

Suitable for use in an ultrasonic bath
(only for tips)

Symbols

CE XXXX — CE marking with identification number of the Notified Body

REF — Catalogue number

SN — Serial number

Date of manufacture

Manufacturer

MD — Medical Device

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

135°C — Sterilizable up to the stated temperature

Thermo washer disinfectable

HIBC — Data structure in accordance with Health Industry Bar Code

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

Consult Instructions for use

℞ only — Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients
Prior to initial use please read the Instructions for use. These explain how to use your medical device and guarantee a smooth and efficient operation.


Observe the safety notes.

Intended use
This medical device is an air-powered sonic 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 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 requirements of 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 if it is used in compliance with the following directions:

> The medical device must be used in accordance with these Instructions for use.
> The medical device has no components that can be repaired by the user.
Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 47).

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).
- 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 each time before using.
- Do not operate the medical device if it is damaged.
- Perform a test run each time before using.
- Avoid overheating at the treatment site.
- Do not look directly into the light source.
- Do not use the medical device as a light probe.
- 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.

Tips

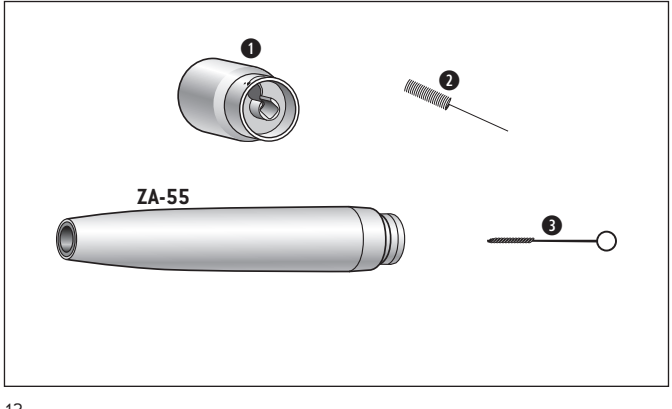
- > Only use tips that have been approved by W&H and the associated tip changers.
- > With periodontal tips, the medical device is suitable for the removal of concretions in the subgingival region, but not for applications which demand sterile conditions. If possible, choose the lower performance range when carrying out periodontal treatments on hypersensitive patients in order to guarantee optimum pain-free treatment.
- > Ensure that the original shape of the tips is not affected (e.g . by being dropped).
- > The tips must not be bent back into shape or resharpened.
- > Locate and secure the tip only with the medical device switched off.
- > Never touch the tips when vibrating.
- > Insert the tip changer onto the inserted tip of the stationary medical device after every treatment (protection against injury and infection, tip protection).
- > Do not touch into the tip changer (with tip inserted).
- > Check for the effect of wear on the tips using the accompanying tip card.
- > Change tips if there are visible signs of wear.
- > Depending on the tip and power setting, the amplitude can exceed 200 µm.

Hygiene and maintenance prior to initial use

> The medical device is not sterilized when delivered.
> The packaging is non-sterilizable.

> Clean and disinfect the medical device, the tips and the tip changer.
> Sterilize the medical device, the tips and the tip changer.

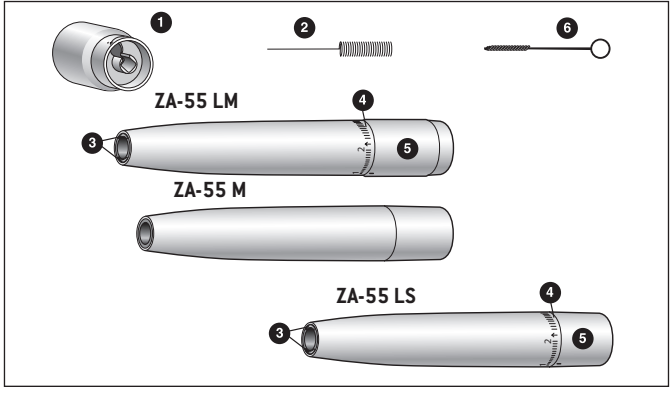
3. Product description



Scaler with Roto Quick connection

1. Tip changer
2. Nozzle cleaner
3. Small cleaning brush

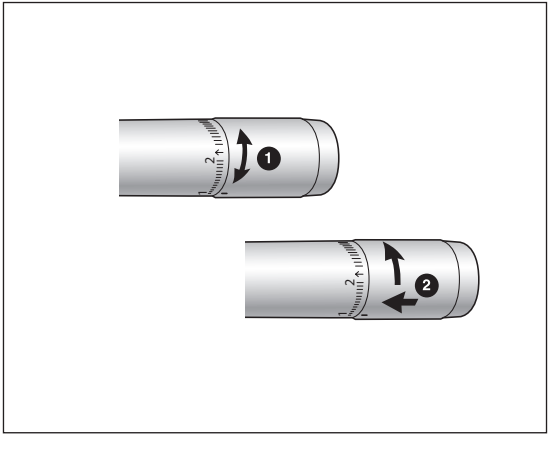
Product description



Scaler with/without light and *Multiflex®* / Sirona® connection**

1. Tip changer
2. Nozzle cleaner
3. Optic outlet*
4. Power level marking*
5. Adjuster ring for the power setting*
6. Small cleaning brush

* Only on ZA-55 LM / ZA-55 LS



Adjuster ring for the power setting on the scaler (ZA-55 LM / ZA-55 LS)

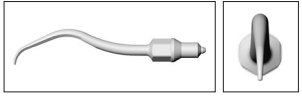
> Power level marking 1: Gentle
> Power level marking 2: Standard
> Power level marking 3: Short-term for increased ablation

Power level marking 3: Avoid any type of overinstrumentation.

