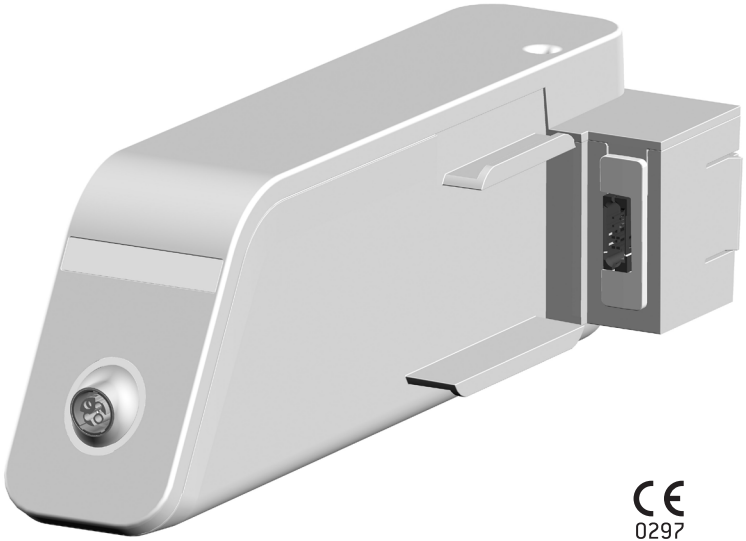
Instructions for Use



CE
0297

piezomed II PLUS
module

SP-210 M

Contents

Contents

Symbols

WARNING!
(risk of injury)

ATTENTION!
(to prevent damage occurring)

General explanations, without risk to persons or objects

CE marking with identification number of the Notified Body

Follow Instructions for Use

Medical Device

Manufacturer

Date of manufacture

Catalogue number

Serial number

Do not dispose of with domestic waste

Thermo washer disinfectable

Sterilizable up to the stated temperature

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

Data structure in accordance with Health Industry Bar Code

Symbols

This way up

Fragile, handle with care

Keep dry

Do not re-use

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

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.

Class II equipment

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

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.

Humidity limitation

Temperature limitation

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, maxillo-facial surgery and periodontics.


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


Qualifications of the user
Only suitably qualified medical, technical and specialist trained staff may use the medical device. We have based our development and design of the medical device on the physician target group.

Introduction

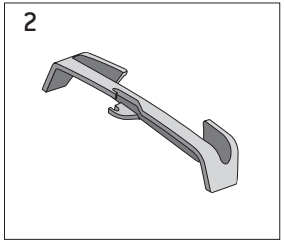
Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

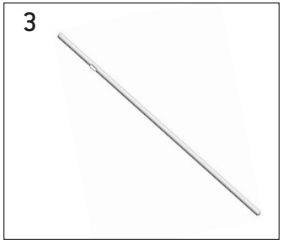
> The medical device must be used in accordance with these Instructions for Use.
> The medical device has no components that can be repaired by the user.
> Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 60).
> The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 ("Installation of electrical equipment in rooms used for medical purposes") or with the regulations applicable in your country.
> Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

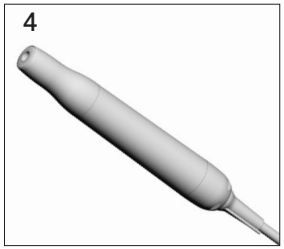
Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

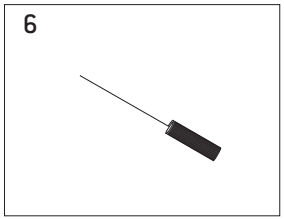
Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

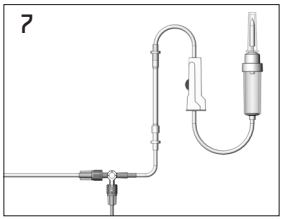
2. Scope of delivery











Scope of delivery

No.	REF	Description	Scope of delivery	Optional in the set
1	30507000	Piezomed module Plus II SP-210 M	X	
2	07721800	Universal support	X	
3	08067690	Stand	X	
4	30392000	Handpiece SA-40 L with 1,8 m cable		X
4	30408000	Handpiece SA-40 with 1,8 m cable		X
5	06276700	Instrument changer		X
6	00636901	Nozzle cleaner		X
7	08072750	Irrigation tubing set 2.2 m incl. Y-manifold (6 pcs, disposable item)		X

