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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

Call customer service
### Symbols on the control unit

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⬇️</td>
<td>Follow instructions for use</td>
</tr>
<tr>
<td>👇</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>⏳</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>⌚</td>
<td>Do not dispose of with domestic waste</td>
</tr>
<tr>
<td>📦</td>
<td>Data Matrix code for product information including UDI (Unique Device Identification)</td>
</tr>
<tr>
<td>🌐</td>
<td>CE mark with identification number of the Notified Body</td>
</tr>
</tbody>
</table>

- **Class II equipment**
- **Article number**
- **Serial number**
- **Supply voltage of the control unit**
- **Alternating current**
- **Electric power input of the control unit**
- **Supply current**
- **Frequency of the alternating current**
Symbols on the packaging

- **CE mark**
  with identification number
  of the Notified Body

- **This way up**

- **Fragile, handle with care**

- **Keep away from rain**

- **»Der Grüne Punkt« (The Green Dot)**
  trademark of Duales System
  Deutschland GmbH

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

- **Data Matrix code**
  for product information including UDI
  (Unique Device Identification)

- **Data structure in accordance with**
  Health Industry Bar Code

- **Temperature limits**

- **Humidity, Limitation**

- **Caution:**
  According to Federal law, this medical device
  may only be sold by or on the order of a dentist,
  physician or any other medical practitioner
  licensed by the law of the State in which he or she
  practices and intends to use or order the use of this
  medical device.
Symbols on the irrigation tubing set

- **Consult instructions for use**
- **Not for re-use**
- **Latex free**

- **CE mark**
  - with identification number of the Notified Body

- **Batch code**

- **Use by**

- **Sterilized using ethylene oxide**

**Caution:** According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices and intends to use or order the use of this medical device.
1. Introduction

For your safety and the safety of your patients
These instructions explain how to use your product. 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.

It is therefore essential that you observe the safety notes on pages 13 to 19.

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 Piezomed and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user
The Piezomed dental surgical unit is intended for use by suitably qualified and trained medical, technical and specialist staff only. We have based our development and design of the Piezomed on the »physician« target group.
Introduction

Production according to EU Directive
EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and it applies to the dental surgical unit

> Piezomed SA-320

in the condition as supplied by us. This declaration does not apply to non-specified fittings, mountings etc.

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

> The Piezomed must be used in accordance with these Instructions for use.
> The Piezomed has no components that can be repaired by the user. Assembly, 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 of 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 device invalidates all claims under warranty and any other claims.
2. Electromagnetic compatibility (EMC)

Notes on electromagnetic compatibility (EMC)
Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H only guarantees compliance of the control unit with the EMC Directives when it is used with original W&H accessories and spare parts. The use of accessories and spare parts that have not been approved by W&H may lead to increased emission of electromagnetic interference or to reduced resistance to electromagnetic interference.

You can find the current EMC manufacturer’s declaration on our website at http://wh.com or, alternatively, you can also request a copy directly from the manufacturer.

HF communication equipment
Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.
3. Unpacking

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

② Lift out the insert with the control unit.

③ Remove the sterilization cassette.

④ Remove the irrigation tubing set.

⑤ Remove the carton containing the accessories supplied.

W&H packaging is environmentally friendly and can be disposed of by industrial recycling companies.

However, we recommend that you keep the original packaging.
## 4. Scope of delivery

<table>
<thead>
<tr>
<th>Control unit</th>
<th>30078000</th>
<th>30078001</th>
<th>30078002</th>
<th>30078003</th>
<th>30078004</th>
<th>30078005</th>
<th>30078006</th>
<th>30078007</th>
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<tbody>
<tr>
<td>REF 06985000 Handpiece with 1.8 m cable</td>
<td>X</td>
<td></td>
<td>X</td>
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<td>X</td>
<td></td>
<td></td>
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<tr>
<td>REF 07159200 Handpiece with 3.5 m cable</td>
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<td></td>
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<td>REF 30264001 Foot control S-NW</td>
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<tr>
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<tr>
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<tr>
<td>REF 06177800 Motor support</td>
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<td>REF 04005900 Stand</td>
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<td>X</td>
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<tr>
<td>REF 06276700 Instrument changer</td>
<td></td>
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<td></td>
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<tr>
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<td></td>
<td>X</td>
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<tr>
<td>Mains cable country-specific</td>
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</tbody>
</table>
5. Safety notes

