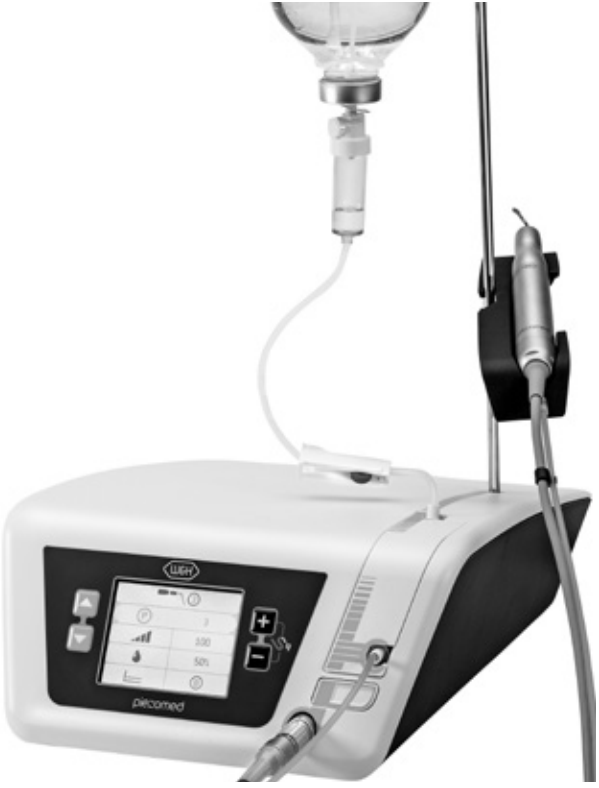
Instructions for Use



CE
0297

piezomed

SA-320

Contents

Contents

Symbols in the Instructions for Use

WARNING!
(risk of injury)

ATTENTION!
(to prevent damage occurring)

General explanations, without risk to persons or objects

Thermo washer disinfectable

Sterilizable up to
the stated temperature

Suitable for ultrasonic bath

Type B applied part (not suitable for intracardiac application)

Symbols

on the control unit


Follow Instructions for Use


Date of manufacture


Do not dispose of with domestic waste


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


CE marking with identification number of the Notified Body


Class II equipment


Foot control


On / Off


Electric fuse


Earth

Medical Device

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, CSA CAN/CSA-C22.2 NO. 60601-1:2014. 25UX – Control No.

Catalogue number

Serial number

V Supply voltage

AC Alternating current

VA Power consumption of the control unit

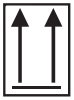
A Supply current

Hz Frequency of the alternating current


Manufacturer

Symbols on the packaging

CE marking
with identification number
of the Notified Body



This way up

Fragile, handle with care

Keep dry

"Der Grüne Punkt" (The Green Dot) trademark of Duales System Deutschland GmbH

MD

Medical Device

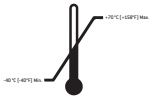
MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005, ANSI/AAMI ES60601-1: A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012, CAN/CSA-C22.2 No. 60601-1:2008, CSA CAN/CSA-C22.2 NO. 60601-1:2014.
25UX – Control No.

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

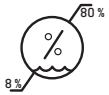
Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard

HIBC

Data structure in accordance with Health Industry Bar Code



Temperature limitation



Humidity limitation

REF

Catalogue number

SN

Serial number

Date of manufacture

Manufacturer

℞ 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.

Symbols on the irrigation tubing set

CE marking
with identification number
of the Notified Body

Not for re-use

Latex-free

Batch code

Use by

Sterilization with ethylene oxide

Catalogue number

Manufacturer

Keep away from heat

Do not resterilize

Do not use when package is damaged

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

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.

Data structure in accordance with Health Industry Bar Code

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

CE 0297

Production according to EU Directive
The medical device meets the requirements of Directive 93/42/EEC.

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.

In addition to unauthorized assembly, installation, modification of or repairs to the control unit and non-compliance with our instructions, improper use will void the warranty and release us from all 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. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions in regard to EMC and must be installed and put into operation in accordance with the EMC notes included.

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.

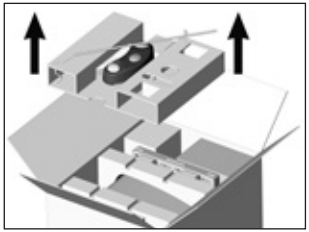
HF communications equipment
Portable HF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.

The medical device may be interfered by other equipment, even if these other devices comply with CISPR (International special committee on radio interference) emission requirements.

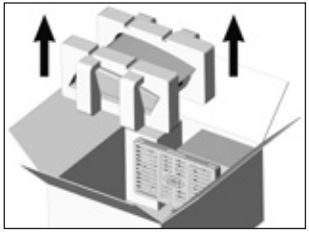
Use of this medical device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this medical device and the other equipment should be observed to verify that they are operating normally.

