Instructions for Use

piezomed CLASSIC
piezomed PLUS

Handpiece with cable

SA-40 / SA-40 L

CE
0297

Contents

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

Suitable for ultrasonic bath

Symbols

on the medical device / on the packaging

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

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

 Type B applied part (not suitable for intracardiac application)

REF — Catalogue number

 Sterilizable up to the stated temperature

 Date of manufacture

SN — Serial number

 Thermo washer disinfectable

 Manufacturer

HIBC — Data structure in accordance with Health Industry Bar Code

LOT — Batch code

MD — Medical Device

Symbols

on the medical device / on the packaging

Temperature limitation

Humidity limitation

℞only

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

1. Introduction

For your safety and the safety of your patients
These Instructions for use explain how to use your medical device. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients, are of paramount importance to us.

Observe the safety notes.

Intended use
Piezoceramic oscillating system for treatment of organic hard and soft tissue in dental surgery, implantology, maxillofacial surgery and periodontics.

Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user
Only suitably qualified medical, technical and specialist trained staff may use the medical device. We have based our development and design of the medical device on the physician 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.
> The medical device has no components that can be repaired by the user. Only the components approved by the manufacturer may be replaced (LED socket).
> Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

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.
> Check the medical device for damage and loose parts each time before using.
> Do not operate the medical device if it is damaged.
> Only put the medical device into operation when the handpiece sleeve is attached.
> Avoid overheating at the treatment site.
> If the LED fails, change the LED socket.
> Only change the LED socket when the handpiece is stationary.
> Always operate the handpiece with the LED socket fitted.
> Do not look directly into the light source.
> Perform a test run each time before using.
> The medical device is not approved for operation in potentially explosive atmospheres.
> The medical device is not approved for operation in oxygen rich Environment.

> Do not twist or kink the cable! Do not coil it too tightly!

Instruments

> Only use instruments approved by W&H and the associated instrument changer.
> Make sure that the instrument used complies with the instrument group displayed.
> An overview for the correct power setting is included with each instrument.
> Ensure that the original shape of the instrument is not changed (e.g. by dropping).
> Instruments must not be bent back to shape or reground.
> Only insert the instrument when the handpiece is at rest.
> Never touch the instrument when vibrating.
> Remove the instrument from the handpiece after every treatment and place it in the instrument stand (provides protection against injury and infection).
> Ensure there is sufficient coolant directly at the treatment site.
> The instruments Z25P and Z35P may only be operated with a coolant setting of max. 35%. Setting the coolant flow rate too high may result in perforation of the Schneiderian membrane.

- > Keep the handpiece moving at all times when operating the instrument.
- > Do not exert too much pressure on the instrument. This can cause the instrument to heat up or break, resulting in injury to the patient.
- > Do not make any levering motions with the instrument.
- > Never let the instrument run freely without coolant.

Coolant supply

The medical device is designed for use with physiological saline solution.

- > Always ensure the correct operating conditions and cooling function.
- > Use only suitable coolants and follow the manufacturer's medical data and instructions.
- > In case of coolant supply failure, the medical device must be stopped immediately.
- > Use the W&H irrigation tubing set or accessories approved by W&H.
- > Make sure that the coolant filling function has been carried out prior to every application.

Risks due to electromagnetic fields
This medical device is suitable for use on patients with cardiac pacemakers.
The functionality of other active implantable medical devices (AIMD) (e.g. ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if the patient has other active implantable medical devices (AIMD) before using the medical device and inform about the risks.
> Do not place the applied part on the patient's body.

Hygiene and maintenance prior to initial use

> Clean and disinfect the handpiece with cable, the instruments and the instrument changer.
> Sterilize the the handpiece with cable, the instruments and the instrument changer.

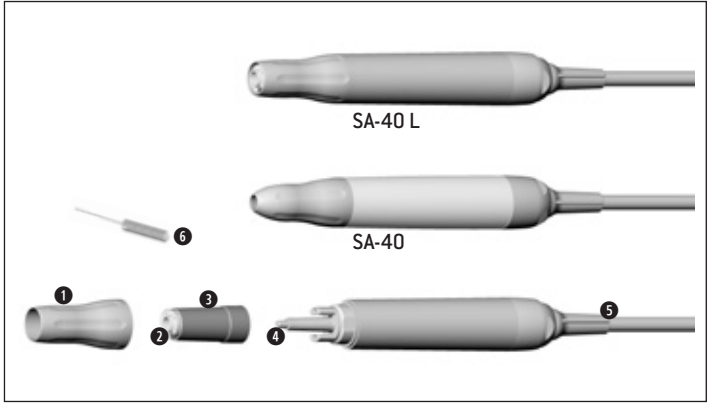
Test run

Do not hold the handpiece with cable at eye level!