Compatible with the Piezomed module Plus II:

REF	Description
30504000	Implantmed Plus II SI-2100 (Control unit)
30505000	Implantmed Plus II SI-2101 (Control unit)
30506000	Implantmed Plus II SI-2102 (Control unit)

3. 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.
- > The medical device is not approved for operation in potentially explosive atmospheres.
- > The medical device is not approved for operation in oxygen rich environment.

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.

Safety notes

- > Disconnect the control unit from the power supply in case of danger.
- > Turn off the control unit at the power switch
- > Pull the power plug out of the socket

Software update

The control unit must be continuously supplied with power during the update. Interruptions may lead to data loss or device failure.

Coolant supply

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

- > Always ensure the correct operating conditions and cooling function.
- > Use only suitable coolants and follow the manufacturer's medical data and instructions.
- > Only use an irrigation tubing set approved by W&H or accessories approved by W&H.

Sterile medical devices

- > Only use the medical device if the sterile packaging is undamaged and unopened.
- > Note the expiration date.
- > Replace the medical device immediately after every treatment.
- > Dispose of the medical device in accordance with the applicable regulations.

Safety notes

Hygiene and maintenance prior to initial use

> Clean and disinfect the module, the universal support and the stand.
> Sterilize the universal support.

Risks due to electromagnetic fields

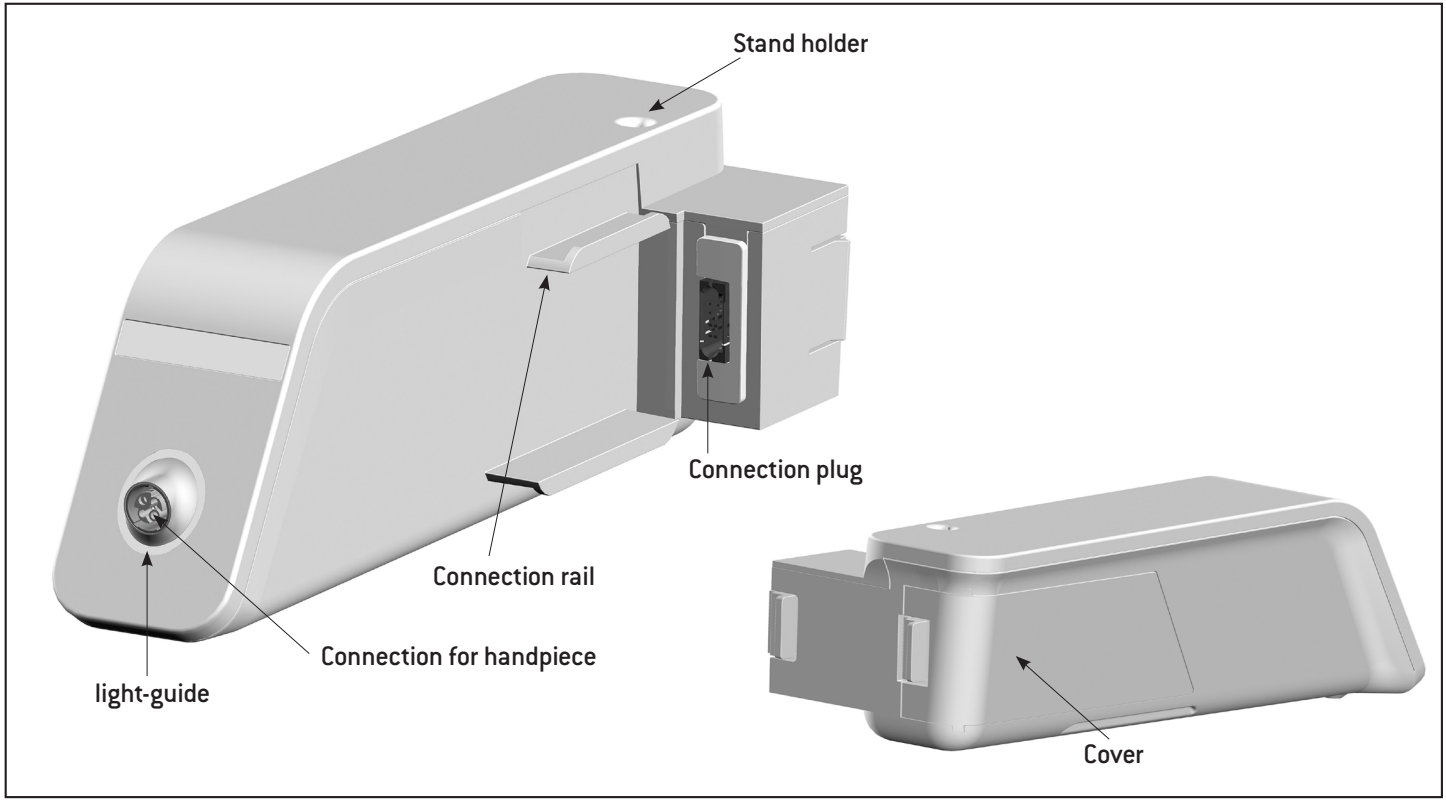
The functionality of active implantable medical devices (AIMD) (e.g. cardiac pacemaker, ICD) can be affected by electric, magnetic and electromagnetic fields.