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

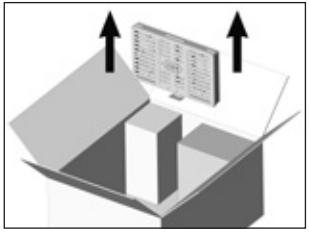
3. Unpacking



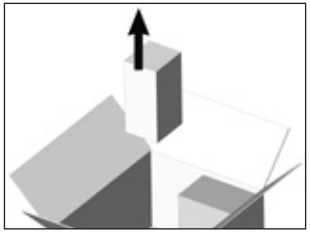
❶ Lift out the insert with the stand and the foot control.



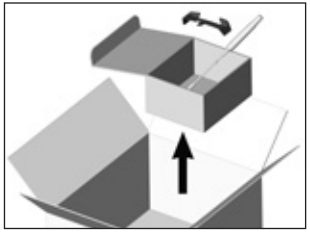
❷ Lift out the insert with the control unit.



❸ Remove the sterilization cassette.



❹ Remove the irrigation tubing set.



❺ 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.

4. Scope of delivery

	Control unit	30078000	30078001	30078003	30078004	30078005	30078006	30078007
REF 06985000	Handpiece with 1.8 m cable	X		X	X	X		
REF 07159200	Handpiece with 3.5 m cable		X				X	X
REF 07004400	Foot control S-N1	X	X					
REF 30264001	Foot control S-NW					X		X
REF 07795800	SPI dongle				X	X	X	X
REF 04653500	Handle for foot control	X	X			X		X
REF 436360	Irrigation tubing set 2.2 m (3 pcs, disposable item)	X		X	X	X		
REF 436410	Irrigation tubing set 3.8 m (3 pcs, disposable item)		X				X	X
REF 07172900	Sterilization cassette	X	X		X	X	X	X
REF 07173100	Instrument set “Bone“	X	X		X	X	X	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						

5. 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.

The control unit is classed as "conventional equipment" (closed equipment without protection against the ingress of water).

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 is easily accessible.

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. 50%.
- > 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.

Safety notes

Risks due to electromagnetic fields

This handpiece with cable complies with the reference values defined in EN 50527-2-1/2016 for active implantable medical devices (AIMD) and cardiac pacemakers.

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillators (ICD) can be affected by electric, magnetic and electromagnetic fields. This medical device is suitable for use on patients with unipolar and bipolar pacemakers or ICD, if a safety distance between the control unit and the cardiac pacemaker or ICD of at least 30 cm (11,8 inch) is maintained.

> Find out if patient or user have implanted systems before using the medical device and consider the application.
> Weigh the risks and benefits.
> Make appropriate emergency precautions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.

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.
> Use the W&H irrigation tubing set or accessories approved by W&H.

Irrigation tubing set

Sterile disposable irrigation tubing sets are supplied with the equipment.

> Note the expiration date and only use disposable irrigation tubing with undamaged packaging.
> Replace the disposable irrigation tubing immediately after every treatment.
> Follow your local and national laws, directives, standards and guidelines for disposal.

Hygiene and maintenance prior to initial use

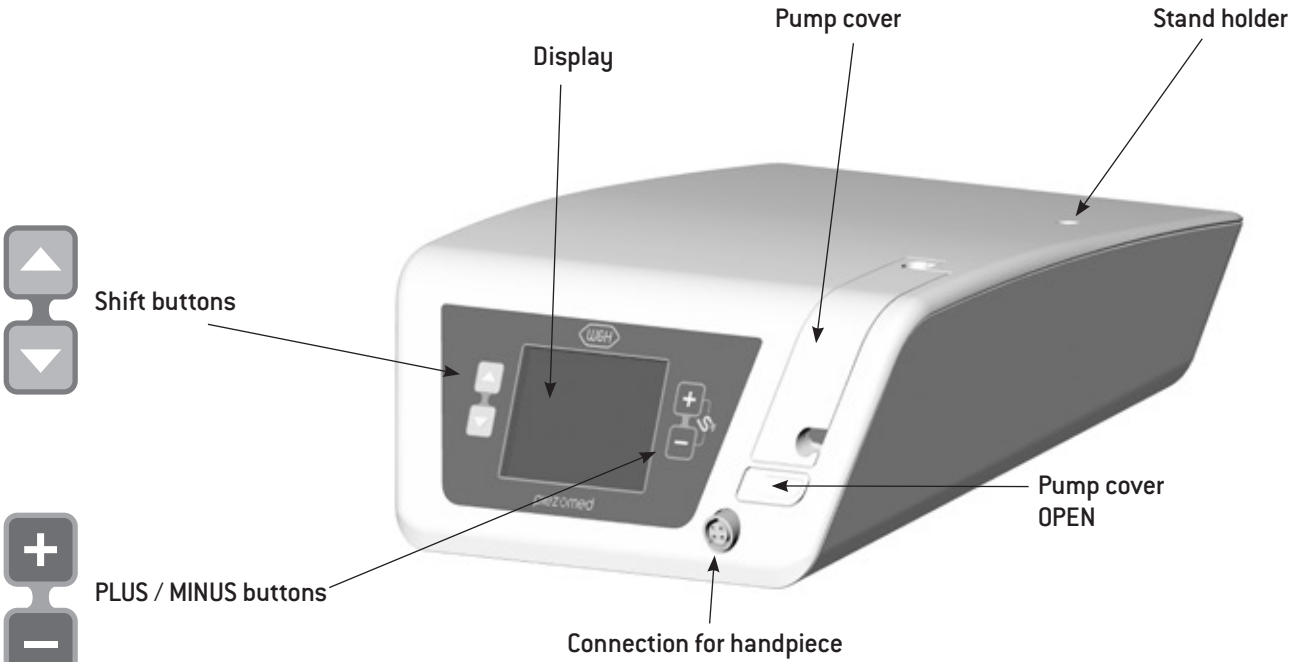
> Clean the control unit.
> Clean and disinfect the handpiece with cable, the universal support, the stand, the instruments and the instrument changer.
> Sterilize the handpiece with cable, the universal support, the instruments and the instrument changer.

