Instructions for Use
Edition USA

piezomed PLUS
SA-435 M

piezomed CLASSIC
SA-430 M

CE
0297

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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

Type B applied part
(not suitable for intracardiac application)

Symbols

on the medical device

Follow Instructions for Use

Date of manufacture

Do not dispose of with domestic waste

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

Foot control

Manufacturer

CE marking with identification number of the Notified Body

Medical Device

Catalogue number

Serial number

DC – direct current

V Electric voltage (volt)

Hz Frequency (hertz)

MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012, ANSI/AAMI ES60601-1:2005/A2:2021, CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1:14/A2:22, IEC 80601-2-60:2019. 25UX – Control No.

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

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.

Data structure in accordance with Health Industry Bar Code

Temperature limitation

Humidity limitation

MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009/(R)2012 + A2:2010/(R)2012, ANSI/AAMI ES60601-1:2005/A2:2021, CAN/CSA-C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-1:14/A2:22, IEC 80601-2-60:2019. 25UX – Control No.

Catalogue number

Serial number

Date of manufacture

Manufacturer

℞only

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

1. Introduction

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

Observe the safety notes.

Indications for use
Piezoelectric ultrasonic device, consisting of handpieces and associated instruments, intended for:

- Bone Cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures;
- Scaling applications, including:
  Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;
  Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;
  Endodontic: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha-condensation and retrograde preparation;
  Restorative and Prosthetics: Cavity preparation, removal of prostheses, finishing of crown preparations.

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

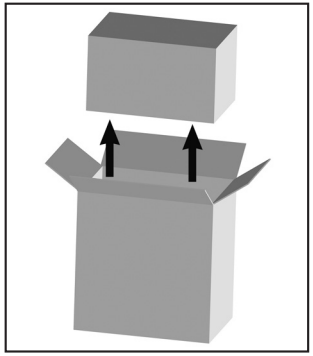
Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

> 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 authorised W&H service partner (see page 58).
> 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.

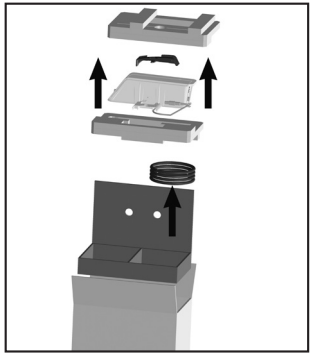
Improper use, unauthorized assembly, modification of or repairs to the control unit or the handpiece with cable and non-compliance with our instructions or the use of accessories and spare parts unauthorized by W&H will void the warranty and release us from all other claims.

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

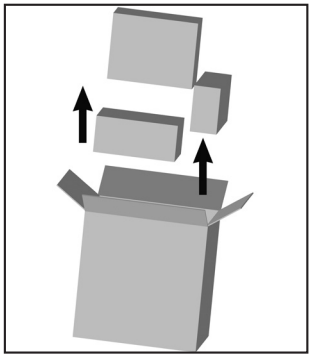
2. Unpacking



❶ Remove the carton.



❷ Lift out the insert with the stand, Instructions for Use, universal support, control unit and mains cable.



❸ Remove the packaging and remove the power supply, irrigation tubing set and accessories.

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		30406000	30407000
REF 07721800	Universal support	X	
REF 08067690	Stand	X	
Mains cable country-specific		X	

Optional included in set

REF 30392000	Handpiece SA-40 L with 1.8 m cable (only for SA-435 M)
REF 30392001	Handpiece SA-40 L with 3.5 m cable (only for SA-435 M)
REF 30408000	Handpiece SA-40 with 1.8 m cable
REF 00636901	Nozzle cleaner
REF 30264000 REF 07759700	Foot control S-NW Dongle S-NW CAN-Bus
REF 30495000 REF 08165950	Foot control S-NW3 Dongle S-NW3 CAN-Bus
REF 30285000	Foot control S-N2
REF 06276700	Instrument changer
REF 07883900	Power supply
REF 08072750	Irrigation tubing set 2.2 m incl. Y-manifold (6 pcs. disposable)
REF 08041710	Irrigation tubing set 3.8 m incl. Y-manifold (6 pcs. disposable)

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 the medical device if it 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.
- > Avoid overheating at the treatment site.
- > The responsibility for the use and timely shutdown of the system lies with the user.
- > Ensure that it is possible to complete the operation safely should the units or instruments fail.
- > Never touch the patient and the electrical contacts on the medical device simultaneously.
- > Make sure that no computer viruses are transferred to the control unit by an external data medium (USB stick).