❶ Set power level 1 to 2 by turning the adjuster ring.
> There is a safety lock at power level 2.
❷ To bypass it, press the adjuster ring forwards and turn it to power level 3.

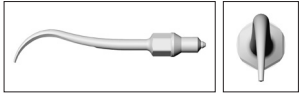
The following tips have been approved for power level marking 1 – 3 (ZA-55 LM / ZA-55 LS).

Intended use of approved W&H tips:

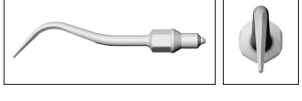


Prophylaxis tips

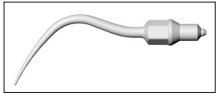
1AU: Universally applicable, also for cambered molar surfaces inclined towards lingual.



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

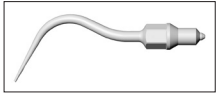


3AU: For removing plaque from the neck of the tooth and removing nicotine stains.

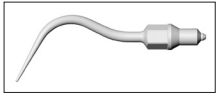


Periodontology tips

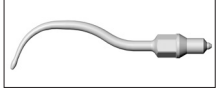
1AP: Removal of subgingival deposits, especially suitable for deep periodontal pockets.



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



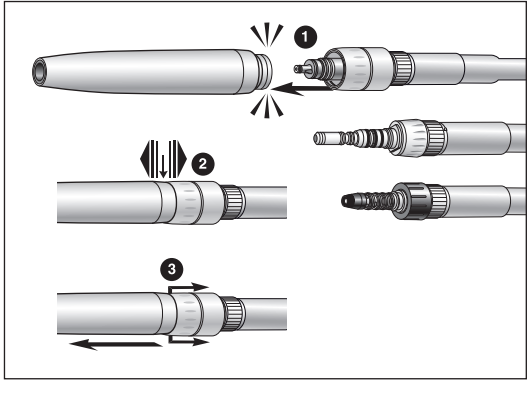
2APl: Left-curved tip for removal of subgingival deposits.



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.

> Always use a coolant adaptor when performing a surgical treatment .
> When using a coolant adaptor, it must be ensured that the water supply to the dental treatment unit is switched off.



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

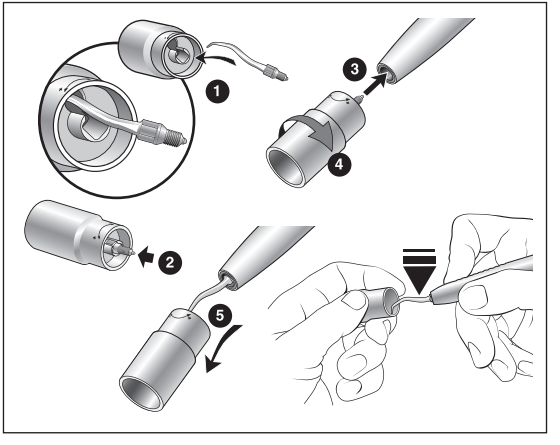
❶ Push the medical device onto the Roto Quick / *Multiflex®* / Sirona®** coupling.

❷ Verify full engagement.

❸ Pull the retention sleeve of the Roto Quick coupling back and remove the medical device by pulling in an axial direction.

or

Remove the medical device from the *Multiflex®* / Sirona®** coupling by pulling in an axial direction.

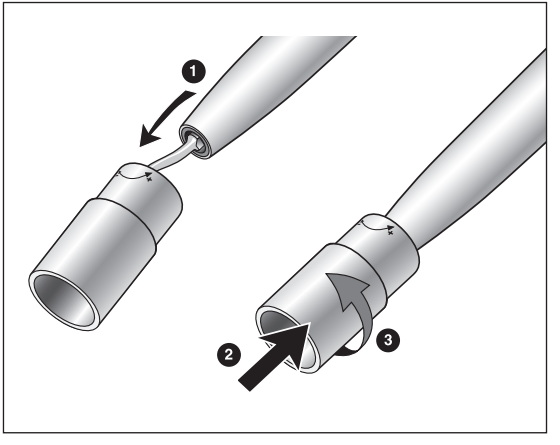


Inserting the tip

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.

Verify full engagement.

Press the tip with about 10 N (= 1 kg) pressure onto a firm object to test the loading capacity of the tip



Removing the tip

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 medical device at eye level!

> Attach the medical device to the supply hose.
> Insert the tip.
> Put the medical device into operation.

In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant supply 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.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar (43.5 psi) 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.
> Check signs of wear on the tips (see tip card).

