

Instructions for Use



CE
0297

piezomed

SA-320

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Symbols



WARNING!
(risk of injury)



CE marking with identification
number of the Notified Body



Class II equipment



ATTENTION!
(to prevent damage occurring)



Type B applied part (not
suitable for intracardiac
application)



Foot control



General explanations, without
risk to persons or objects



Thermo washer disinfectable



Off



Follow Instructions for Use



Sterilizable up to
the stated temperature



On



Date of manufacture



Suitable for ultrasonic bath



Electric fuse



Manufacturer





















Medical Device



Earth

Symbols

	DataMatrix Code for product information including UDI (Unique Device Identification)		Catalogue number		Frequency (hertz)
	This way up		Serial number		Batch code
	Fragile, handle with care		Electric voltage (volt)		Do not re-sterilize
	Keep dry		Alternating current		Do not re-use
	“Der Grüne Punkt“ (The Green Dot) trademark of Duales System Deutschland GmbH		Power consumption (volt-ampere)		Use by
	Do not dispose of with domestic waste		Electric current (ampere)		Do not use if package is damaged

Symbols



Latex-free



Sterilization with ethylene oxide



Single sterile barrier system



Keep away from heat

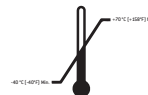


Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard

R_{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.



Temperature limitation



Humidity limitation



Data structure in accordance with Health Industry Bar Code



MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005, ANSI/AAMI ES60601-1: A1:2012 + C1:2009/[R]2012 + A2:2010/[R]2012, CAN/CSA-C22.2 No. 60601-1:2008, CAN/CSA-C22.2 NO. 60601-1:2014. 25UX – Control No.

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

Drive unit with a 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.

Introduction

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:

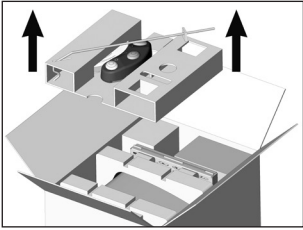
- > The medical device must be used in accordance with these Instructions for Use.
- > The medical device has no components that can be repaired by the user.
- > Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 68).
- > The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 [“Installation of electrical equipment in rooms used for medical purposes”] or with the regulations applicable in your country.
- > Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

Improper use, unauthorized assembly, modification or repair to the medical device, 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.

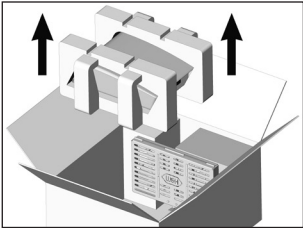


Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

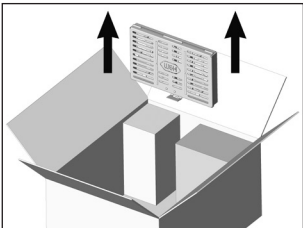
2. Unpacking



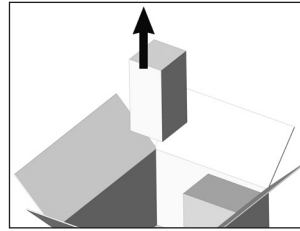
- ① Lift out the insert with the stand and the foot control.



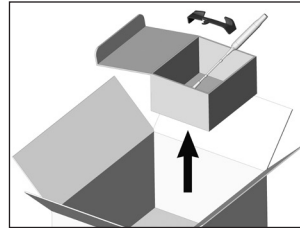
- ② Lift out the insert with the control unit.



- ③ Remove the cassette.



- ④ Remove the irrigation tubing set.



- ⑤ Remove the carton containing the accessories supplied.

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies. However, we recommend that you keep the original packaging.

3. Scope of delivery

	Control unit	30078000	30078003
REF 06985000	Handpiece with 1.8 m cable	X	X
REF 07004400	Foot control S-N1	X	
REF 04653500	Handle for foot control	X	
REF 436360	Irrigation tubing set 2.2 m [3 pcs, disposable item]	X	X
REF 07172900	Cassette	X	
REF 07173100	Instrument set "Bone"	X	
REF 07721800	Universal support		X
REF 04005900	Stand		X
REF 06276700	Instrument changer		X
REF 00636901	Nozzle cleaner		X
	Mains cable country-specific		X

4. 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 when the medical device is damaged.
- > Check the parameter settings every time you restart.
- > In case of coolant supply failure, the medical device must be stopped immediately.
- > Perform a test run each time before using.
- > Do not look directly into the light source.
- > Avoid overheating at the treatment site.
- > Ensure that it is possible to complete the operation safely should the units or instruments fail.
- > Only put the handpiece with cable into operation when the handpiece sleeve is attached.
- > The responsibility for the use and timely shutdown of the system lies with the user.
- > 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.



The medical device is not approved for operation in potentially explosive atmospheres.



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

Safety notes



- > Use only original W&H fuses.
- > Never touch the patient and the electrical contacts on the medical device simultaneously.



Power failure

In the event of a power failure, if the control unit is switched off, or when switching between programs, the last values set are saved and re-activated on power-up.

System failure

A total system failure does not constitute a critical fault.



Mains cable / Power switch

- > Only use the mains cable supplied.
- > Plug the mains cable only into a power socket with protective contact.
- > Set up the control unit so the power switch and the socket are easily accessible at all times.



Disconnect the medical device in dangerous situations from the power supply!

- > Pull the power supply out of the socket.

Safety notes



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%.
- > 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.
- > Depending on the tip and power setting, the amplitude can exceed 200 µm.

Safety notes

Control unit



Risks due to electromagnetic fields

The functionality of active implantable medical devices (AIMD) (e.g. cardiac pacemaker, ICD) can be affected by electric, magnetic and electromagnetic fields.

- > Find out if the patient has active implantable medical devices (AIMD) before using the medical device and inform about the risks.

Handpiece with cable



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.

Safety notes

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.
- > Only use an irrigation tubing set approved by W&H or accessories approved by W&H.




Sterile medical devices (irrigation tubing set)



- > Only use the medical device if the sterile packaging is undamaged and unopened.
- > Note the expiration date.
- > Replace the medical device immediately after each treatment and after each patient. Reuse may lead to infection.
- > Dispose of the medical device in accordance with the applicable regulations.