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

Safety notes

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 supply
> Only use the power mains cable/supply supplied.
> Plug the mains cable only into a power socket with protective contact.

Disconnect the medical device in dangerous situations from the power supply!
> Pull the power plug/power supply out of the socket.

Safety notes

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.

Foot control

Follow the directions and safety notes in the Instructions for Use of the foot control.

Foot control S-NW/S-NW3

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

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 country-specific laws, directives, standards and guidelines for disposal.

Change application

When changing the application an acoustic signal sounds (risk of injury).

Hygiene and maintenance prior to initial use

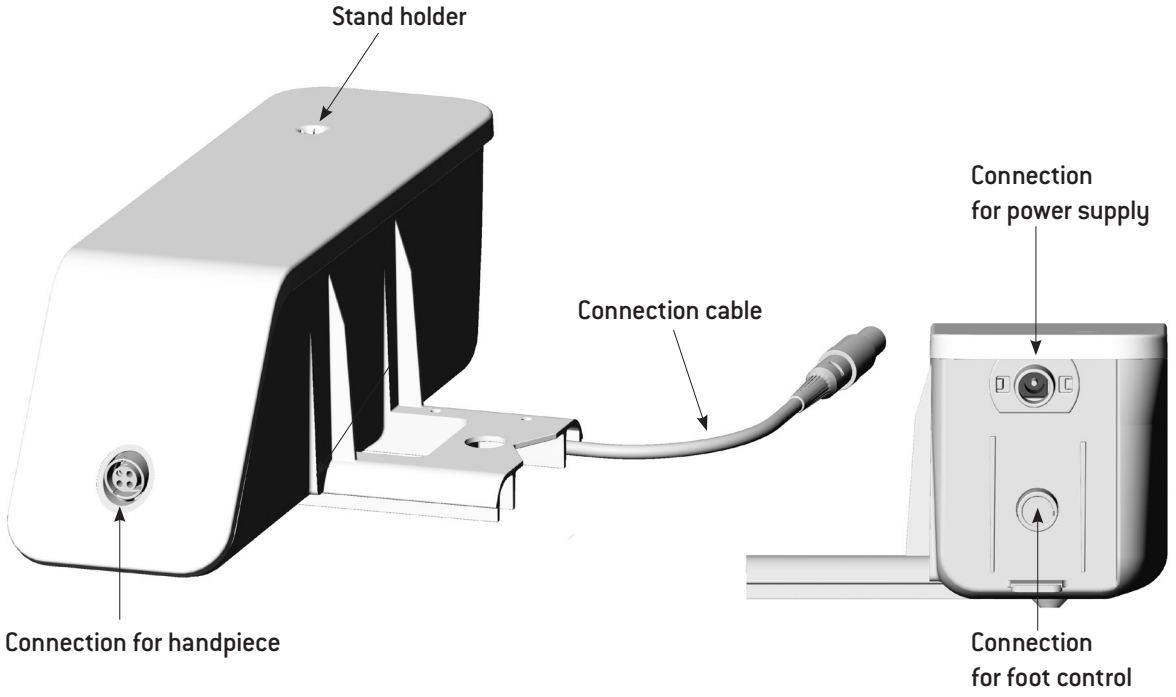
> Clean the control unit.
> Clean and disinfect the universal support and the stand.
> Sterilize the universal support.