Please observe the following instructions under all circumstances

> Before using the Piezomed for the first time, store it at room temperature for 24 hours.
> Check the Piezomed and the handpiece with cable for damage and loose parts (e.g. instrument, LED) each time before using. Correct any faults or refer to an authorized W&H service partner.
> Do not operate the Piezomed if it is damaged.
> Check the parameter settings every time the device is restarted.
> Make sure that the operation can be completed safely even if a device or instrument malfunctions.
> Make sure that the coolant filling function has been carried out prior to every application.
> Perform a test run each time before using.
> Avoid eye contact with the optic outlet.
> Never touch the patient and the connection for the foot control simultaneously.
> Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
> Turn off the handpiece immediately in the event of failure in the coolant supply (max. operating time without coolant is 15 seconds).
> When changing the fuse, disconnect the device from the power supply and only use W&H original fuses.
> Only replace the LED socket when the handpiece is at rest.
> The ESD spring contact on the underside of the foot control must touch the floor during operation.
> Avoid overheating at the treatment site.
> Always operate the handpiece with the handpiece cap fitted!

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.
Safety notes

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

This medical device complies with the reference values defined in EN 50527-2-1/2011 for unipolar and bipolar pacemakers and is therefore suitable for patients with pacemakers.
> Keep a safe distance of at least 30 cm between the control unit and your patients during operation.
Safety notes

Inappropriate use
Improper use, in addition to incorrect assembly, installation, modification or repairs of the Piezomed or failure to comply with our instructions invalidates all claims under warranty and any other claims.

Danger zones M and G
In accordance with IEC 60601-1 / ANSI/AAMI ES 60601-1, the control unit and the motor with cable are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

Piezomed is not suitable for use in oxygen enriched atmospheres.

Zone M is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.

Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.
Safety notes

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

Mains cable
Only use the mains cable supplied.
Only connect to a grounded socket outlet.

⚠️ Set up the device so that the power switch is easily accessible.
In dangerous situations, the device can be disconnected from the power supply using the power switch or mains cable.
The power switch can also be used to safely stop the device.

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

System failure
A total system failure does not constitute a critical fault.
Safety notes

Intermittent operating mode S3 (1min/6min)
The Piezomed is designed for intermittent operating mode S3 with an operating time of 1 minutes and a pause time of 6 minutes. If the operating mode specified 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.

Coolant
The Piezomed is designed for use with physiological saline solution. Use only suitable irrigation fluids and follow the manufacturer’s medical data and instructions. Use the W&H irrigation tubing set or accessories approved by W&H.
You can purchase the coolant bottle or the coolant bag at a drugstore.

Sterility of irrigation tubing set
Sterile irrigation tubings are supplied with the equipment. These irrigation tubings are disposable articles and must be discarded after each treatment! Please note the expiry date and the relevant regulations for disposal of irrigation tubings. Only use disposable irrigation tubings with undamaged packaging.

Applied parts (parts that come into contact with the patient)
> Handpiece with cable, instruments
Safety notes

Foot control S-NW / S-N1

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

> The ESD spring contact on the bottom of the foot control must be in contact with the ground during operation.

ESD is the abbreviation for “electrostatic discharge”.

ESD is the abbreviation for “electrostatic discharge”.
Safety notes

Foot control S-NW

Disposable batteries

> Replace the disposable batteries at the first prompt (battery icon on display).
> Replace batteries outside zone M only.
> Use only high-quality disposable alkaline AA / Mignon / LR6 / 1,5 V batteries. Risk of explosion if the wrong type of battery is used.
> Do not mix new, old or different types of disposable batteries.
> Do not use rechargeable batteries.
> When inserting disposable batteries make sure that they are correctly oriented.
> Always keep spare batteries on hand.
> Dispose of faulty or flat batteries immediately and correctly via recycling systems. Do not dispose of batteries in domestic waste.