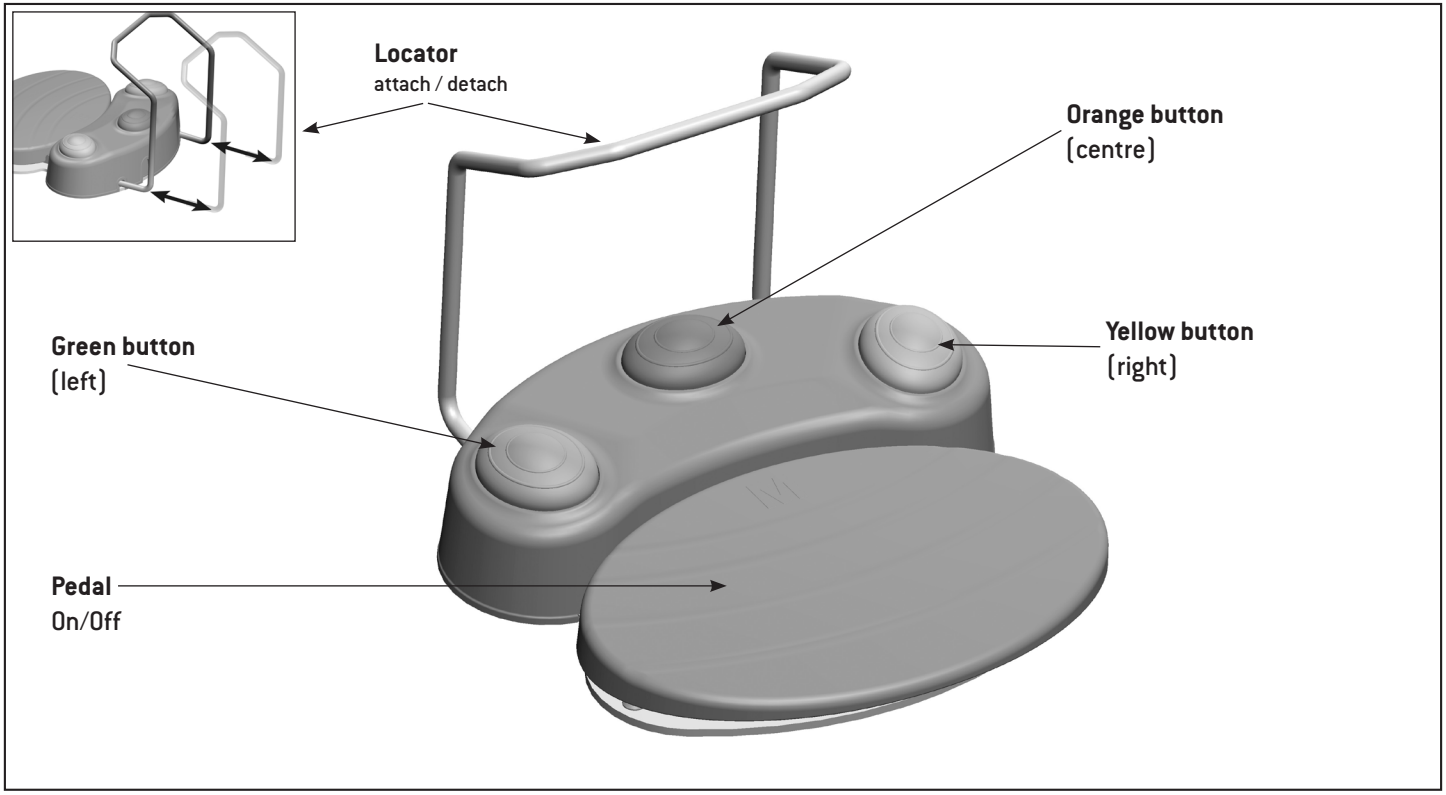
Find out if the patient has active implantable medical devices (AIMD) before using the medical device and inform about the risks.