Safety notes


Hygiene and maintenance prior to initial use

-  > Clean the control unit.
-  > Clean and disinfect the handpiece with cable, the universal support, the stand, the instruments and the instrument changer.
-  > Sterilize the handpiece with cable, the universal support, the instruments and the instrument changer.

Test run

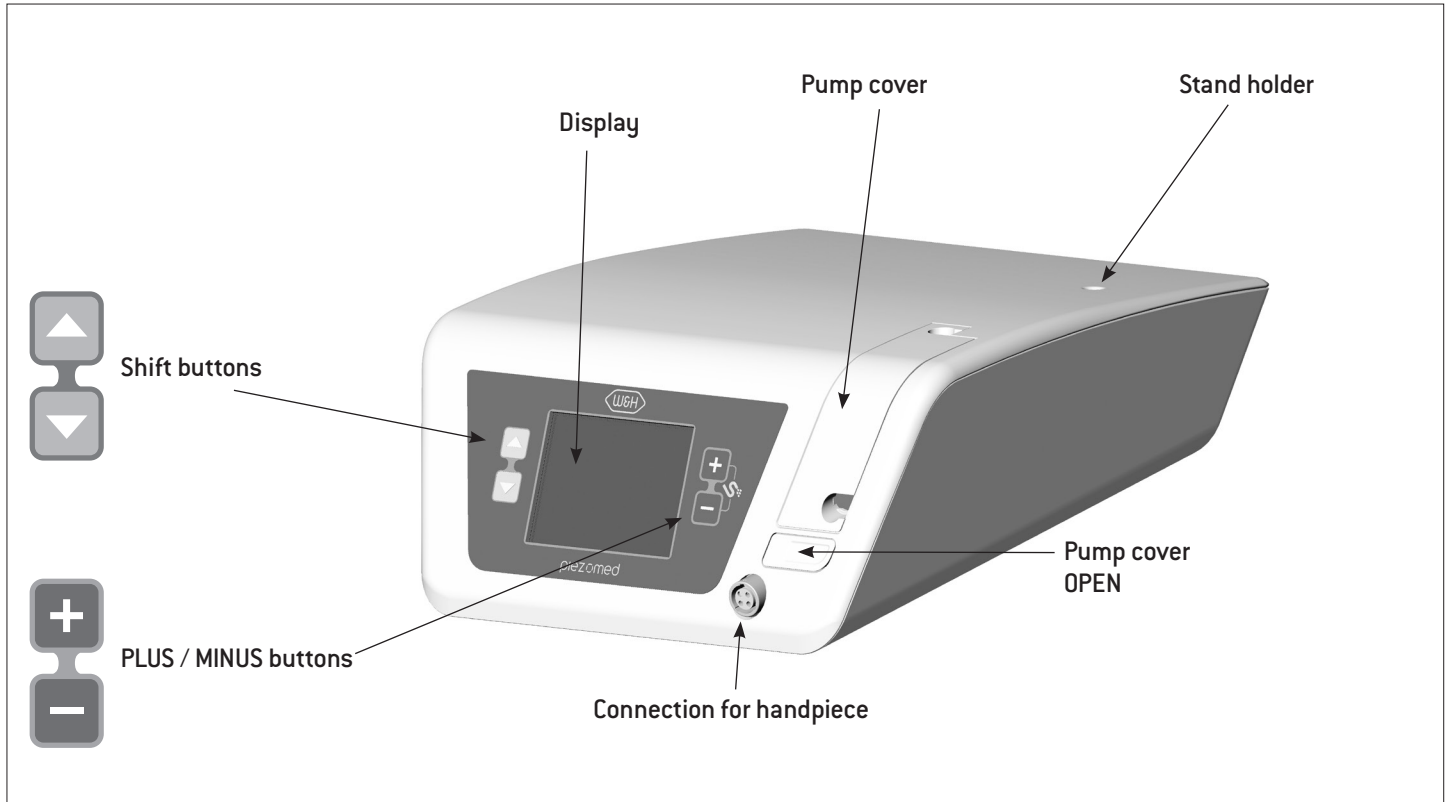
-  Do not hold the handpiece with cable at eye level!

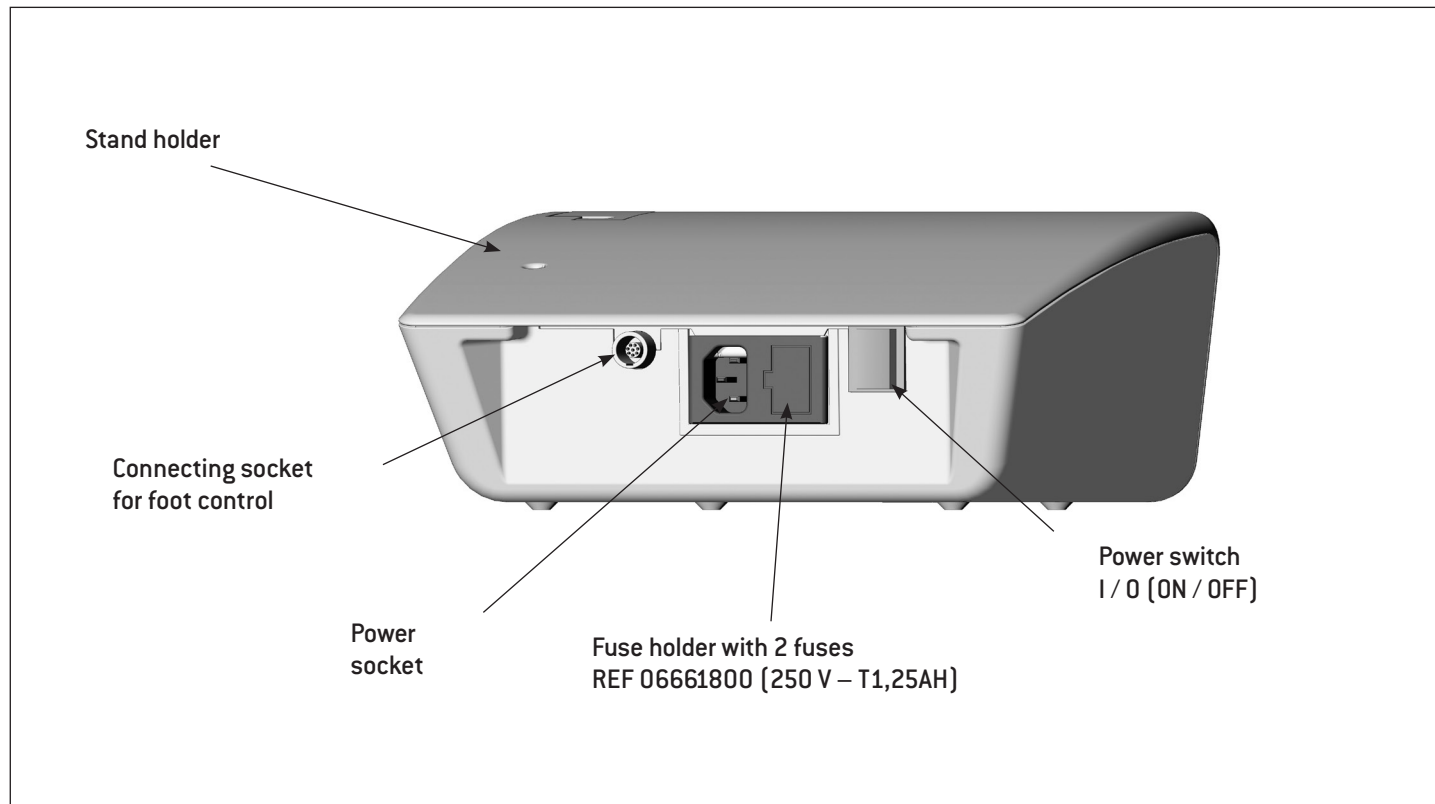
- > Attach the handpiece with cable to the control unit.
- > Insert the instrument.
- > Put the control unit into operation.