Disposable batteries may cause damage due to leakage or corrosion.
> Remove the disposable batteries if you are not going to use the foot control for a longer period.

Hygiene and maintenance prior to initial use

> The handpiece with cable, the motor support, the instruments and the instrument changer is not sterilized when delivered.
> Clean and disinfect the handpiece with cable, the motor support, the stand, the instruments and the instrument changer.
> Sterilize the handpiece with cable, the motor support, the instruments and the instrument changer.
6. Description of front panel

Shift buttons
PLUS / MINUS buttons
Motor connecting socket
Display
Pump arm
OPEN
Stand holder
7. Description of rear panel

- Power socket
- Fuse holder with 2 fuses
  REF 06661800 (250 V – T1,25AH)
- Power switch
  I/O (ON/OFF)
- Connecting socket for foot control
- Stand holder
8. Description of foot control S-N1/S-NW

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

- **GREEN**
  - Pump
  - ON / OFF

- **ORANGE**
  - Change program

- **YELLOW**
  - Activate boost function

- **Handle**
  - attach / detach
9. Description handpiece with cable

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

🪗 The handpiece with cable is defined as a type B applied part.

Temperature information
- Temperature of the handpiece at the operator side: max. 55°C (131°F)
- Temperature of the handpiece at the patient side (front area of the handpiece): max. 48°C (118.4°F)
- Temperature of the handpiece at the patient side (LED ring): max. 48°C (118.4°F)
- Temperature of the working part (tip): max. 41°C (105.8°F)
10. Starting operation – General

Always place the Piezomed on a flat level surface.
Ensure that the Piezomed can be disconnected easily from the power supply.

1. Connect the mains cable and the foot control.
   Pay attention to the positioning!

2. Insert the motor cable.
   Pay attention to the positioning!

3. Insert the stand.
   Pay attention to the positioning!
   (Maximum load capacity 1.5 kg)

4. Attach the motor support and lock it.
Starting operation – General

1. Insert the irrigation tubing.
2. Open the pump arm.
3. Fit the irrigation tubing.
4. Follow the same sequence when removing the irrigation tubing.
5. Close the pump arm.
6. Connect the spray tube to the handpiece.
7. Connect the Piezomed to the power supply.
   Disconnect the Piezomed from the power supply.
8. Switch the Piezomed on or off at the power switch.
9. Once it has been switched on, the coolant filling function will appear on the display and the PLUS/MINUS buttons will flash.
Starting operation – Coolant filling function

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

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

1. Coolant filling function

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

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

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

Inserting a instrument

1. Position the instrument on the handpiece thread.

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

3. Carefully pull off the instrument changer.

   Check the secure attachment of the instrument by pulling axially.

   Press the instrument on a hard surface with approx. 1 N (=100 g) to test the load bearing capacity of the instrument.

Removing a instrument

1. Attach the instrument changer to the instrument.

2. Twist off the instrument with the instrument changer.

   Keep the instrument in the instrument stand until a hygienic maintenance process is carried out.
12. Control unit operation – Setup settings

Calling up the setup settings

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

Operating hours counter

Foot control

Volume

Instrument detection

Reset

Variable or ON / OFF

Volume display

activate/deactivate

Return

To exit the setup settings, select Return ▼ using the shift button t.
Confirm with the PLUS button.
Setup settings – Foot control S-N1

To change from VARIABLE to ON / OFF

1. Foot control
2. Select setting

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

= ON / OFF
Setup settings – Volume

1. Volume
2. Increase volume
3. Decrease volume

Mute
Setup settings – Reset factory settings

The device will restart after the factory settings have been reset.