Intermittent periodic duty S3 (80 s ON / 330 s OFF)

The medical device is designed for intermittent periodic duty S3 with 80 seconds ON and 330 seconds OFF. This may be repeated a maximum of four times. If the specified operating mode is observed no overheating of the system and therefore no injury to the patients, users or third parties arises. The responsibility for the use and timely shutdown of the system lies with the user.

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


Stand holder
Connection plug
Connection rail
Connection for handpiece
light-guide
Cover


Locator
attach / detach
Orange button
(centre)
Green button
(left)
Yellow button
(right)
Pedal
On/Off

Standard button configuration

Green button

> **Change coolant volume:** Press the green button to change the coolant volume in increments of 10%.
> **Start coolant filling function:** Keep the green button depressed to start the coolant filling function.
This function is always configured on the left button, even if user-defined configurations are saved.

Orange button

> **Switch program (pre-defined instruments):** Press the orange button to switch programs in ascending order.
> **Switch application:** Press the orange button for 3 seconds until an acoustic signal is emitted.

An acoustic signal sounds when switching application.

Yellow button

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.

User-defined button configuration
The green and orange buttons can be configured individually under Settings, Button Configuration.


Check the selected profile and the associated device settings before each use.

Green button
Coolant volume can now only be changed on the display.
> **Switch application:** Press the green button to switch application.


An acoustic signal sounds when switching application.

> **Switch tooth position:** Press the green button to switch tooth position.

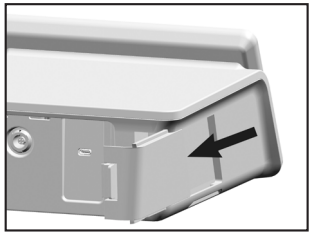
Orange button
Switch program (pre-defined instruments): Press the orange button to switch programs in ascending order.

The light-guide, an LED display around the handpiece connection, visually displays the following information to make use easier:

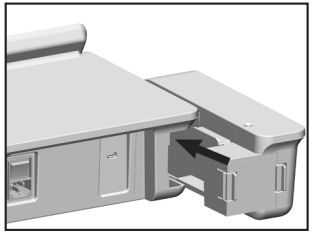
Colour	LED display	Information
White	Lights up	Active application, Automatic instrument detection deactivated
	Flashes	Cable connected successfully
–	Off	Inactive application
Red	Lights up	Warning / error (for details see System messages)

5. Start-up

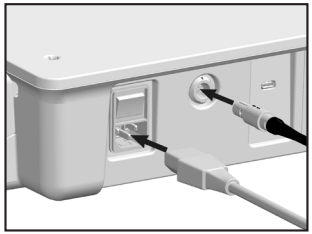
Place the control unit and module on a flat, level surface.