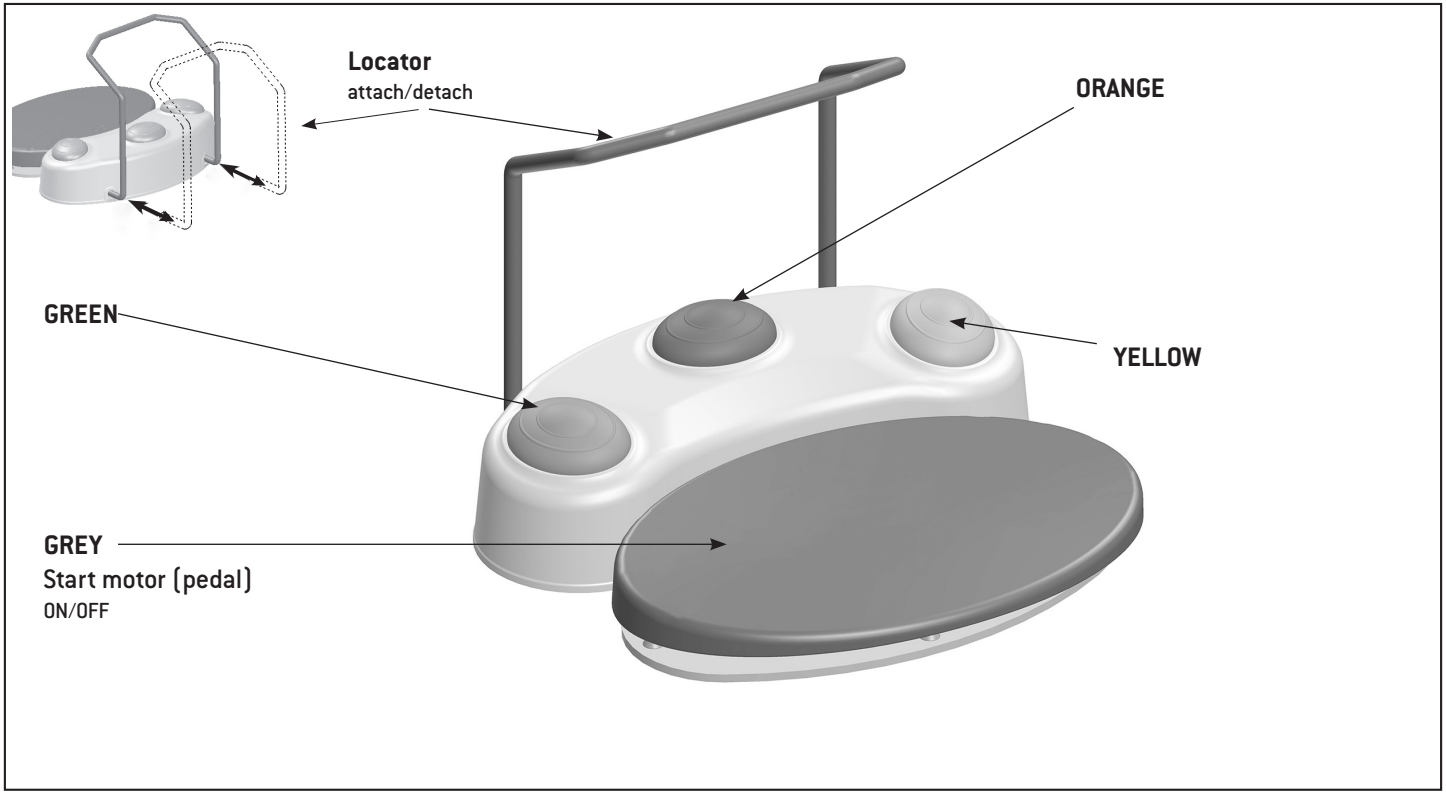
Test run

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.


Stand holder
Connection
for power supply
Connection cable
Connection for handpiece
Connection
for foot control


Locator
attach/detach
ORANGE
GREEN
YELLOW
GREY
Start motor (pedal)
ON/OFF

ORANGE

S-N2/S-NW/S-NW3: Change program

Press the ORANGE button to change programs in ascending order.

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

S-NW/S-NW3: Switching between multiple control units

Press the ORANGE button for 3 seconds.

S-NW/S-NW3: Change application

Press the ORANGE button for 3 seconds until an acoustic signal sounds.