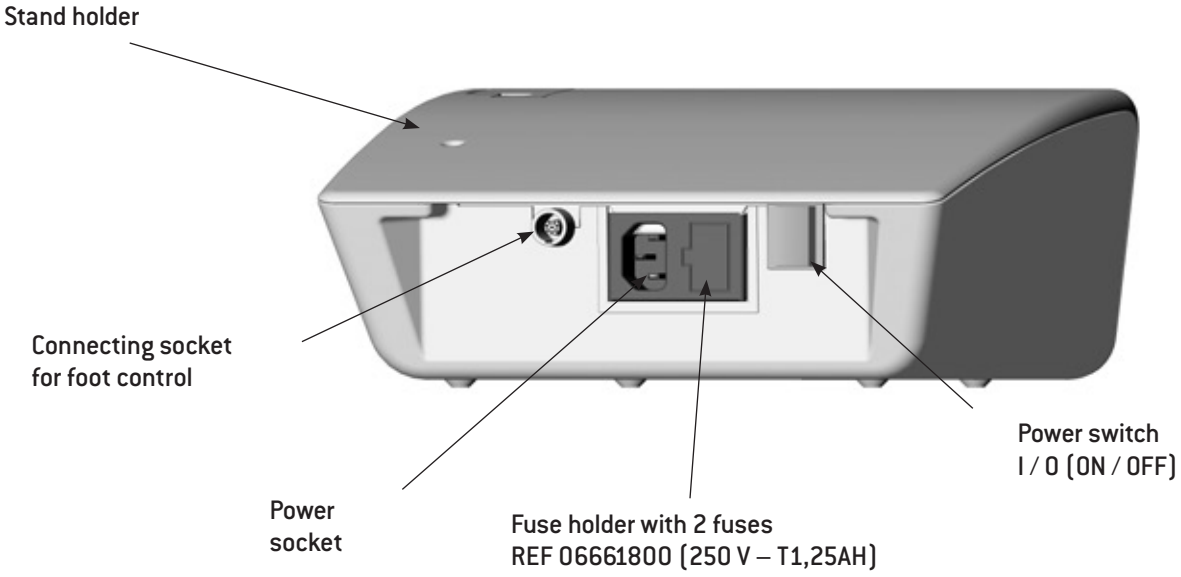
Test run

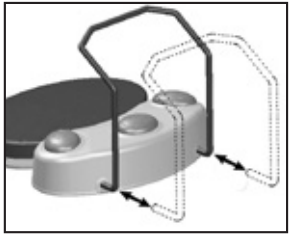
Do not hold the handpiece with cable at eye level!

> 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.


Pump cover
Stand holder
Display
Shift buttons
Pump cover
OPEN
PLUS / MINUS buttons
Connection for handpiece


Stand holder
Connecting socket
for foot control
Power
socket
Fuse holder with 2 fuses
REF 06661800 (250 V – T1,25AH)
Power switch
I / O (ON / OFF)



Handle
attach / detach

ORANGE
Change program

GREEN
Pump
ON / OFF

YELLOW
Activate boost function

GREY
Start motor (pedal)
VARIABLE or ON / OFF
(Factory setting = variable)