1. Reset

2. Start reset countdown

3. The reset countdown can be interrupted within 5 seconds
### 13. Factory settings (Instrument group 1 – 3)

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th></th>
<th></th>
<th>Group 2</th>
<th></th>
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<th>Group 3</th>
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<tbody>
<tr>
<td><strong>Program</strong></td>
<td>P1</td>
<td>P2</td>
<td>P3</td>
<td>P1</td>
<td>P2</td>
<td>P3</td>
<td>P1</td>
<td>P2</td>
<td>P3</td>
<td></td>
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<tr>
<td><strong>Power</strong></td>
<td>20</td>
<td>30</td>
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<td>45</td>
<td>55</td>
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<td>70</td>
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<td><strong>Coolant</strong></td>
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<tr>
<td>*<strong>Boost function</strong></td>
<td>🔄</td>
<td>🔄</td>
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<td>🔄</td>
<td>🔄</td>
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</table>

* Using the Boost function, you can boost performance by 20% for 15 seconds.
  Activate the boost function by pressing the yellow button on the foot control.
14. Control unit operation – Main menu settings

Calling up the main menu settings

Press the ▲ or ▼ button, to select the required menu.
The selected menu is framed green.

Press the ▲ and ▼ button to switch from the main menu settings into the Setup menu settings.
Main menu settings – Changing the program (P1 – P3)

1. Program
2. Next program
3. Previous program
Main menu settings – Change power

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

1. Power
2. Increase power
3. Reduce power

By keeping the PLUS / MINUS button pressed you can continuously increase / decrease the power.
Main menu settings – Changing the coolant flow

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

1. Coolant

2. Increase flow rate in 10 % steps

3. Decrease flow rate in 10 % steps

Coolant OFF

The max. operating time without coolant is 15 seconds.

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

Press the PLUS/MINUS buttons at the same time to activate the coolant filling function at any time.
Main menu settings – Changing the operating mode

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

+ - 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.
15. Foot control operation

**ORANGE**

S-N1 / S-NW: Changing the program

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

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

Hold the ORANGE button down and 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 of the foot control. 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% for 15 seconds. Activate the boost function by pressing the yellow button on the S-N1 foot control.
16. Test run

⚠️ Do not hold the handpiece at eye level.

- Connect the handpiece with cable to the control unit.
- Insert the instrument.
- Start the Piezomed.

- In the event of malfunctions (e.g. vibrations, unusual noises, overheating, coolant failure or leakage), or change of LED colour, stop Piezomed immediately and contact an authorized W&H service partner.
## 17. Error messages / emergency mode

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Foot control not recognized]</td>
<td>Foot control not recognized</td>
<td>&gt; Connect foot control correctly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Connect correct foot control</td>
</tr>
<tr>
<td>![Foot control error]</td>
<td>Foot control error</td>
<td>&gt; Connect foot control correctly</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Connect correct foot control</td>
</tr>
<tr>
<td>![Info: Foot control recognized]</td>
<td>Info: Foot control recognized</td>
<td></td>
</tr>
<tr>
<td>![Handpiece not recognized]</td>
<td>Handpiece not recognized</td>
<td>&gt; Connect handpiece</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check LED socket (correctly attached, defective)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check handpiece coupling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check supply hose</td>
</tr>
<tr>
<td>![Handpiece error]</td>
<td>Handpiece error</td>
<td>&gt; Handpiece must be dry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check handpiece coupling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check supply hose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check instrument</td>
</tr>
<tr>
<td>![Info: Handpiece recognized]</td>
<td>Info: Handpiece recognized</td>
<td></td>
</tr>
<tr>
<td>![Instrument not recognized]</td>
<td>Instrument not recognized</td>
<td>&gt; Insert the instrument</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Check instrument (only use W&amp;H-approved instruments)</td>
</tr>
<tr>
<td>![Info: Instrument group recognized]</td>
<td>Info: Instrument group recognized</td>
<td></td>
</tr>
</tbody>
</table>
## Error messages / emergency mode