S-N2: Change application

Press the ORANGE button for 3 seconds until an acoustic signal sounds.

GREEN

Press the green button to change the coolant volume in steps of 20%

Press and hold the GREEN button to activate the coolant filling function.

YELLOW

Boost function

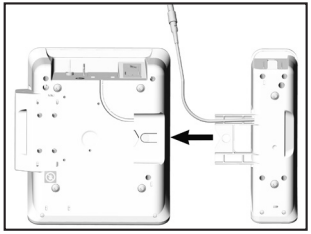
Keep the yellow button depressed to activate the boost function.

The boost function increases power during operation to 100%, irrespective of the set value on the display.

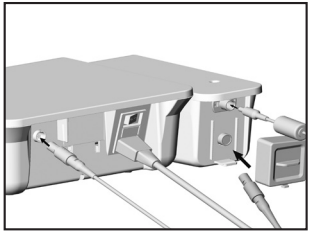
6. Start-up

Place the medical device on a flat level surface.

Ensure that the medical device can be disconnected from the power supply at any time.

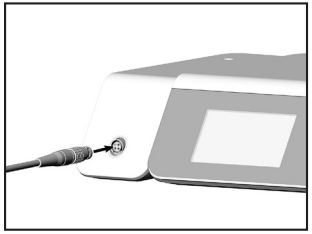


❶ Attach the control unit until it engages.



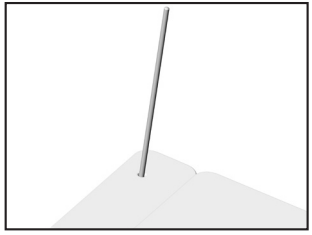
❷ Connect the connection cable to the SI-10xx foot control connection.
Connect the power supply, foot control or dongle to the SA-4xx M.

Pay attention to the positioning!



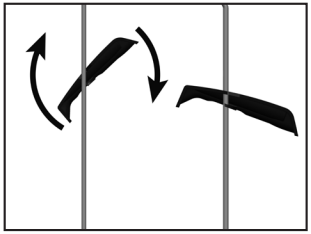
❸ Connect handpiece cable.

Pay attention to the positioning!

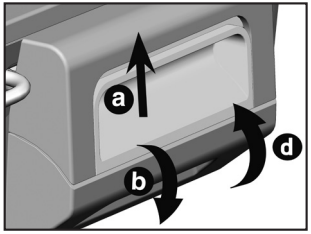


❹ Insert the stand.

Pay attention to the positioning!



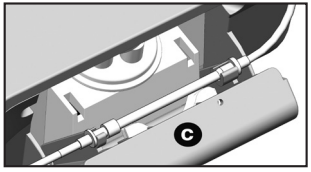
❺ Attach the universal support and lock it.



❻ Insert the irrigation tubing.

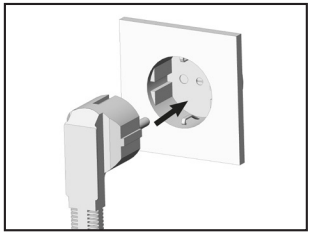
> Open the pump cover (a,b).

> Insert the irrigation tubing (c).

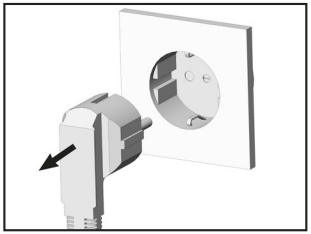


> Close the pump cover (d).

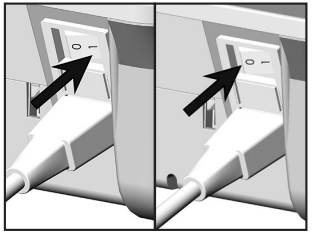
Control unit switching on and off



❶ Plug the mains cable/power supply into an earthed power socket.



❶ Pull the power plug out of the socket.



❷ Switch on/off the control unit at the power switch.

SA-430 M / SA-435 M

Ensure that the SA-430 M / SA-435 M is connected to the power supply before switching on the control unit at the power switch.