-  > 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.

5. Description

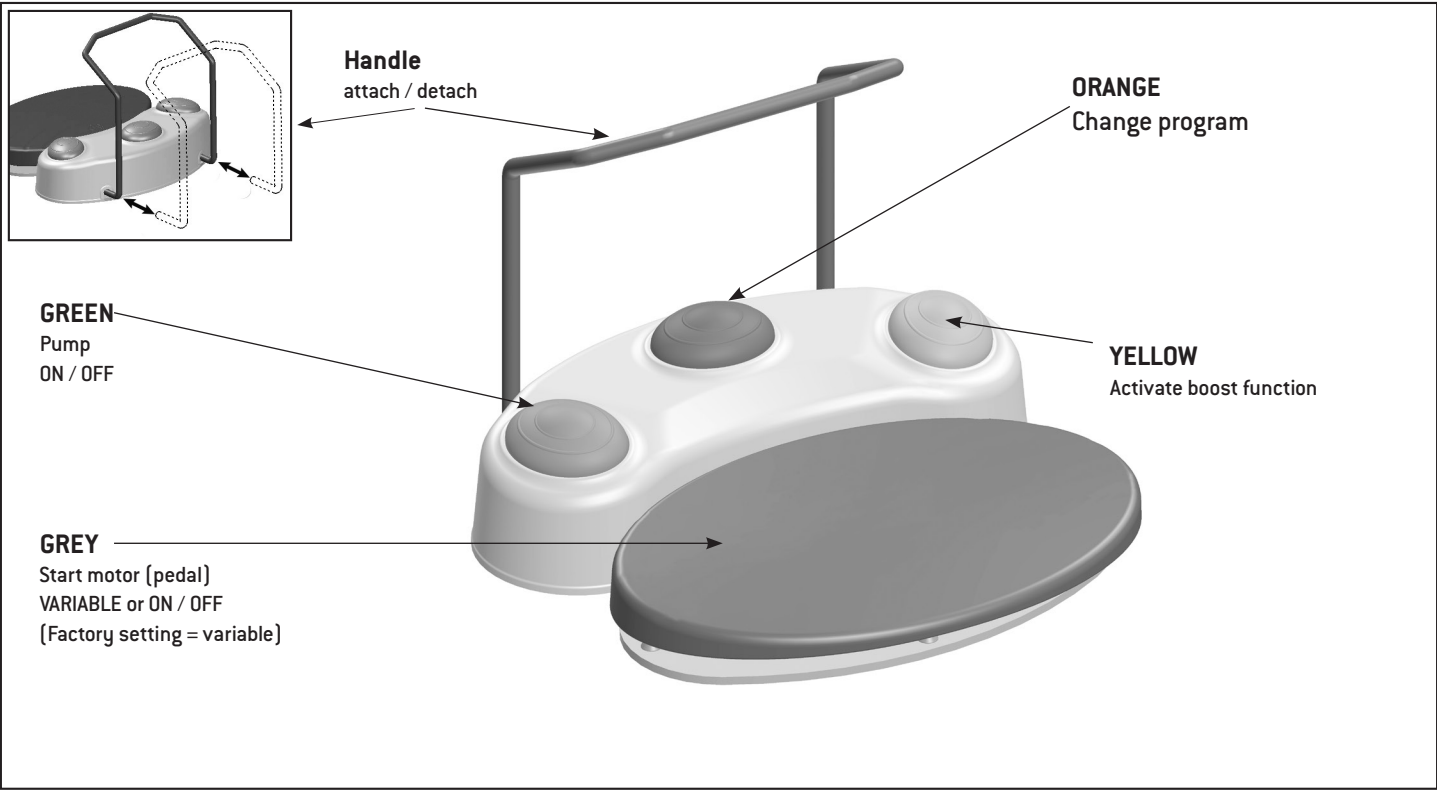
of front panel





Description

Foot control S-N1/S-NW



ORANGE

S-N1 / S-NW: Changing the program

- > Press the ORANGE button to select programs 1 to 3 in ascending order.



When changing from the last program to the first program a longer acoustic signal sounds (risk of injury).

S-N1: Changing the program

- > Keep the ORANGE button depressed to select programs 3 to 1 in descending order.

S-NW: Switching between multiple control units



Keep the ORANGE button pressed to switch between the control units.

Pump ON / OFF

Only when the motor is stationary can the pump be switched on or off by operating the GREEN button.

When the pump is switched off, the pump symbol on the display is crossed out.