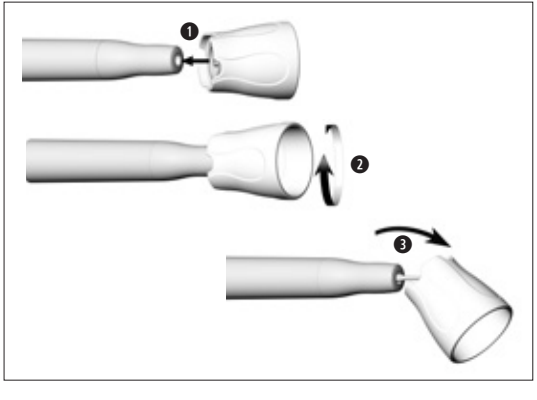
> Attach the handpiece with cable to the control unit.
> Insert the instrument.
> Put the medical device into operation.

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.

3.Description

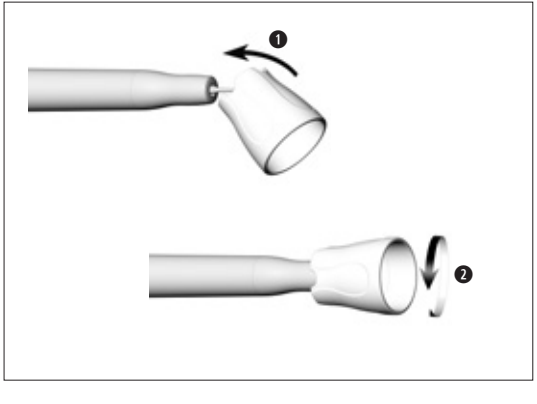


1. Handpiece cap
2. Light source
3. LED socket
4. Thread
5. Coolant tube
6. Nozzle cleaner



1. Position the instrument in the instrument changer on the handpiece thread.
2. Turn the instrument changer until it snaps into place.
3. Carefully pull off the instrument changer.

Verify full engagement.



❶ Attach the instrument changer to the instrument.
❷ Unscrew the instrument with the instrument changer.

Keep the instrument in the stand until a hygiene and maintenance process is carried out.

> Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

> Wear protective clothing, safety glasses, face mask and gloves.
> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

> The instruments can be reprocessed in the instrument stand (REF 07134900).

> The medical device must not be oiled
> The medical device must not be disassembled.

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

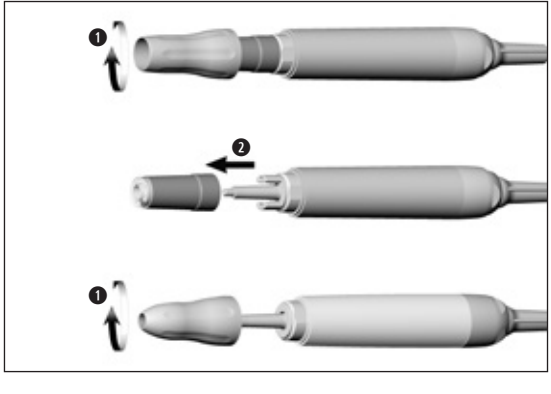
> We recommend a regular service for the W&H handpiece with cable after 250 processing cycles or one year.
> We recommend to replace the instrument changer after 1000 processing cycles.
> We recommend checking the instruments for material wear after 60 reprocessing cycles.

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 coolant fill function for at least 10 seconds.
> Ensure that all coolant outlets are rinsed out.

> Remove the instrument.
> Remove the handpiece with cable.
> Wipe the entire surface of the handpiece with cable with disinfectant.

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



Disassembling the handpiece / Replacing of the LED socket

SA-40 L

1. Unscrew the handpiece cap.
2. Pull out the LED socket.

SA-40

1. Unscrew the handpiece cap.

Do not place the handpiece with cable and the instrument changer in liquid disinfectant or in an ultrasonic bath.

> Clean the handpiece with cable, the instruments and the instrument changer under running tap water (< 35°C / < 95°F).
> Rinse and brush off all internal and external surfaces.
> Remove liquid residues using compressed air.

Instruments
Clean and disinfect diamond coated instruments 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 100CC" ultrasonic bath and the cleaning agent and disinfectant "StammopurDR8" (DR H Stamm, Berlin) and "CaviCide™" (Firma Metrex).

Cleaning of the coolant tubes / spray nozzles

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

❶ Clean outlets carefully with the nozzle cleaner to remove dirt and deposits.
❷ Blow through the coolant tube and coolant outlets using compressed air.

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

Cleaning of the light source

Avoid scratching the light source!

❶ Wash the light source with cleaning fluid and a soft cloth.
❷ 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 basic suitability of the handpiece with cable, the instruments and the instrument changer for effective manual disinfection was provided by an independent test laboratory using the “mikrozid® AF wipes” disinfectant (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.

Instruments and coolant tube

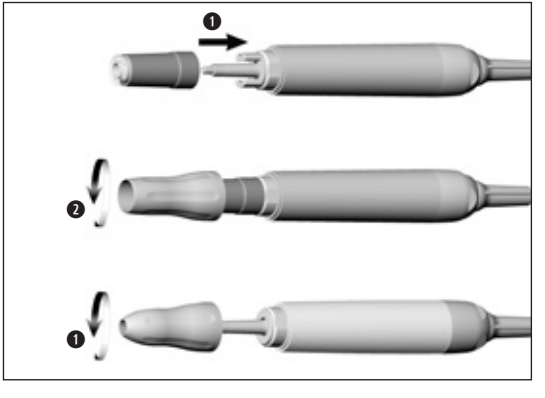
> Only use approved and validated adaptors for products with voids for your washer disinfector.