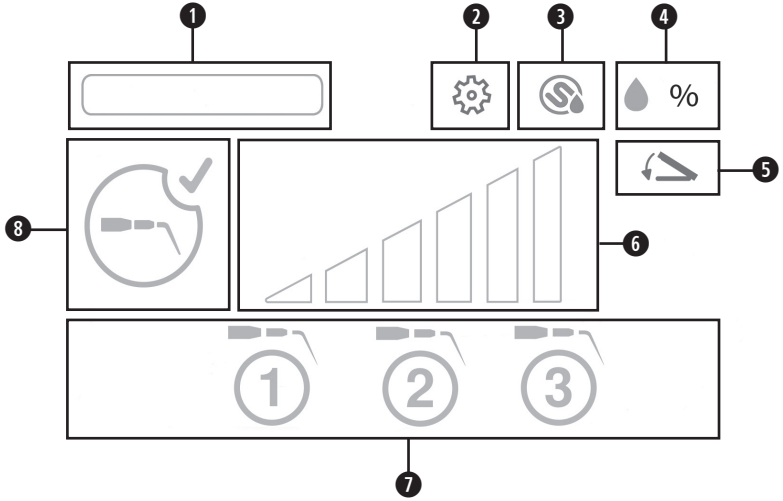
Make sure that the coolant filling function has been carried out prior to every application.

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

Coolant filling function

Start the coolant filling function by confirming the entry.

The coolant filling functions lasts for 15 seconds.
Press any button on the display or the foot control to stop the coolant filling function.



❶	Instruments library
❷	Setup
❸	Coolant filling function
❹	Coolant volume
❺	Foot control
❻	Power
❼	Instrument group
❽	Information

Bone quality

In instrument group 3, the power settings are displayed according to bone quality (D1, D2, D3).

D3 > 40%

D2 > 70%

D1 > 85%

No bone quality is displayed for under 40%.

“Auto Detection”

> Instrument detection assists the user and helps to avoid incorrect settings.
> Only deactivate the „Auto Detection“ if instrument detection fails during treatment.

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

My instruments

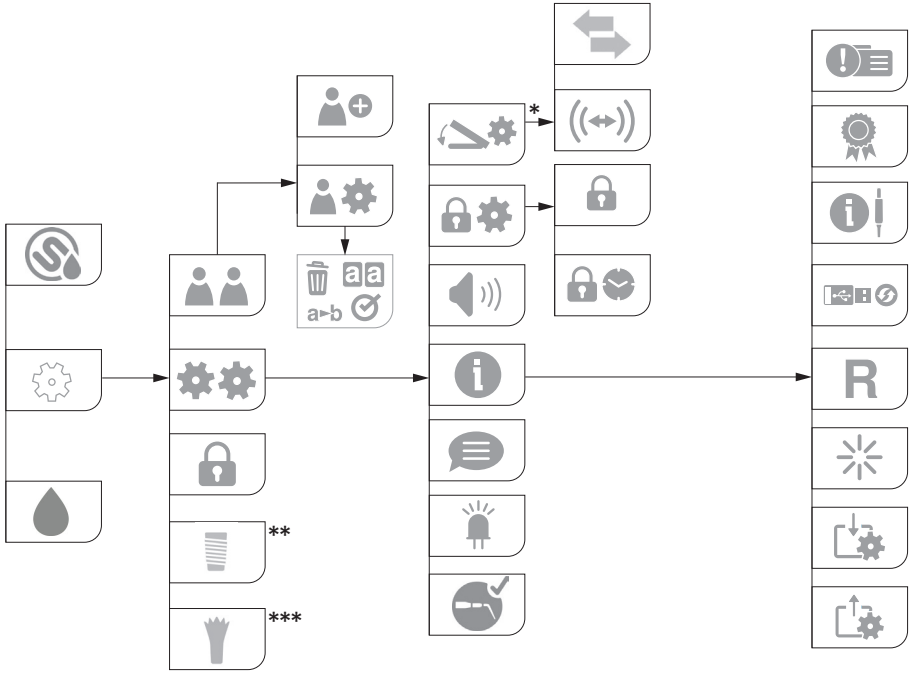
“My instruments” is only available with “Auto Detection” and displays all available instruments.