❶ Remove cover from control unit.

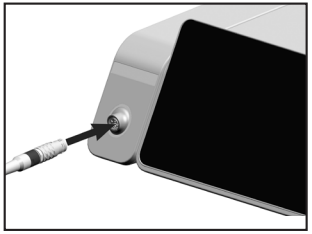


❷ Push the module along the connection rail onto the control unit until it engages.



❸ Connect the mains cable and wired foot control (only for SI-2100) on the control unit.

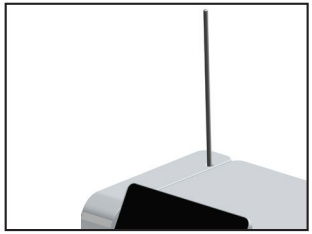
Pay attention to the positioning!



❹ Insert the handpiece cable.

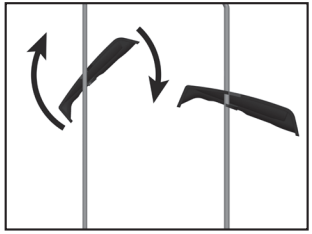
Pay attention to the positioning!

Start-up

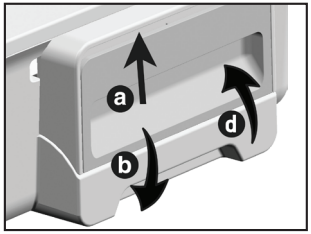


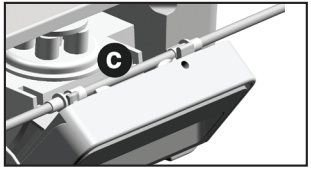
❺ Insert the stand.

Pay attention to the positioning!



❻ Attach the universal support and lock it.



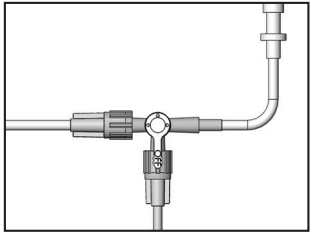


❼ Fit the irrigation tubing

> Open the pump cover (a, b).

> Fit the irrigation tubing (c).

> Close the pump cover (d).

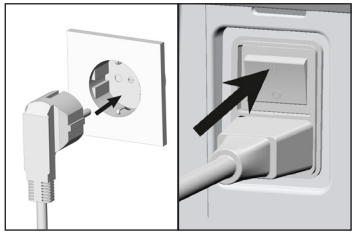


❽ Move the controller on the irrigation tubing (Y-switch) to the correct position.

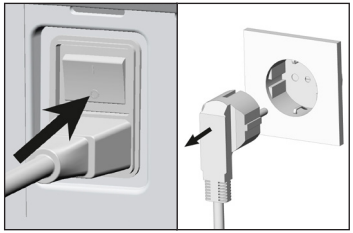
Start-up

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

Before switching on the control unit with the power switch, the module and the foot control must be connected.



Switching ON
Plug the mains cable into a power socket with protective contact.
Switch the control unit on at the power switch.