- > Press the GREEN button to increase the quantity of coolant in stages.
- > Keep the GREEN button depressed to decrease the quantity of coolant in stages, or to turn this off.

Boost function

Using the boost function, you can boost performance by 20% of the set value for 15 seconds.

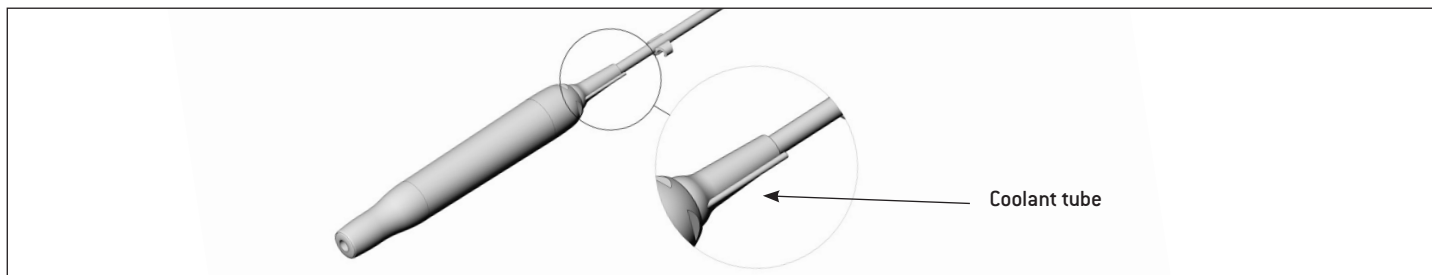
Activate the boost function by pressing the yellow button.

Description

Handpiece with cable



The handpiece with cable must not be disassembled.
The handpiece with cable must not be oiled.



Temperature information



Temperature of the medical device on the operator side:	maximum 56°C (133°F)
Temperature of the medical device on the patient side (front area of the handpiece, LED socket):	maximum 48°C (118.4°F)
Temperature of the working part (instrument):	maximum 41°C (105.8°F)

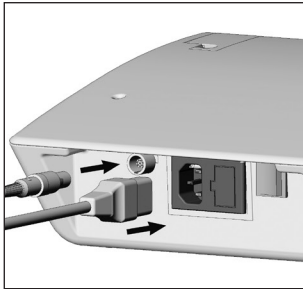
6. Start-up



Place the control unit on a flat, level surface.



Ensure that the control unit can be disconnected from the power supply at any time.



- 1** Connect the mains cable and the foot control.



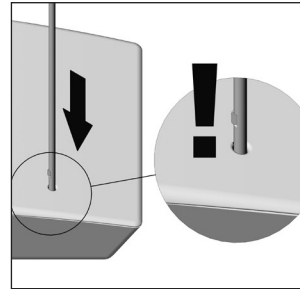
Pay attention to the positioning!



- 2** Insert the handpiece cable.



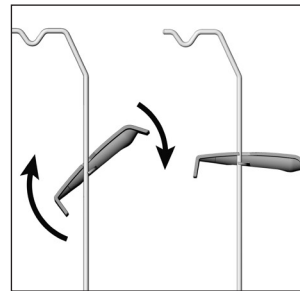
Pay attention to the positioning!



- 3** Insert the stand.

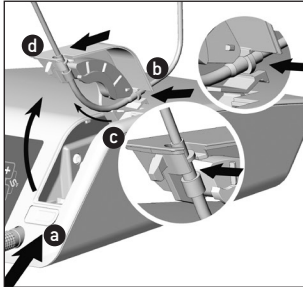


Pay attention to the positioning!
(Maximum load capacity 1.5 kg)



- 4** Attach the universal support and lock it.


Start-up

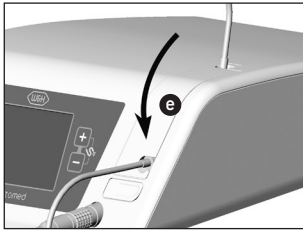


5 Insert the irrigation tubing.

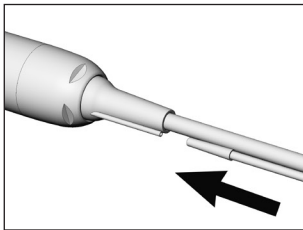
> Open the pump cover. a

> Fit the irrigation tubing b c d .

 Follow the same sequence when removing the irrigation tubing.

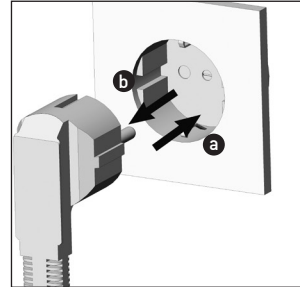


> Close the pump cover. e



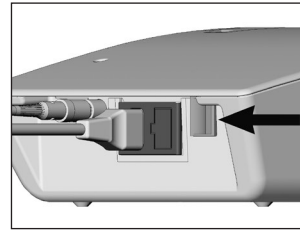
6 Connect the spray tube to the handpiece.

Switching on and off

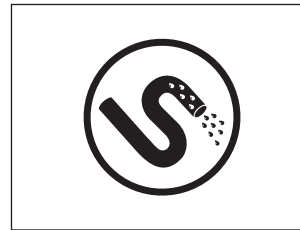


7 Connect the control unit to the power supply. a

Disconnect the control unit from the power supply. b



8 Switch the control unit on or off at the power switch.



9 Once it has been switched on, the coolant filling function will appear on the display and the PLUS/MINUS buttons will flash.



Make sure that the coolant filling function has been carried out prior to every application.



The coolant filling function will only appear on the display if a handpiece is connected.



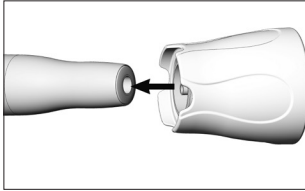
- 1 Coolant filling function
- 2 Press the PLUS/MINUS buttons at the same time to activate the coolant filling function.
- 3 Press any button on the device to stop the coolant filling function.



The coolant filling function can be started at any time by pressing the PLUS/MINUS buttons.