Choose the instruments which are available in your instrument set and save your preferred settings.

Press the ORANGE button on the foot control to activate the respective instrument with the stored basic settings.

“Auto Detection OFF”

> “Auto Detection” is deactivated.
> “Auto Detection” is not available for handpieces without light.



* Only visible when using the foot control S-NW/S-NW3.
** Visible in Piezo mode / *** visible in Implant mode

8. Icons

User

An activated user cannot be deleted

Add user

Manage user

User settings: Copy, Rename, Activate, Delete

Confirm/save

Switch to next screen

Set foot control

Pairing S-NW/S-NW3

Foot control ON/OFF

System

Implant mode

> Switch from Piezo mode to Implant mode

Piezo mode

> Switch from Implant mode to Piezo mode

Coolant filling function

Grey = Coolant volume set, inactive
Green = Coolant volume set, active

Screen lock

> Activating / deactivating

Set screen lock

> Activating / deactivating
> Interval

Interval time

> Select time

Icons

LED
> Activating / deactivating

Fade-out time
Select time

SOUND
> Activating/deactivating

Language
> Select

“Auto detection”
> Activating/deactivating

“Auto detection OFF”

Device info

Service

Licenes
GPL: GNU General Public License
LGPL: GNU Lesser General Public License

Module info

Reset

Software Update

Reset

Import user settings

Export user settings

Change application
> Activating/deactivating

Switch only between Implant/Piezo mode

Change application OFF

Icons

Setting selected

black = Information
green = Information with selection option

red = error message, work cannot be continued
orange = error message, work can be continued

red = replace batteries

Foot control S-NW/S-NW3

Foot control S-N2

Reduce/increase parameters
> pressing minus/plus
> moving the slider
> pressing onto the line of the slider at any position

9. Error messages

Icon	Description of error	Solution
	WARNING NO HANDPIECE DETECTED	> Unplug the handpiece and plug it back in again > Deactivate AUTO DETECTION If the error message appears again, contact an authorized W&H service partner immediately.
	WARNING NO INSTRUMENT DETECTED	> Insert the instrument If the error message appears again, contact an authorized W&H service partner immediately.
	WARNING AUTO DETECTION OFF	> Manually enter the instrument group > Use the group number from the instrument card or from the Piezomed brochure on wh.com.
	WARNING FOOT CONTROL	> Check plug-in connection of foot control > Check the plug-in connection of the dongle
	WARNING SWITCH COOLANT SUPPLY	> On the irrigation tubing set, set the regulator of the Y-manifold to the correct position. > Press any button on the display or the foot control to confirm the change application.

Error messages

Icon	Description of error	Solution
	WARNING INSTRUMENT DETECTION ERROR	> Check LED socket (correctly attached, defective) > Deactivate AUTO DETECTION
	WARNING SURGERY SCALER	> Check the plug contacts of the handpiece > Allow handpiece to cool for at least 10 minutes
	SYSTEM ERROR	Switch the control unit off and back on again If the error message appears again, contact an authorized service partner immediately.

> If the error messages described cannot be resolved, a check by an authorized W&H service partner is required.
> In case of a total system failure, switch the dental unit off and on again.

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 (43.5 psi) for manual drying.

Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by 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 universal support after 500 processing cycles.

> Clean and disinfect the medical device immediately after every treatment.
> Wipe the universal support and the stand with disinfectant.

❶ Disconnect the handpiece, foot control and power supply from the control unit. Check for any damage on the outer surface of each component.
❷ Lightly wipe all external surfaces of the control unit with a soft, lint-free cloth moistened with a neutral detergent for medical devices according to the manufacturer's instruction.
❸ Use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions for Use supplied by the disinfectant manufacturer.

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 medical device in liquid disinfectant or in an ultrasonic bath.
> Do not immerse the medical device in water or clean it under running water.