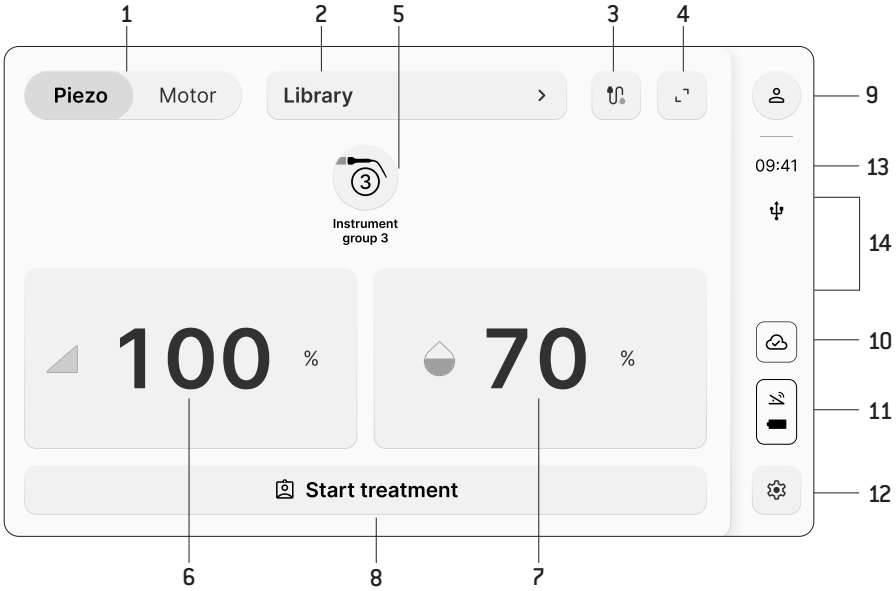


Switching OFF
Switch the control unit off at the power switch.
Pull the power plug out of the socket.

Test run

> Run the coolant filling function.
> Start up the medical device.

In the event of operating malfunctions (e.g. vibrations, unusual noises or overheating) stop the medical device immediately and contact an authorized W&H service partner.



1	Application
2	Library
3	Coolant filling function
4	Show / hide sidebar
5	Instrument group / pre-defined instruments
6	Power
7	Coolant volume
8	Start treatment

Sidebar display:	
9	User
10	ioDent connection
11	Foot control / battery state
12	Settings
Variable sidebar display:	
13	Time
14	Connected component

General

Device information
Information, software licence, certificate, logbook

Information
REF, serial number and software version

Legal and licences
Accept or decline detailed diagnostic data
Software licences

Certificate
Certificate renewal

Logbook
Device messages for service technicians

Language and region
Select language and timezone

Software update
Update software
Follow the directions on the display.
(Info about available software updates at ioDent.com)

General

Reset settings
Restore default settings, factory reset

Default settings
The following settings will be deleted in the selected profile:
> Display
> Sound
> Foot control
> Piezomed

Factory settings
All data and settings will be reset to factory settings.

Display

Screen lock
Activate/deactivate screen lock

Screen lock
Select a time between 1 - 30 minutes

Display

Appearance

Program icons
Select: Modern or classic

Dental numbering system
Select: FDI or UNS
FDI (Féderation Dentaire Internationale = International dental numbering system I-IV)
UNS (Universal Numbering System = American dental numbering system 1-32)

Notifications
Activate/deactivate coolant supply and coolant filling function

Regulate coolant supply
Display notification after application switch

Coolant filling function
Notification after first switch to Piezo application

Display

Time
Activate/deactivate time display

Sound

Activate/deactivate sound

Volume
Select: Standard or high

WiFi

Activate/deactivate WiFi
Update network, connect or disconnect encrypted WIFI
Open networks are not displayed.

Foot control

Characteristic (Piezo)
ON/OFF: Handpiece runs with maximum set power.

Button configuration
Select button allocation: Standard or user-defined (see foot control product description for details)

Piezo

Automatic instrument detection
Activate/deactivate (for details see Instruments under Operation)
Piezo LED
Activate/deactivate

Fade-out time
Select: Between 1 - 30 seconds

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

Options to start:

> If the coolant filling function notification is activated in the settings, the system message “Start coolant filling function” appears when first switched to Piezo application.
> Press and hold down the green foot control button.
> Tap the coolant filling function in the main menu.

The coolant filling function lasts for 15 seconds.
The coolant filling function can be stopped on the display or by pressing the pedal.