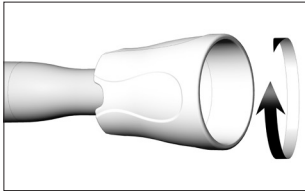
7. Instruments

Insert/remove

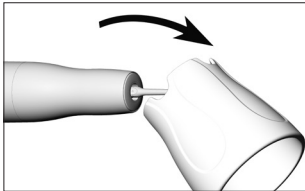


Inserting an instrument

- 1 Position the instrument on the handpiece thread.



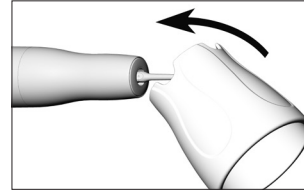
- 2 Turn the instrument changer until it snaps into place.



- 3 Carefully pull off the instrument changer.

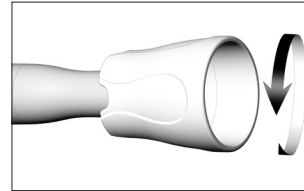


Verify full engagement.



Removing an instrument

- 1 Attach the instrument changer to the instrument.



- 2 Twist off the instrument with the instrument changer.



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

8. Setup settings

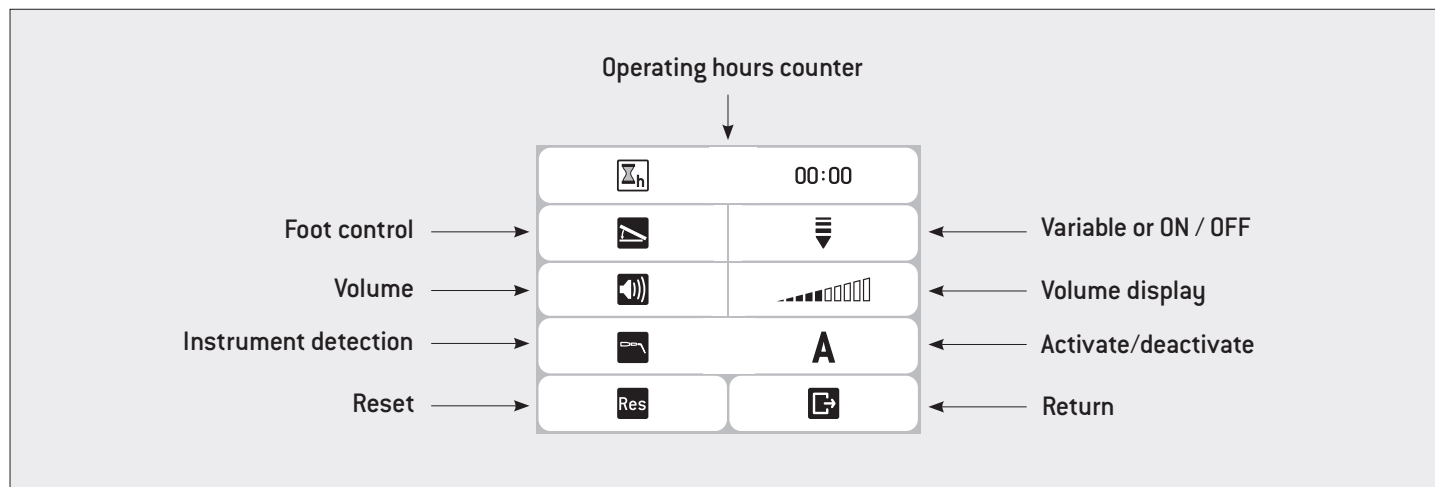
Calling up the setup settings



Press the ▲ and ▼ buttons at the same time to access the setup options.

Press the ▲ or ▼ button to select the setup setting.

The selected Setup setting is framed green.

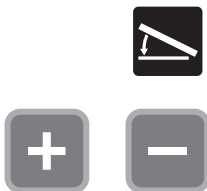


> To exit the setup settings, select Return  using the shift button ▼. Confirm with the PLUS button.



> Instrument detection assists the user and helps to avoid incorrect settings.

To change from VARIABLE to ON / OFF



① Foot control

② Select setting



= VARIABLE (factory setting)

Stepless power regulation of the instrument
(up to the power set in the respective program)



= ON / OFF



① Volume




② Increase volume



③ Decrease volume



Mute

 The control unit will restart after the factory settings have been reset.