Universal support/Stand

> Clean the universal support and the stand 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

> Lightly wipe all external surfaces of the control unit with a soft, lint-free cloth moistened with a neutral detergent for medical devices. Clean surfaces until all visible soil is removed.
> Remove the detergent from all surfaces using a lint-free cloth moistened with distilled water, deionized water, or demineralized water.

Evidence of the medical device's basic suitability for effective manual cleaning was provided by an independent test laboratory using the cleaning agent "LUMINOX®" (Alconox).

Control unit/Universal support/Stand

W&H recommends wiping down with disinfectant.

After removing all visible soil, use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions for Use supplied by the disinfectant manufacturer.

Evidence of the basic suitability of the control unit, universal support and the stand for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant “CaviWipes™” (Metrex).

Universal support/Stand

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.

Evidence of the basic suitability the universal support and the stand 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

Universal support/Stand

> Ensure that the universal support and the stand are completely dry after cleaning and disinfection.
> Remove liquid residues using compressed air.

> Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any medical devices and stand that are still soiled.
> Sterilize the universal support following cleaning and disinfection.

Universal support

Pack the universal support in FDA cleared sterilization packages that meet the following requirements:

- > The sterilization procedure 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 loading sterilization package must not be under tension.

Universal support

W&H recommends sterilization according to ANSI/AAMI ST55, ANSI/AAMI ST79.

> 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 universal support.

Recommended sterilization procedures

> "Dynamic-air-removal cycle" (type B, S)
  132°C (270°F) for at least 4 minutes
> "Gravity-displacement cycle" (type N)
  121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the universal support's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

"Dynamic-air-removal cycle" (type B, S):	132°C (270 °F) – 4 minutes*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

Minimum drying times:

"Dynamic-air-removal cycle" (type B, S):	132°C (270°F) – 30 minutes**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55, ANSI/AAMI ST79

Universal support

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

11. 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

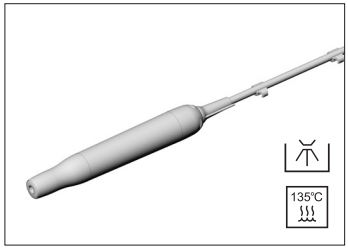
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

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

> Always return equipment in the original packaging.

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

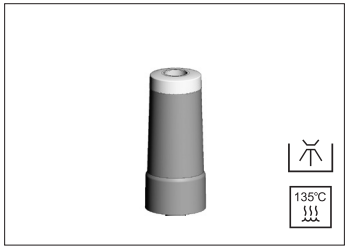
Use only original W&H accessories and spare parts or accessories approved by W&H!
Suppliers: W&H partners (Link: https://www.wh.com)



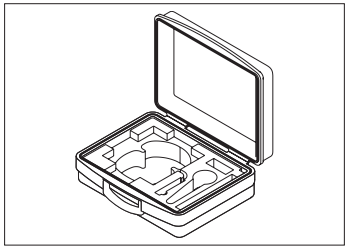
30392000
Handpiece SA-40 L with 1,8 m cable incl. 5 clips

30392001
Handpiece SA-40 L with 3,5 m cable incl. 10 clips

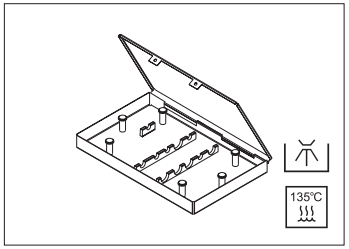
30408000
Handpiece SA-40 with 1,8 m cable incl. 5 clips



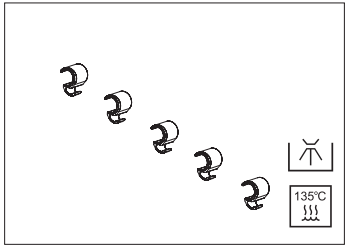
06205600
LED socket



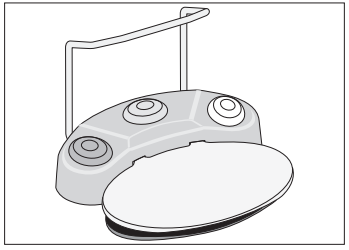
07962790
Transportation case



07172900
Cassette



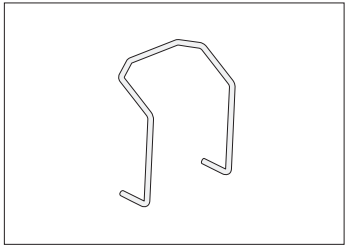
08046870
Clips (5 pcs)