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<tr>
<th>Error</th>
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</tr>
</thead>
</table>
| ![Icon](instrument-detection-error.png) | Instrument detection error | > Check LED socket (correctly attached, defective)  
   > (Activate emergency mode [see pages 42–43] or change the LED socket) |
| ![Icon](press-button-keypad-pressed.png) | Press button (keypad) pressed during power-on | > Switch off the device and restart                                      |
| ![Icon](temperature-error.png) | Error electronics temperature | > Switch off device and allow to cool down  
   > Observe permissible ambient temperature  
   > Observe operating mode               |
| ![Icon](scanner-timeout.png)  | Scaler timeout | > Check foot control  
   > (must not be active for longer than 15 minutes without interruption) |
| ![Icon](system-error.png)     | System error | > Switch off the device and restart  
   > If the error message appears again,  
   > contact an authorized W&H service partner |

If the error messages described cannot be resolved by switching off and restarting Piezomed, it is necessary for an authorized W&H service partner to check.

A possible total failure of the device cause by external influences requires switching off and restarting.
Error messages / emergency mode

Emergency mode should only be activated if the LED socket stops working during treatment.

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

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

2. Instrument tip detection deactivated.

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

3. Press the PLUS/MINUS buttons at the same time to activate the coolant filling function.
Error messages / 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.
18. Hygiene and maintenance

**General notes**

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 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) and 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.
Hygiene and maintenance

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.

Limitations on processing

Processing cycles

- We recommend a regular service for the W&H handpiece with cable after 500 processing cycles or one year.
- We recommend that the motor support and the stand is replaced after 250 processing cycles.
- We recommend that the instrument changer is replaced after 1000 processing cycles.
- We recommend checking the instruments for material wear after 60 reprocessing cycles.

In the U.S. diamond-coated instruments are intended for single-use only.
Hygiene and maintenance

Clean the medical device immediately after every treatment, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

> Operate the medical device for at least 10 seconds at idle speed.
> Ensure that all coolant outlets are rinsed out.

> Wipe the entire surface of the handpiece with cable, the motor support and the stand with disinfectant.
> Remove the instrument.
> Remove the handpiece with cable.

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

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

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

> Clean the handpiece with cable, the motor 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.

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

> The ESD spring contact on the bottom of the foot control must be cleaned regularly.

> Clean and disinfect instruments in an ultrasonic bath.

Evidence of the instruments basic suitability 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 »StammopurDR8 (DR H Stamm, Berlin)«.
Hygiene and maintenance

Manual cleaning

Cleaning the spray nozzles
1 Use the nozzle cleaner to remove dirt and deposits from the outlets.
   The nozzle cleaner can be cleaned in an ultrasonic bath and/or in the washer disinfecter.

Cleaning the coolant channel
2 Blow through the coolant channel with the compressed air.
   If the exit openings or coolant channels are blocked, contact an authorized W&H service partner.

Cleaning of the optic outlet

Avoid scratching of the optic outlet!
1 Wash the optic outlet with cleaning fluid and a soft cloth.
2 Dry the optic outlet with the compressed air or carefully with a soft cloth.
   Carry out a visual inspection after cleaning each time. Do not put the handpiece into operation if the optic outlet is damaged and contact an authorized W&H service partner.
Hygiene and maintenance

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

> W&H recommends wiping down with disinfectant.

Evidence of the handpiece with cable, the motor support, the stand, the instruments and the instrument changer basic suitability for effective manual disinfection was provided by an independent test laboratory using the »mikrozid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).
Hygiene and maintenance

Handpiece with cable / Motor 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.

> Use the W&H adaptor kit REF 07233500 for the washer disinfector to prepare the instruments.

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

Automated cleaning and disinfection

Mechanical cleaning and disinfection internal and external

1. Screw the W&H adaptor into the adaptor on the injector rail.
2. Screw the instrument onto the W&H adaptor.

Evidence of the basic suitability of the handpiece with cable, the motor 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
Hygiene and maintenance

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

> Ensure that the handpiece with cable, the motor support, the stand, the instruments and the instrument changer are completely dry internally and externally after cleaning and disinfection.