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 medical device, the tip and the tip changer with disinfectant.
> Remove the tip.
> Remove the medical device.

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

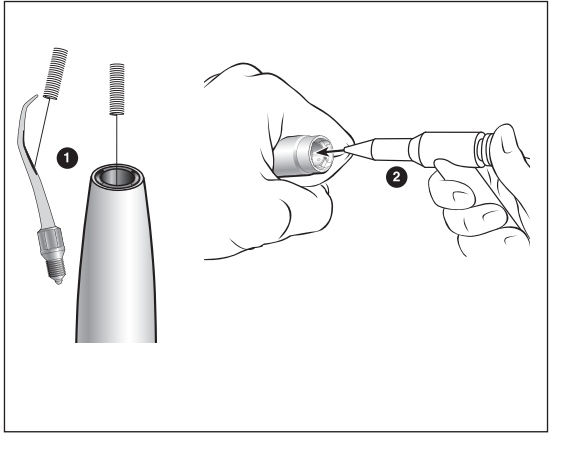
Do not place the medical device and the tip changer in liquid disinfectant or in an ultrasonic bath.

Tips
You can clean and disinfect the tips in the ultrasonic bath/disinfection bath.

Clean and disinfect diamond coated tips in an ultrasonic bath.

Evidence of the medical device's basic suitability for effective manual cleaning and disinfection was provided by an independent test laboratory using the "Bandelin Type RK 100 CC" ultrasonic bath and the cleaning agents and disinfectansts "StammopurDR8" (DR H Stamm, Berlin) and “CaviCide™” (Metrex).

> Clean the medical device, the tip and the tip changer under running tap water (< 35 °C / < 95 °F).
> Rinse and brush off all internal and external surfaces.
> Remove any liquid residues using compressed air.



Cleaning the spray nozzles

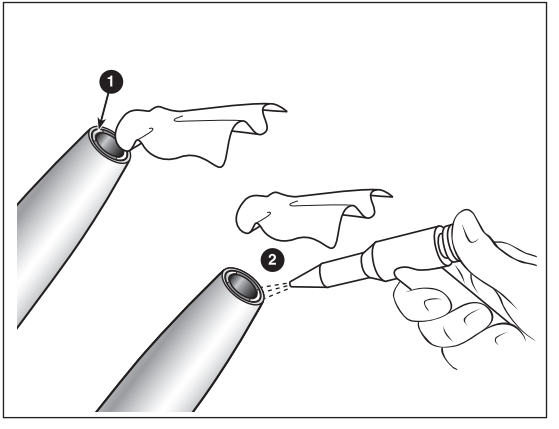
❶ Clean coolant outlets carefully with the nozzle cleaner to remove dirt and deposits.

Clean and disinfect the nozzle cleaner in an ultrasonic bath and/or in the washer disinfector.

Cleaning the coolant tube

❷ Blow through the coolant tube using compressed air.

If it proves impossible to correct the malfunction, please contact an authorized W&H service partner.



Cleaning of the light source (ZA-55 LM / ZA-55 LS)

Avoid scratching 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.

> 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 and washer disinfector adaptors.

Tips

> Only use approved and validated adaptors for products with voids for your washer disinfector.

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 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 tip and the tip changer following cleaning and disinfection.

Lubrication

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

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

Sterilize the medical device following cleaning, disinfection and lubrication.

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.

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

00636901	Nozzle cleaner
07308100	Tip changer
05452400	Small cleaning brush

Scan the QR code to find accessories, consumables and spare parts for this medical device.

W&H tips:

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

Approved tips from suppliers: Brasseler, VDW

8. Technical data

Proxeo scaler		ZA-55	ZA-55 LM / ZA-55 M	ZA-55 LS
Coupling hose side acc. to standard		W&H Roto Quick	*Multiflex*®*	*Sirona*®*
Operating pressure	(bar)	3.4 ± 0.3**	3.4 ± 0.3**	3.4 ± 0.3**
Water setting range (Recommended water pressure)	(bar)	0.7 – 2 (1.5)	0.7 – 2 (1.5)	0.7 – 2 (1.5)
Coolant flow rate	acc. to ISO 18397 (ml/min)	20 – 50	20 – 50	20 – 50
Lowest permitted coolant flow rate	(ml/min)	30	30	30
Air consumption	acc. to ISO 18397 (Nl/min)	< 66 / < 36***	< 66 / < 36***	< 66 / < 36***
Oscillating frequency	(kHz)	6	6	6
Oscillation amplitude	acc. to ISO 18397 / see safety notes (µm)	< 200	< 200	< 200
Chucking system****		screw-in		

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

** Adjust the operating pressure using a manometer at power level 3 (ZA-55 LM, ZA-55 LS).

*** Actual readings

**** For tips which are not approved for use in the medical device by the manufacturer, the user must choose the correct operating conditions in order to ensure that there is no risk to the user, the patient or third parties.

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 (metal):	maximum 51°C (123.8 °F)
Temperature of the working part (tip):	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 % (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

9. Disposal

Ensure that the parts are not contaminated on disposal.

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

> Medical device

> 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 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 24 months from the date of purchase. Accessories and consumables 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.

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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