30285000
Foot control S-N2

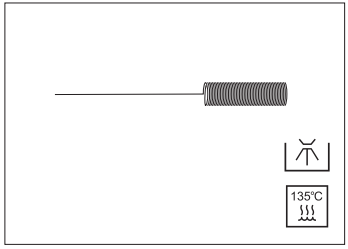
30264000
Foot control S-NW

30495000
Foot control S-NW3

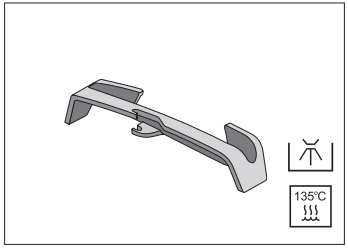


04653500
Handle for foot control

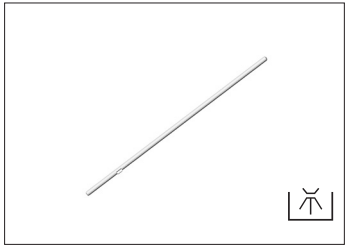
Accessories, consumables, spare parts and other recommended medical devices by W&H



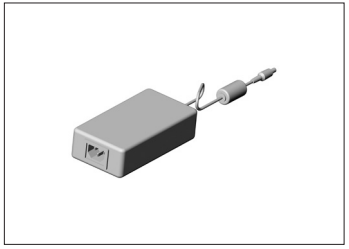
00636901
Nozzle cleaner



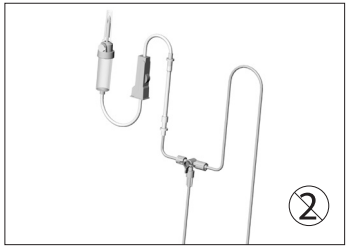
07721800
Universal support



08067690
Stand



07883900
Power supply



08072750
Irrigation tubing set 2.2 m incl. Y-manifold (6 pcs, disposable item)

08041710
Irrigation tubing set 3.8 m incl. Y-manifold (6 pcs, disposable item)

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

13. Technical data

Control unit	**SA-430 M**	**SA-435 M**
Supply voltage:	100 – 240 V	
Operating voltage:	30 – 32 V DC	
Frequency:	50 – 60 Hz	
Maximum power output (ultrasonic):	18 W	24 W
Operating frequency:	22 – 35 kHz	
Coolant flow rate at 100 %:	at least 90 ml/min	
Operating mode:	S3 (80s on/330s off) maximum 4 repeats	
Dimensions in mm (height x width x depth):	90 x 140 x 285	
Weight:	635 g	685 g
Length handpiece cable:	1.8 m	1.8 m / 3.5 m
Foot control:	S-N2 / S-NW / S-NW3	

Technical data

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

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

Class I medical electrical equipment (to avoid the risk of electric shock, the power supply must only be connected to a supply mains with protective earth!)

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

Type B applied part (not suitable for intracardiac application)

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

14. 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		
Proximity magnetic fields IEC/EN 61000-4-39	30 kHz	8 A/m	
	134,2 kHz	65 A/m	
	13,56 MHz	7,5 A/m	

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

15. 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

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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/dental 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/dental 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	

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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 (cassette, irrigation tubing set, clips, nozzle, cleaner, O-rings, adaptor set) are not covered by the warranty.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty accompanied by proof of purchase must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 months warranty

Authorized W&H service partners

Find your nearest authorized W&H service partner at http://wh.com
Simply go to the menu option “Service” for full details.

Or simply scan the QR code.

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Software version SA-430 M:
Surgery scaler: 01.xx.xx

Software version SA-435 M:
Surgery scaler: 01.xx.xx
Tip detection: 01.xx.xx

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Subject to alterations