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

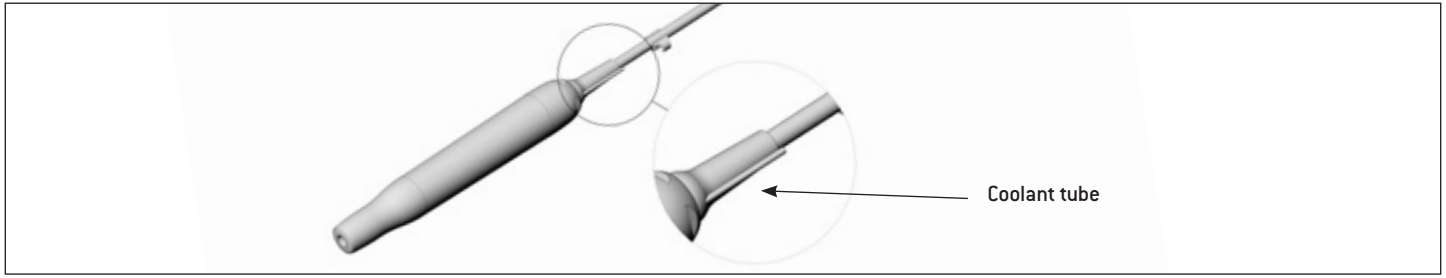
Only when the motor is stationary can the pump be switched on or off by operating the GREEN button.
When the pump is switched off, the pump symbol on the display is crossed out.

> 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.

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



The handpiece with cable is a type B applied part (not suitable for intracardiac application).

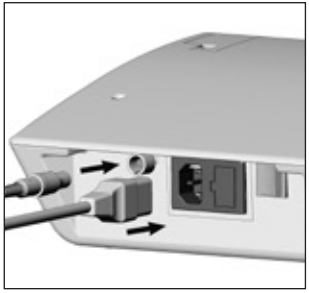
Temperature information

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

7. Start-up

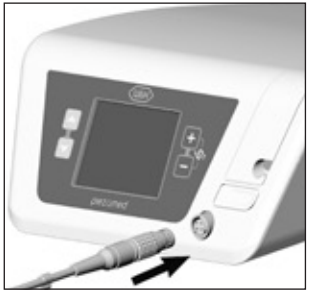
Place the control unit on a flat, level surface.

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



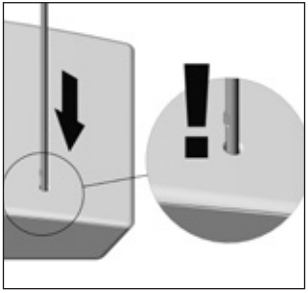
❶ Connect the mains cable and the foot control.

Pay attention to the positioning!



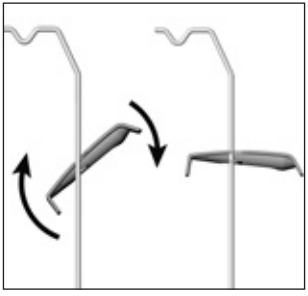
❷ Insert the handpiece cable.

Pay attention to the positioning!

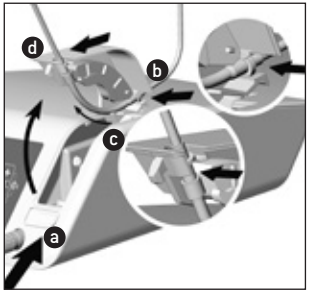


❸ Insert the stand.

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



❹ Attach the universal support and lock it.

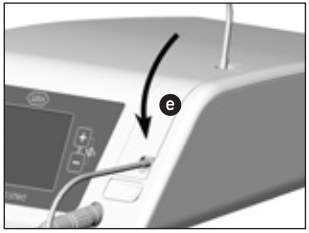


❺ Insert the irrigation tubing.

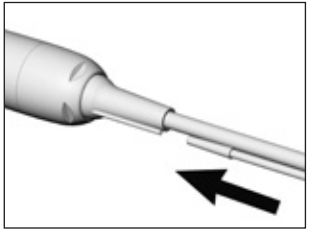
> Open the pump cover. ⓐ

> Fit the irrigation tubing ⓑⓒⓓ .

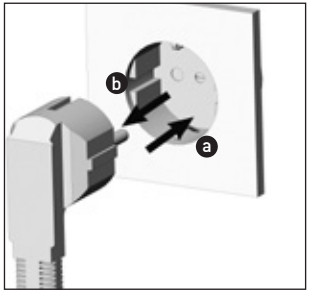
Follow the same sequence when removing the irrigation tubing.



> Close the pump cover. ⓔ

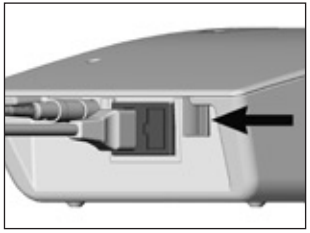


❻ Connect the spray tube to the handpiece.

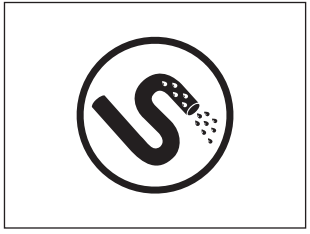


❼ Connect the control unit to the power supply. ⓐ

Disconnect the control unit from the power supply. ⓑ



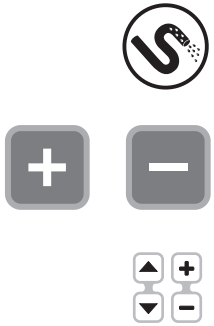
❽ Switch the control unit on or off at the power switch.