Automatic instrument detection

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

> Disable the automatic instrument detection if it fails during the treatment. Adjust the instrument group, power and coolant volume manually according to the instrument card.
> The instrument's maximum power setting is shown on the instrument card.

Automatic instrument detection is not possible when using the SA-40 handpiece and must therefore be deactivated.

Library

The library is only available when automatic instrument detection is activated. All instruments are divided by application. Only the instruments assigned to the respective instrument group will be displayed as active. Choose the instruments available in your instrument set and save your preferred settings.
The selected instruments will be shown in the main menu.

Bone quality

In instrument group 3, the bone quality (D1, D2, D3) will be displayed with the power setting.
D1 > 85%
D2 > 70%
D3 > 40%
No bone quality is displayed for under 40%.

User

Use the default profile or create an individual profile.
Changes will be synchronised automatically as soon as there is a connection to ioDent.

Creating users
A maximum of seven users can be created.

Check the selected profile and the associated device settings before each use.

Treatment documentation is possible on the ioDent platform and a USB stick

> The treatment can either be imported via ioDent or created manually.
> Documentation is only possible if a patient ID has been selected.
> A text file (csv) and a PDF will be saved on the USB stick.

Start treatment

> Create treatment.
> Enter patient ID manually.
> Select tooth position: One or more tooth positions can be created.

> Each created treatment can be changed at any time.
> The treatment date is saved automatically at the start.
> A maximum of 50 treatments can be created. The oldest treatment will be overwritten when a new one is created manually. During synchronisation via ioDent, the treatments to be deleted must be selected and deleted manually.

Ensure that the correct patient ID and the associated tooth position have been selected for the documentation.

Complete treatment

The patient ID must be completed after treatment has been carried out.

> Created treatments can be deleted on the control unit.
> The documentation remains on ioDent and the USB stick.
> Final deletion can be carried out in ioDent or on the USB stick.

The patient ID and tooth position must be created.

Start scan function

> Tap on the Scan icon.
> Multiple materials can be recorded consecutively.
> Position the QR code 10-15 cm (4-6 inches) in front of the display, so that it is shown clearly.
> A green frame appears when the scan has been successful. The material data cannot be changed.
The QR code must be generated in line with ISO/IEC 15415, in order to be able to use the scan function.

The display brightness can be adapted in order to make the QR code easier to read.

If the QR code is not recognised, tap on the photo icon to initiate the scan manually.
The material number and material name can be entered manually.

> The scanned material can be allocated to one or more tooth positions.
> Additional photos may be taken for each material.
> The materials list will be displayed for the respective patient ID.

Check that the scanned code is correct.

> The treatment and all recorded materials can be deleted on the control unit.
> Final deletion must be carried out in ioDent.

Certificate renewal

> An active WiFi connection is required to renew the device certificate.
> The required one-time password must be requested from an authorized W&H service partner.

Connecting to the ioDent platform

> An active WiFi connection is required to connect the control unit to ioDent.
> Generate the code to register the control unit.
> To connect the control unit permanently to your ioDent account, enter the registration code manually in your ioDent device management or scan the QR code on the display.

Check the transferred data for completeness and correctness.

9. System messages

System messages will be shown on the display and are divided into 4 categories:

Icon	Colour	System message
	Blue	Information
	Orange	Warning
	Red	Error
	Green	Update completed successfully

> A remedial measure is shown on the display for each system message.
> If the described system message cannot be resolved, the unit will need to be inspected by an authorized W&H service partner.
> The system message can be closed via the display or by pressing the pedal.
> In case of a total system failure, switch the control 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 for manual drying.

Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by, for example: the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).

The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Send worn or damaged medical devices and/or medical devices with material changes to an authorized W&H service partner.

Processing cycles

> We recommend a regular service for the W&H universal support after 250 processing cycles.

> Clean the module immediately after every treatment.
> Wipe the module, the universal support and the stand with disinfectant.