① Reset



② Start reset countdown



③ The reset countdown can be interrupted within 5 seconds

9. Operation

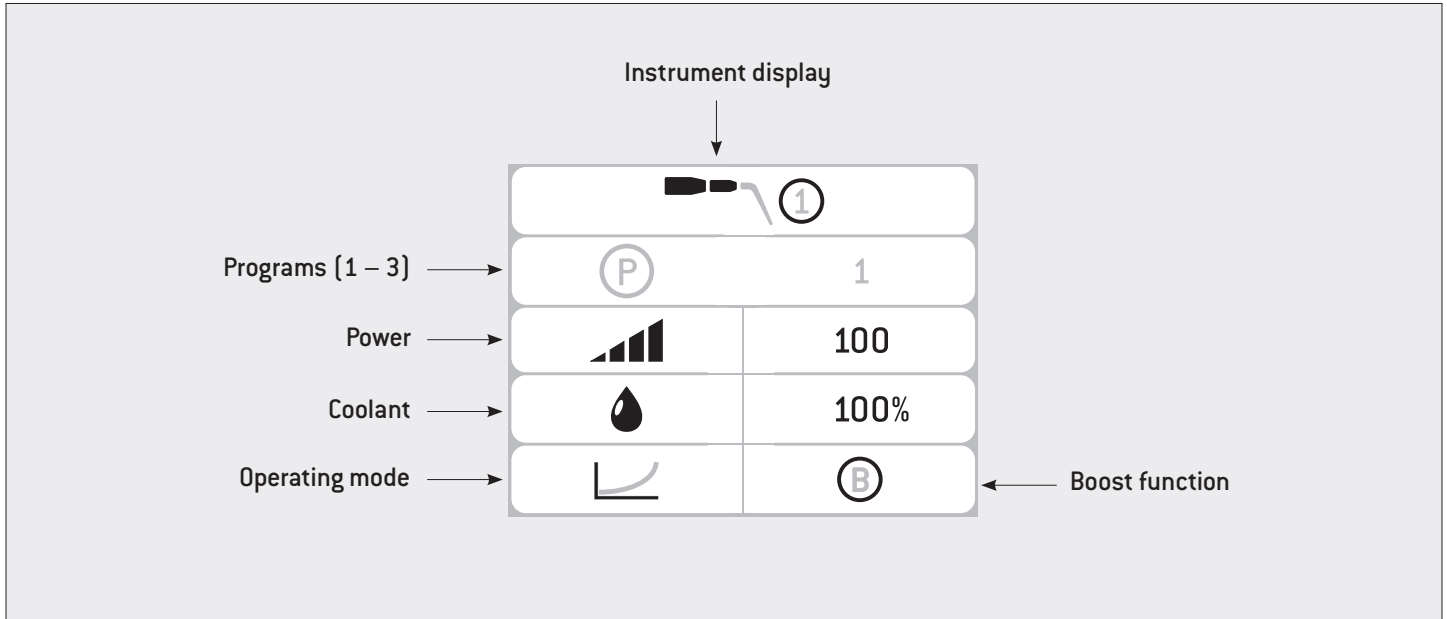
Main menu settings

Calling up the main menu settings



Press the ▲ or ▼ button to select the required menu.

The selected menu is framed green.



Press the ▲ and ▼ button simultaneously to switch from the main menu settings into the setup menu settings.




① Program



② Next program



③ Previous program

 The power range can be set from 5 – 100. Each change is immediately saved in the selected program.




❶ Power



❷ Increase power



❸ Reduce power

 By keeping the PLUS / MINUS button pressed you can continuously increase / decrease the power.



The instrument's maximum power setting is shown on the instrument card.



The coolant quantity can be set from 10 – 100. Each change is immediately saved in the selected program. You can also change the coolant quantity during use.



① Coolant



② Increase flow rate in 10 % steps



③ Decrease flow rate in 10 % steps



Coolant OFF




The max. operating time without coolant is 15 seconds.



By keeping the PLUS / MINUS button pressed you can continuously increase / decrease the coolant flow rate.



Press the PLUS/MINUS buttons at the same time to activate the coolant filling function at any time.

 Each change is immediately saved in the selected program.
You cannot change the operating mode during application.



① Changing the operating mode



> Basic: The handpiece power remains the same irrespective of the load on the instrument.





















> Smooth: In the "Smooth" mode the power is reduced with increasing pressure on the instrument.



> Power: In the "Power" mode the power is increased with increasing pressure on the instrument.

10. Factory settings









Instrument group 1 – 3

	Group 1			Group 2			Group 3		
Program	P1	P2	P3	P1	P2	P3	P1	P2	P3
Power	20	30	40	45	55	65	70	80	90
Coolant	50%	50%	50%	50%	50%	50%	60%	60%	60%
Operating mode									
*Boost function									








* Using the boost function, you can boost performance by 20% of the set value for 15 seconds.
Activate the boost function by pressing the yellow button on the foot control.

11. Error messages

Error	Description	Solution
	Foot control not recognized	<ul style="list-style-type: none"> > Connect foot control correctly > Connect correct foot control
	Foot control error	<ul style="list-style-type: none"> > Connect foot control correctly > Connect correct foot control
	Info: Foot control recognized	
	Handpiece not recognized	<ul style="list-style-type: none"> > Connect handpiece > Check LED socket (correctly attached, defective) > Check handpiece coupling > Check supply hose
	Handpiece error	<ul style="list-style-type: none"> > Handpiece must be dry > Check handpiece coupling > Check supply hose > Check instrument
	Info: Handpiece recognized	
	Instrument not recognized	<ul style="list-style-type: none"> > Insert the instrument > Check instrument (only use W&H-approved instruments)
	Info: Instrument group recognized	

Error messages

Error	Description	Solution
	Instrument detection error	<ul style="list-style-type: none"> > Check LED socket (correctly attached, defective) (Activate emergency mode [see pages 40–41] or change the LED socket)
	Button (keypad) pressed during power-on	<ul style="list-style-type: none"> > Switch off the device and restart
	Error electronics temperature	<ul style="list-style-type: none"> > Switch off device and allow to cool down > Observe permissible ambient temperature > Observe operating mode
	Scaler timeout	<ul style="list-style-type: none"> > Check foot control (must not be active for longer than 15 minutes without interruption)
	System error	<ul style="list-style-type: none"> > Switch off the device and restart > If the error message appears again, contact an authorized W&H service partner

- > If the described problem cannot be resolved, the unit will need to be inspected by an authorized W&H service partner.
- > In case of a total system failure, switch the control unit off and on again.

12. Emergency mode



Only activate the emergency mode if instrument detection fails during treatment.



Press the ▲ and ▼ buttons at the same time to access the setup settings.




① Press the PLUS/MINUS button to deactivate instrument tip detection.



② Instrument tip detection deactivated.



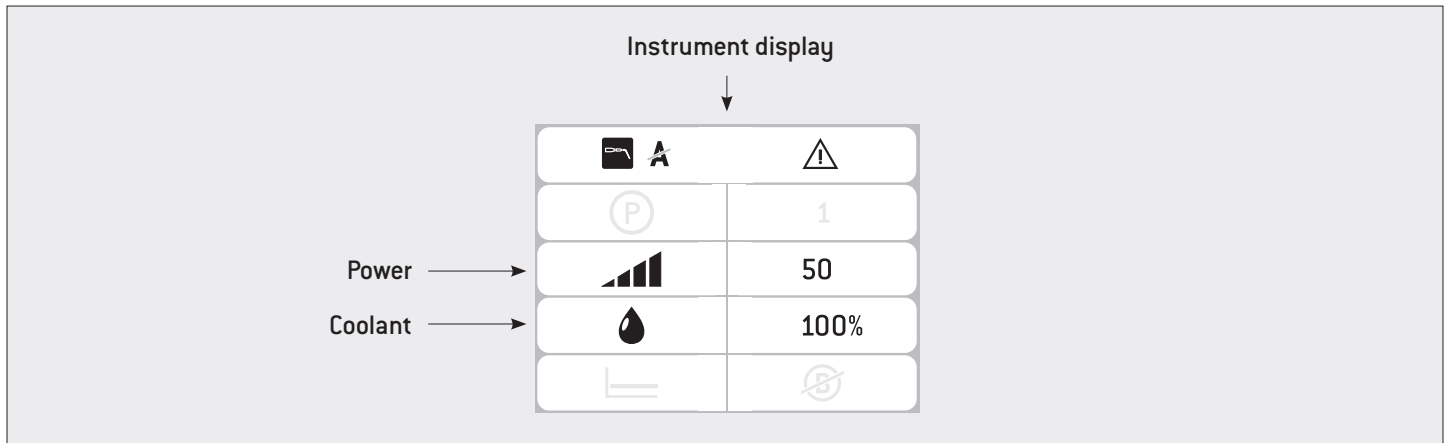
To exit the setup settings, select Return  using the shift button ▼ .
Confirm with the PLUS button.