❾ 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.

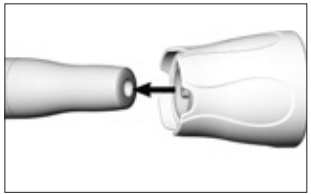


❶ Coolant filling function

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

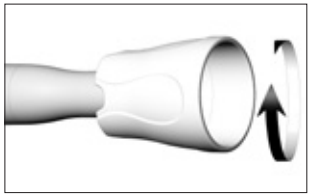
❸ Press any button on the device to stop the coolant filling function.

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

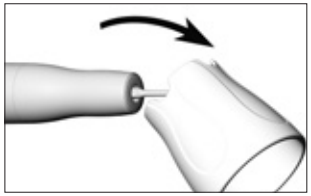


Inserting an instrument

❶ Position the instrument on the handpiece thread.

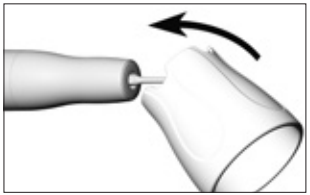


❷ Turn the instrument changer until it snaps into place.



❸ Carefully pull off the instrument changer.

⚠ Verify full engagement.



Removing an instrument

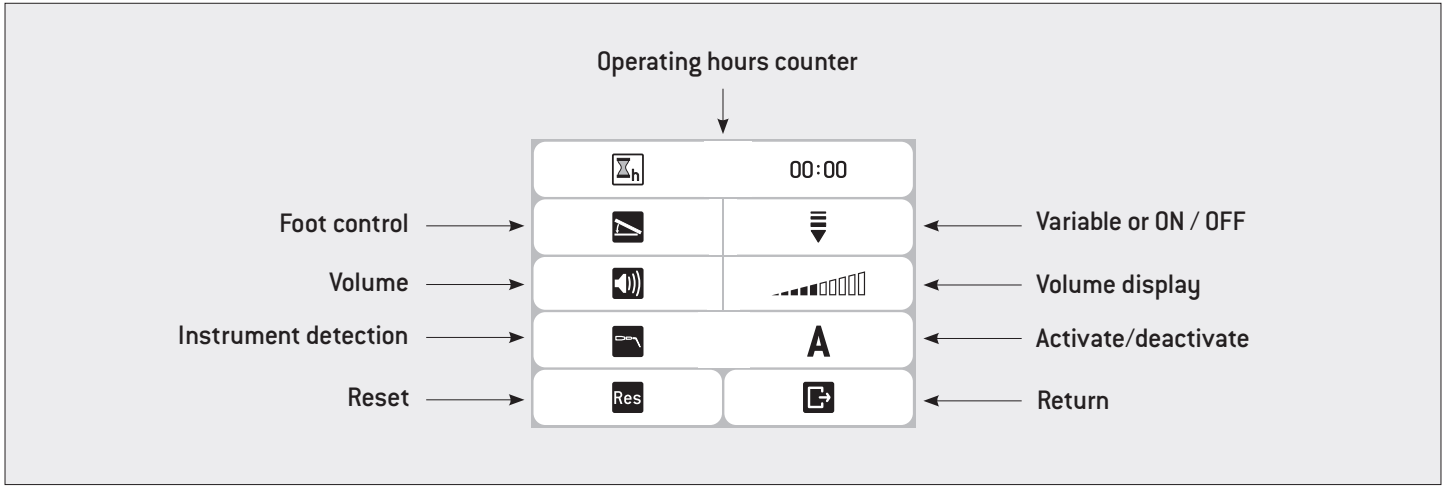
❶ Attach the instrument changer to the instrument.

❷ Twist off the instrument with the instrument changer.

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

Calling up the setup settings

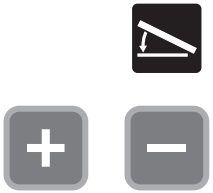
Press the ▲ and ▼ buttons at the same time to access the setup options.
Press the ▲ or ▼button to select the setup setting.
The selected Setup setting is framed green.



> 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



❶ Foot control

❷ Select setting

= VARIABLE (factory setting)
Stepless power regulation of the instrument
(up to the power set in the respective program)