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

Universal support / Stand

> Do not place the universal support and the stand in liquid disinfectant or in an ultrasonic bath.

Universal support / Stand

> Clean the universal support and the stand under running tap water (< 35 °C / < 95°F).
> Rinse and brush off all external surfaces.
> Remove any liquid residues using compressed air.

Module

> Do not immerse the module in water or clean it under running water.

Evidence of the module's basic suitability for effective manual cleaning was provided by an independent test laboratory using tap water < 35°C and towels/cloth "WIPEX ® WET DESI premium" (NORDVLIES GmbH, Bargteheide).

Module / Universal support / Stand

W&H recommends wiping down with disinfectant.

Evidence of the basic suitability of the module, the universal support and the stand for effective manual disinfection was provided by an independent test laboratory using the disinfectants “mikrozid® AF wipes” (Schülke & Mayr GmbH, Norderstedt) and “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 and washer disinfector adaptors.

The module is 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.

Universal support / Stand

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

Universal support

Pack the universal support in 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 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 universal support.

Recommended sterilization procedures

> "Dynamic-air-removal prevacuum cycle" (type B) / "Steam-flush pressure-pulse cycle" (type S)*/**
> 134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes
> "Gravity-displacement cycle" (type N)**
  121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

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

"Dynamic-air-removal prevacuum cycle" (type B):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Steam-flush pressure-pulse cycle" (type S):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

Drying times:

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

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

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

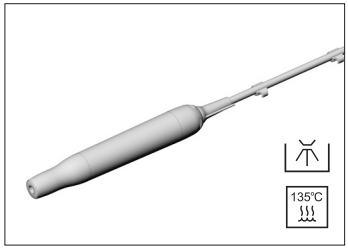
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

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

Always return equipment in the original packaging!

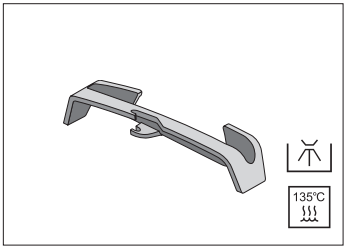
12. Accessories, consumables, spare parts and other recommended medical devices by W&H

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

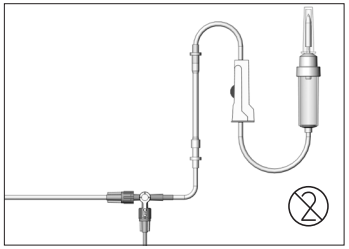


30392000
Handpiece SA-40 L with 1,8 m cable incl. 5 clips

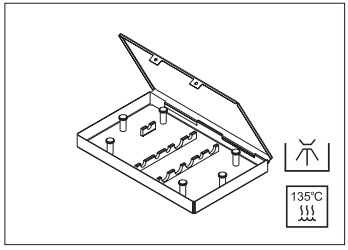
30408000
Handpiece SA-40 with 1,8 m cable incl. 5 clips



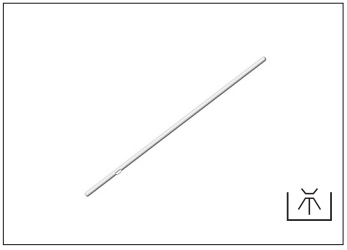
07721800
Universal support



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



07172900
Cassette



08067690
Stand

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

13. Technical data

Module	**SP-210 M**
Maximum power output (ultrasonic):	24 W
Operating frequency:	22 – 35 kHz
Coolant flow rate at 100 %:	at least 90 ml/min
Operating mode:	S3 (80 s ON / 330 s OFF) maximum 4 repeats
Dimensions in mm (height x width x depth):	99 x 93 x 283
Weight:	755 g

Ambient conditions

Temperature during storage and transport:	-30°C to +70°C (-22°F to +158°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10°C to +30°C (+50°F to +86°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 Equipment according to IEC 60601-1/ANSI/AAMI ES 60601-1

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

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

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

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	

Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase. Accessories and consumables are 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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