③ Press the PLUS/MINUS buttons at the same time to activate the coolant filling function.


Emergency mode

In emergency mode, it is not possible to switch between programs, change the mode or activate the boost function.



The power range can be set between 5 and 70.

The coolant quantity can be set between 10 and 100.

 The coolant quantity cannot be deactivated in emergency mode.



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).



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 Österreichische 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 500 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 handpiece with cable 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, the universal support and the stand with disinfectant.



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

-  > Do not place the handpiece with cable, the universal support, the stand and the instrument changer in liquid disinfectant or in an ultrasonic bath.

Handpiece with cable / Universal support / Stand / Instruments / Instrument changer

- > Clean the handpiece with cable, the universal support, the stand, the instruments and the instrument changer under running tap water [$< 35\text{ °C}$ / $< 95\text{ °F}$].
- > Rinse and brush off all internal and external surfaces.
- > Remove any liquid residues using compressed air.



Control unit

- > Do not immerse the control unit in water or clean it under running water.

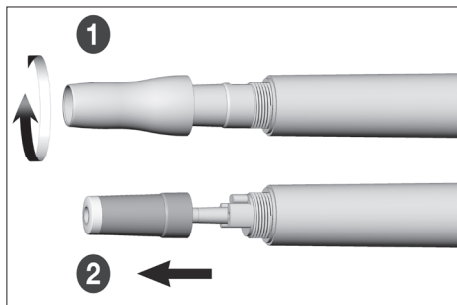


Instruments

- > Clean and disinfect diamond coated instruments in an ultrasonic bath.



Evidence of the basic suitability of the instruments 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 agent and disinfectant “Stammopur DR8” (DR H Stamm, Berlin) and “CaviCide™” (Metrex).



Disassembling the handpiece / Replacing of the LED socket

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

Cleaning of the coolant tubes / spray nozzles



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

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

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!

Wash the light source with cleaning fluid and a soft cloth.



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.

Handpiece with cable / Universal support / Stand / Instruments / Instrument changer

-  > W&H recommends wiping down with disinfectant.
-  Evidence of the basic suitability of the handpiece with cable, the universal support, the stand, the instruments and the instrument changer for effective manual disinfection was provided by an independent test laboratory using the "mikrofid® AF wipes" disinfectant (Schülke & Mayr GmbH, Norderstedt) and "CaviWipes™" (Metrex).

Handpiece with cable / Universal support / Stand / Instruments / Instrument changer



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.



- > The control unit and foot control are not approved for automated cleaning and disinfection.



Evidence of the basic suitability of the handpiece with cable, the universal support, the stand, 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

Handpiece with cable / Universal support / Stand / Instruments / Instrument changer



- > Ensure that the handpiece with cable, the universal support, the stand, the instruments and the instrument changer are completely dry internally and externally after cleaning and disinfection.
- > Remove liquid residues using compressed air.

Inspection – Handpiece with cable / Universal support / Stand / Instruments / Instrument changer



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

Handpiece with cable / Universal support / Instruments / Instrument changer



Pack the handpiece with cable, the universal support, 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.

Handpiece with cable / Universal support / Instruments / Instrument changer




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 universal support, 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 universal support, 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

Handpiece with cable / Universal support / Instruments / Instrument changer



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

14. Service



Periodic inspection

Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.

The periodic inspection covers the complete medical device and must only be performed by an authorized service partner.

Service

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.



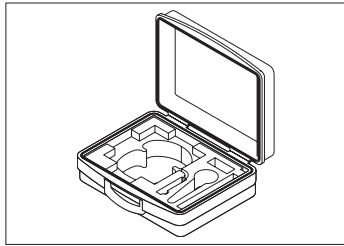
> Always return equipment in the original packaging!

> Do not coil the cable around the handpiece and do not twist or kink the handpiece cable. (Risk of damage)

15. Accessories, consumables, spare parts and other recommended medical devices by W&H

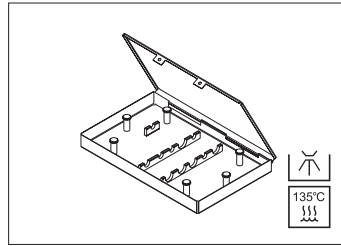


Use only original W&H accessories and spare parts or accessories approved by W&H!
Suppliers: W&H partners (Link: <https://www.wh.com>)