= ON / OFF

❶ Volume

❷ Increase volume

❸ Decrease volume

Mute

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

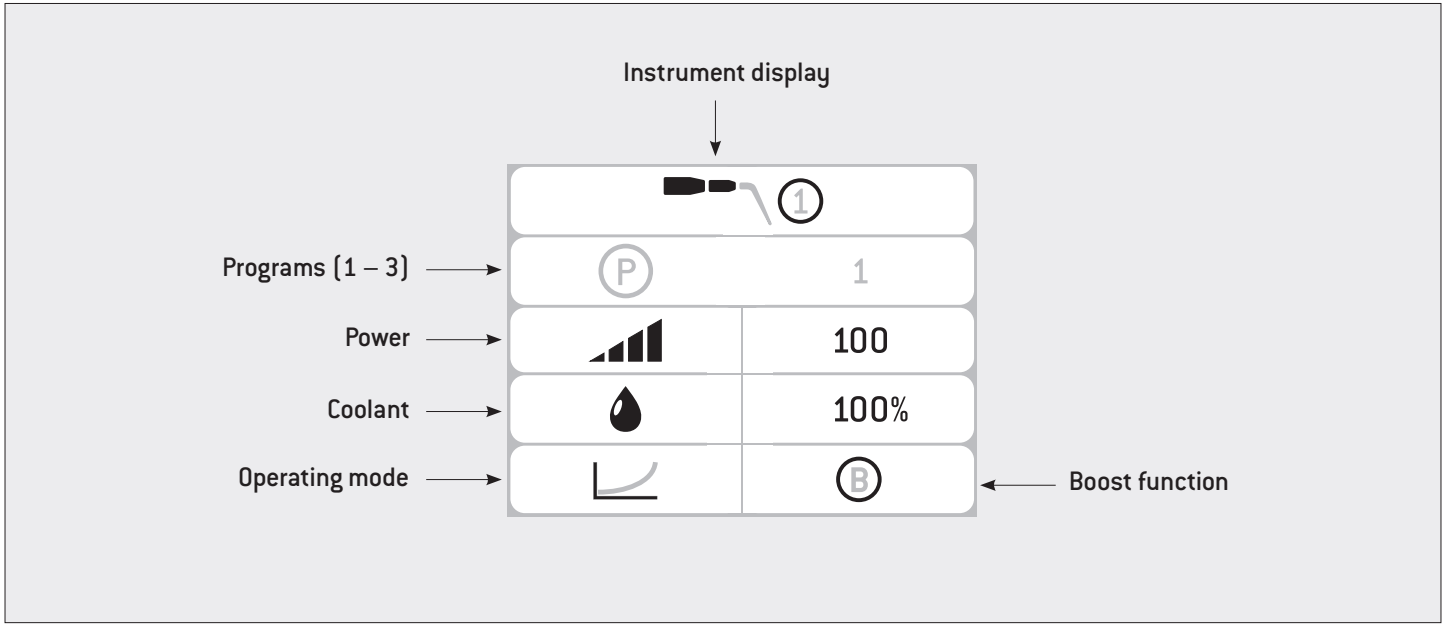
❶ Reset

❷ Start reset countdown

❸ The reset countdown can be interrupted within 5 seconds

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.

❶ Program

❷ Next program

❸ 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.

❶ Coolant

❷ Increase flow rate in 10 % steps

❸ 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.

❶ 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.

11. 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.

12. Error messages

Error	Description	Solution
	Foot control not recognized	> Connect foot control correctly > Connect correct foot control
	Foot control error	> Connect foot control correctly > Connect correct foot control
	Info: Foot control recognized	
	Handpiece not recognized	> Connect handpiece > Check LED socket (correctly attached, defective) > Check handpiece coupling > Check supply hose
	Handpiece error	> Handpiece must be dry > Check handpiece coupling > Check supply hose > Check instrument
	Info: Handpiece recognized	
	Instrument not recognized	> Insert the instrument > Check instrument (only use W&H-approved instruments)
	Info: Instrument group recognized	

Error messages

Error	Description	Solution
	Instrument detection error	> Check LED socket (correctly attached, defective) (Activate emergency mode [see pages 40–41] or change the LED socket)
	Button (keypad) pressed during power-on	> Switch off the device and restart
	Error electronics temperature	> Switch off device and allow to cool down > Observe permissible ambient temperature > Observe operating mode
	Scaler timeout	> Check foot control (must not be active for longer than 15 minutes without interruption)
	System error	> 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.

13. 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.

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

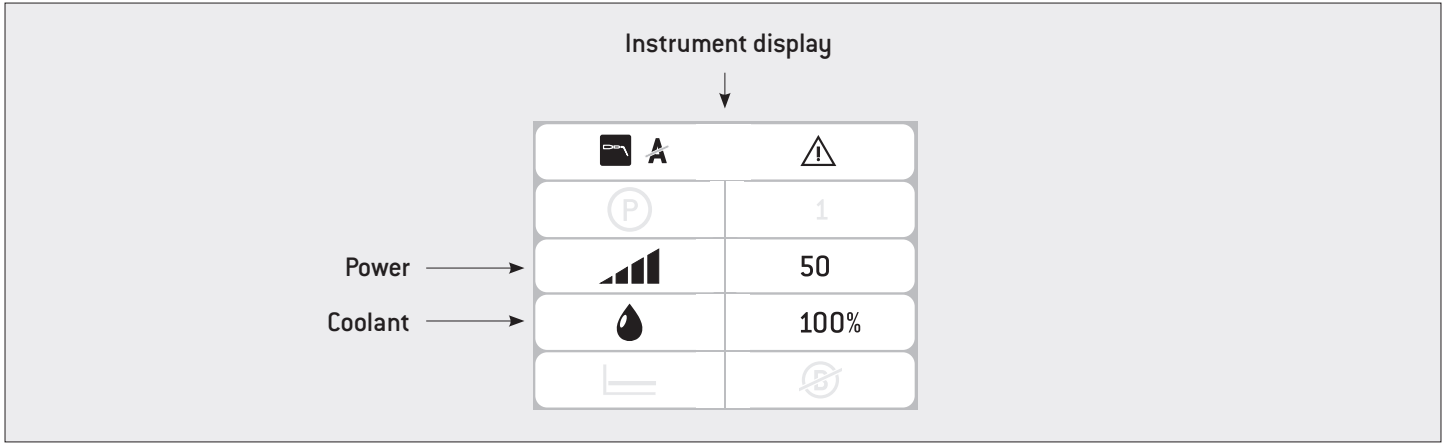
❷ Instrument tip detection deactivated.