Evidence of the basic suitability of the handpiece with cable, the instruments and the instrument changer 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 handpiece with cable, the instruments and the instrument changer are completely dry internally and externally after cleaning and disinfection.
> Moisture in the handpiece with cable may cause a malfunction! (Risk of short circuit)
> Remove liquid residues using compressed air.

> Check the handpiece with cable, the instruments and the instrument changer after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess the handpiece with cable, the instruments and the instrument changer that are still soiled.
> Sterilize the reassembled handpiece with cable, the instruments and the instrument changer following cleaning and disinfection.



Reassembling the medical device /
Replacing of the LED socket

Reassemble the medical device following cleaning and disinfection.

SA-40 L

1. Fit LED socket onto medical device.
2. Screw on the handpiece cap.

SA-40

1. Screw on the handpiece cap.

Pack the handpiece with cable, the instruments and the instrument changer 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 handpiece with cable, the instruments and the instrument changer.

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
> Maximum sterilization temperature 135°C (275°F)

Evidence of the basic suitability of the handpiece with cable, the instruments and the instrument changer 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)) and the Systec VE-150* steam sterilizer (Systec).

"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*/**

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**

* 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.

> Always return equipment in the original packaging.
> Do not coil the cable around the handpiece and do not twist or kink the handpiece cable. (Risk of damage)

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 (Link: https://www.wh.com)

00636901	Nozzle cleaner
04019000	Clips (5 pcs)
06205600	LED socket
07134900	Instrument stand
06276700	Instrument changer

8. Technical data

		SA-40 / SA-40 L
Maximum power consumption	(W)	24
Frequency (ultrasonic)	(kHz)	22-35
Coolant flow rate at 100 %	(ml/min)	at least 90
Operating mode		S3 (80s on/330s off) maximum 4 repeats

Type B applied part (not suitable for intracardiac application)

Temperature information

Temperature of the medical device at the operator side:	maximum 55°C (131°F)
Temperature of the medical device at the patient side (light source):	maximum 48°C (118.4°F)
Temperature of the medical device on the patient side (front area of the handpiece):	maximum 48°C (118.4°F)
Temperature of the working part (instrument):	maximum 41°C (105.8°F)

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport:	8% to 80% (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
Altitude:	up to 3,000 m above sea level
Overvoltage category:	II
Pollution level:	2

9. Data on electromagnetic compatibility according to IEC/EN 60601-1-2

Operating environment and EMC warning notes
This medical device is neither life-sustaining nor coupled to the patient. It is suitable for operation both in domestic healthcare and in facilities used for medical purposes except rooms/areas, in which EMC interference of high-intensity may occur. The customer and/or the user should assure that this medical device is set up and used in an environment of the specified type and/or in accordance with the specifications of the manufacturer. This medical device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

No special precautions are necessary to maintain the basic safety and essential performance of this medical device.

Essential performance
This medical device has no critical functions and therefore does not have any essential performance features.

RF communications 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	
Mains terminal disturbance voltage (Conducted Emissions) CISPR 11/EN 55011 [150 kHz – 30 MHz]	Group 1 Class B
Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B
Harmonic distortion IEC/EN 61000-3-2	Class A
Voltage fluctuations and flicker IEC/ EN 61000-3-3	–
Immunity to electromagnetic interference	
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ± 8 kV Air discharge: ± 2 kV, ±4 kV, ±8 kV, ±15 kV
Radiated RF electromagnetic fields IEC/EN 61000-4-3 [80 MHz – 2,7 GHz]	10 V/m

* There are no deviations or simplifications to IEC/EN 60601-1-2.

Proximity fields from RF wireless communications equipment IEC/EN 61000-4-3	710 / 745 / 780 / 5240 / 5500 / 5785 MHz		9 V/m
	385 MHz		27 V/m
	450 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 MHz		28 V/m
Electrical fast transients / bursts IEC/EN 61000-4-4	Mains supply: ±2 kV Input and output ports: ±1 kV		
Surges IEC/EN 61000-4-5	±1 kV L – N	±2 kV L – PE	±2 kV N – PE
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 V 6 V in ISM bands and in amateur radio bands		
Power frequency magnetic fields IEC/EN 61000-4-8	30 A/m		
Voltage dips, short interruptions and voltage variations IEC/EN 61000-4-11	0% for 0.5 cycle at 45° steps from 0°-315° 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles		
Proximity magnetic fields IEC/EN 61000-4-39	30 kHz	8 A/m	
	134,2 kHz	65 A/m	
	13,56 MHz	7,5 A/m	

10. Disposal

Ensure that the parts are not contaminated on disposal.

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

> Medical device
> Waste electrical equipment
> Packaging

Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls 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 (nozzle cleaner , instruments, clips, O-rings, adapter kit) 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

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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