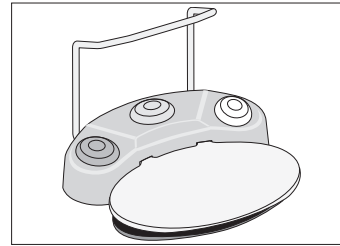
07945930

Transportation case



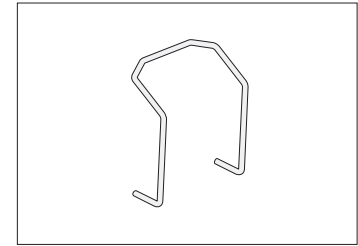
07172900

Cassette



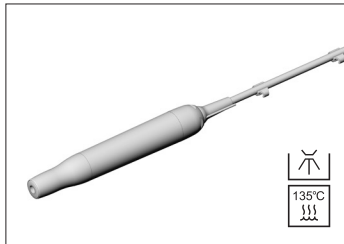
07004400

Foot control S-N1
30264001
Foot control S-NW



04653500

Handle for foot control

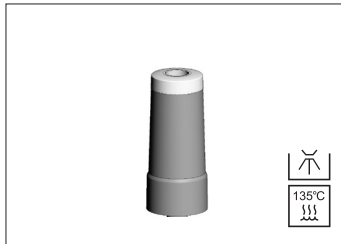


06985000

Handpiece with 1,8 m cable
incl. 5 clips

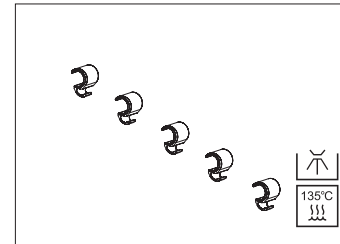
07159200

Handpiece with 3,5 m cable
incl. 10 clips



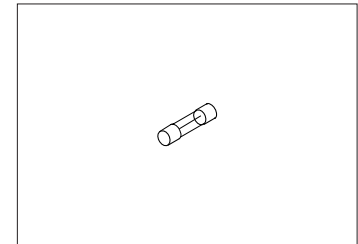
06205600

LED socket



08046870

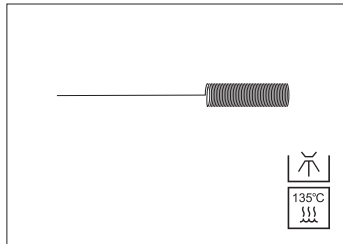
Clips [5 pcs]



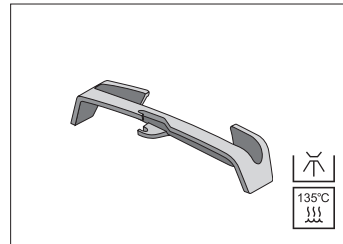
06661800

Fuse T1,25AH

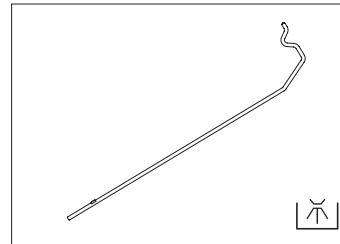
Accessories, consumables, spare parts and other recommended medical devices by W&H



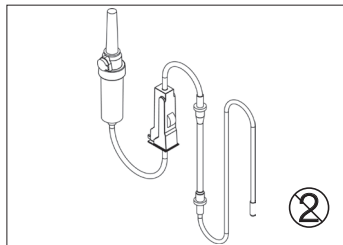
00636901
Nozzle cleaner



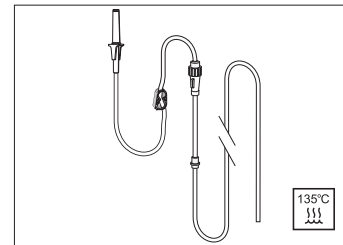
07721800
Universal support



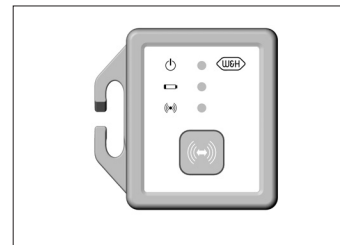
04005900
Stand



04363600
Irrigation tubing set 2.2 m
(3 pcs, disposable item)



04719400
Irrigation tubing set 2.2 m



07795800
SPI dongle

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



16. Technical data

Control unit	SA-320
Supply voltage:	100 – 130 V / 220 – 240 V
Frequency:	50 – 60 Hz
Permitted voltage fluctuation:	±10 %
Nominal current:	0.1 – 1.0 A / 0.1 – 0.5 A
Mains fuse:	2 x 250 V – T1.25AH
Max. power consumption:	90 VA
Max. output power:	24 W
Operating frequency:	22 – 35 kHz
Coolant flow rate at 100 %:	at least 50 ml/min
Operating mode:	S3 (1min/6min)
Dimensions in mm (WxDxH):	256 x 305 x 109
Weight in kg:	7

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

Technical data

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Devices according to IEC 60601-1 / ANSI/AAMI ES 60601-1



Class II medical electrical equipment (protective earth conductor used for functional earth connection only!)



The medical device is classed as equipment without protection against the ingress of water (IPX0).



Type B applied part (not suitable for intracardiac application)



S-N1 / S-NW are waterproof according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

17. 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.

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



RF communication equipment

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.



W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.



Use of this medical device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this medical device and the other equipment should be observed to verify that they are operating normally.



The medical device is not intended for use in the vicinity of HF surgical devices.

Results of the electromagnetic tests

Requirement	Class / Test Level*		
Electromagnetic emissions			
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: ± 2 kV, ± 4 kV, ± 6 kV, ± 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		
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		

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

18. 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

W&H course certificate

for the user

The user has been trained to use the medical device correctly in accordance with the legal regulations (medical devices marketing regulations, medical devices act).

Particular attention has been paid to the chapters on safety notes, start-up, operation, hygiene and maintenance, and service (regular inspections).

Product name	Serial number (SN)
Manufacturer with address	
Distributor with address	

Name of the user	Date of birth and/or personnel number
Hospital/practice/department with address	
Signature of the user	
The signature confirms that the user has been trained to use the medical device and has understood the content.	

Name of the instructor	Date of instruction
Address of the instructor	
Signature of the instructor	



W&H course certificate

for the instructor

The user has been trained to use the medical device correctly in accordance with the legal regulations (medical devices marketing regulations, medical devices act). Particular attention has been paid to the chapters on safety notes, start-up, operation, hygiene and maintenance, and service (regular inspections).

Product name	Serial number (SN)
Manufacturer with address	
Distributor with address	



Name of the user	Date of birth and/or personnel number
Hospital/practice/department with address	
Signature of the user	
The signature confirms that the user has been trained to use the medical device and has understood the content.	



Name of the instructor	Date of instruction
Address of the instructor	
Signature of the instructor	

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 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.



Open Source Software

The software running this product was developed by utilization of the library QT of Digia. As kernel Linux is applied, the initial starting sequence is carried out by using the bootloader U-Boot. For CANopen communication CanFestival is applied.

These and all other software components are copyrighted by W&H Dentalwerk Bürmoos GmbH or third parties.

The source code of the used software components (Linux, Qt, U-Boot and CanFestival) will be provided on request, charging all arising expenses. Please contact: opensource@wh.com

There is no warranty transferring this software, neither implied warranty nor express warranty.

You will find further information concerning the applied license versions and the complete license texts under www.wh.com/en_global/gnu

Alternatively, you can obtain them directly from the manufacturer.



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