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

❸ 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 disinfectant.

Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfecting 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 °C / < 95°F).
> Rinse and brush off all internal and external surfaces.
> Remove any liquid residues using compressed air.

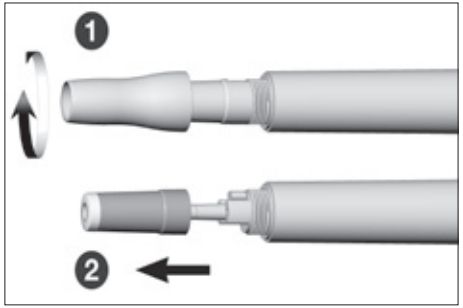
Control unit

> 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

❶ Unscrew the handpiece cap.
❷ Pull out the LED socket.

Cleaning of the coolant tubes / spray nozzles

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

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

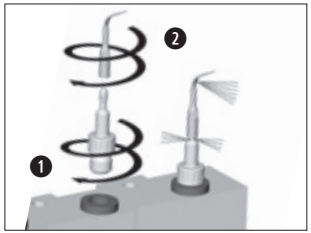
> W&H recommends wiping down with disinfectant.

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 ”mikrozid® 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.

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



Mechanical cleaning and disinfection internal and external

❶ Screw the W&H adaptor into the adaptor on the injector rail.

❷ Screw the instrument onto the W&H adaptor.

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.

15. 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

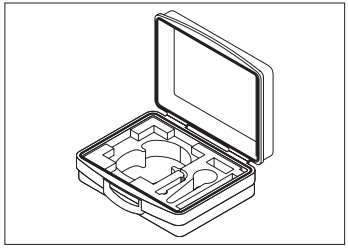
Repairs and returns
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

> Ensure that the medical device has been completely processed before returning it.

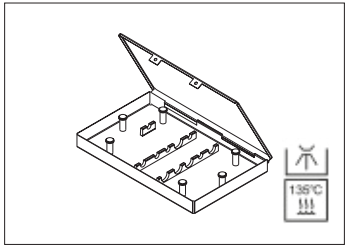
> Always return equipment in the original packaging!
> Do not coil the cable around the handpiece and do not twist or kink the handpiece cable. (Risk of damage)

16. W&H accessories and spare parts

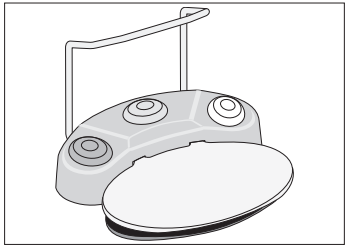
Use only original W&H accessories and spare parts or accessories approved by W&H!
Suppliers: W&H partners (Link: https://www.wh.com)



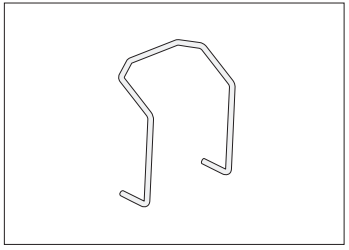
07945930
Transportation case



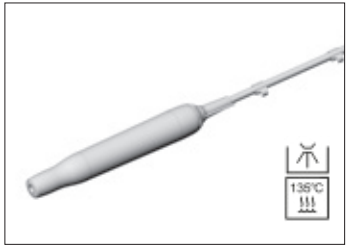
07172900
Sterilization cassette



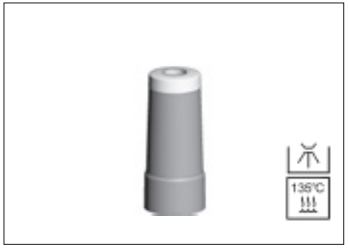
07004400
Foot control S-N1
30264001
Foot control S-NW



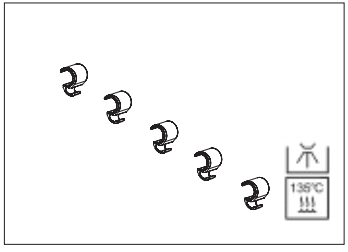
04653500
Handle for foot control



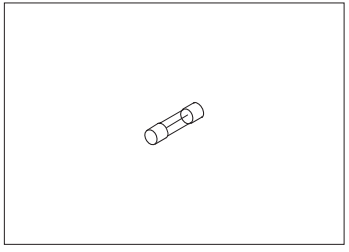
06985000
Handpiece with 1,8 m cable
incl. 5 clips
07159200
Handpiece with 3,5 m cable
incl. 10 clips



06205600
LED socket

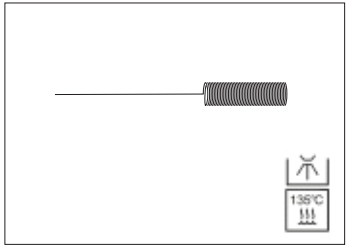


08046870
Clips (5 pcs)

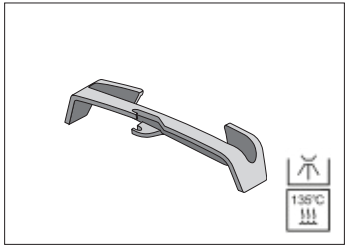


06661800
Fuse T1,25AH

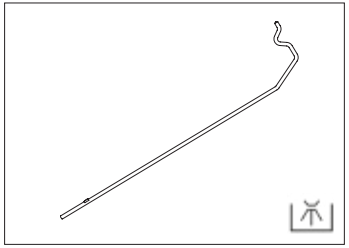
W&H accessories and spare parts



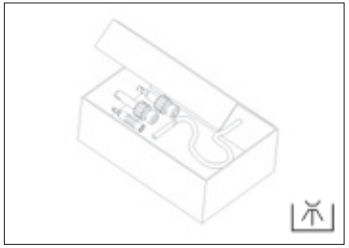
00636901
Nozzle cleaner



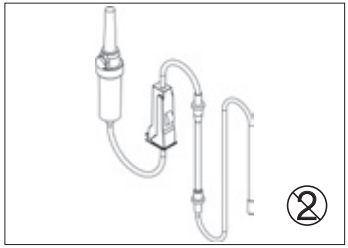
07721800
Universal support



04005900
Stand

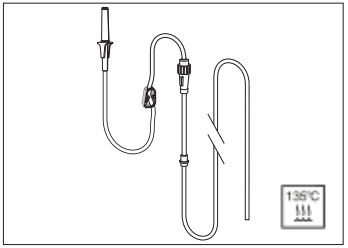


07233500
W&H Adapter kit



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

04364100
Irrigation tubing set 3.8 m
(3 pcs, disposable item)



04719400
Irrigation tubing set 2.2 m

07795800
SPI dongle

17. 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!)

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

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 (instruments, sterilization cassette, irrigation tubing set, clips, nozzle cleaner, O-rings, fuses and adaptor set) 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 Bürmooos 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.

Manufacturer's declaration

Electromagnetic compatibility (EMC)
WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity. Only use original W&H accessories.

cables and accessories	length	reference
Country specific mains cable according to W&H country list	2.5 to 3.1 m	Manufacturer: Feller GmbH
Handpiece with cable	1.8 m	Manufacturer: W&H REF 06985000
Handpiece with cable	3.5 m	Manufacturer: W&H REF 07159200
Foot controller S-N1	2.85 m	Manufacturer: W&H REF 07004400
Foot controller S-NW	Wireless transmission	Manufacturer: W&H REF 30264xxx
SPI Dongle	Wireless transmission	Manufacturer: W&H REF 07795800

Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

Manufacturer's declaration – Electromagnetic Immunity I (Table 2, IEC 60601-1-2:2007)
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 5kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines Both repetition rates	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	0% U_T 0.5 cycle @ 0°,45°,90°,135°,180°,225°,270° & 315° 0% U_T 1 cycle and 70% U_T 25/30* cycles @ 0° 0% U_T 250/300* cycle	Complies to both editions requirements	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3A/m	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the mains (AC) voltage before apply test levels * 25/30 (250/300) means cycles at 50/60Hz				

Electromagnetic Immunity II (Table 4, IEC 60601-1-2:2007)
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
				Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM and amateur radio bands* between 0,15 MHz and 80 MHz	6 V_{rms}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the re-commended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level [b] in each frequency range  Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Immuity level of RF fields from wireless communication devices (Table 9, IEC 60601-1-2:2014)

Test frequency	Band[a]	Service[a]	Modulation[b]	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 –390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[c] ± 5 kH deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the product may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended Separation Distances between portable and mobile HF- communications equipment and the product (Table 6, IEC 60601-1-2:2007)

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Electromagnetic Emission (Table 1, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF-emission CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2 (*)	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 (*)	complies	

(*) Remark: for devices with power consumption of 75 W to 1000 W only

Manufacturer

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