> Remove any liquid residues using compressed air.

Drying
Hygiene and maintenance

Inspection

> Check the handpiece with cable, the motor 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 motor support, the stand, the instruments and the instrument changer that are still soiled.
> Sterilize the handpiece with cable, the motor support, the stand, the instruments and the instrument changer following cleaning and disinfection.
Pack the handpiece with cable, the motor 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 / Motor support / Instruments / Instrument changer

- W&H recommends sterilization according to EN 13060, EN 285 or 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 handpiece with cable, the motor support, the instruments and the instrument changer.

**Recommended sterilization cycles**
- Steam sterilization (type B, S, N)
- Sterilization time at least 3 minutes at 134°C (273°F), 30 minutes at 121°C (250°F)
- Maximum sterilization temperature 135°C (275°F)

Evidence of the handpiece with cable, the motor support, the instruments and the instrument changer 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 prevacuum cycle” (type B): temperature 134°C (273°F) – 3 minutes*
- “Steam-flush pressure-pulse cycle” (type S): temperature 134°C (273°F) – 3 minutes*
- “Gravity-displacement cycle” (type N): temperature 121°C (250°F) – 30 minutes**

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

Handpiece with cable / Motor 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.
19. Servicing

Regular checks
Regular servicing of function and safety including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organization and must include the following procedures:

Control unit
- External visual inspection
- Measurement of device leakage current
- Measurement of patient leakage current
- Visual inspection of internal components on suspicion of safety interference, e.g., mechanical damage of the enclosure or indicators of overheating

Foot control
- External visual inspection
- Measurement of device leakage current
- Measurement of ESD capacity
- Visual inspection of the ESD spring contact on the bottom of the foot control (electrostatic discharge)
- Function test with check to see if the maximum speed can be reached

The regular inspection must only be performed by an authorized W&H service partner.
Servicing

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

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

> Always return equipment in the original packaging.

> Do not coil the cable around the motor and do not twist or kink the motor cable. (Risk of damage)
20. W&H accessories and spare parts

Use only original W&H accessories / spare parts or accessories approved by W&H

- 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
- 04019000 Clips (5 pcs)
- 06661800 Fuse T1,25AH
W&H accessories and spare parts

00636901  Nozzle cleaner

06177800  Motor support

04005900  Stand

07233500  W&H Adapter kit

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

04719400  Irrigation tubing set 2.2 m

07795800  SPI dongle
21. Technical data

Piezomed
Supply voltage:
Frequency:
Permitted voltage fluctuation:
Nominal current:
Mains fuse:
Max. power consumption:
Max. mechanical output power:
Operating frequency:
Coolant flow rate at 100 %:
Operating mode:
Dimensions in mm (WxDxH):
Weight in kg:

SA-320
100 – 130 V / 220 – 240 V
50 – 60 Hz
±10 %
0,1 – 1,0 A / 0,1 – 0,5 A
2 x 250 V – T1,25AH
90 VA
24 W
22 – 35 kHz
at least 50 ml/min
S3 (1min/6min)
256 x 305 x 109
7

Ambient conditions
Temperature for storage and transport:
Air humidity for storage and transport:
Ambient temperature during operation:
Air humidity during operation:
Technical data

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Device 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)

The foot control REF 07004400 conforms to class AP according to IEC 60601-1 / ANSI/AAMI ES 60601-1 in danger zone M

The foot control is water-tight 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
22. Disposal

Ensure that the parts are not contaminated on disposal.

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

- Waste electrical equipment
- Accessories and spare parts
- 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).

<table>
<thead>
<tr>
<th>Product name</th>
<th>Serial number (SN)</th>
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<tbody>
<tr>
<td>Manufacturer with address</td>
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<tr>
<td>Distributor with address</td>
<td></td>
</tr>
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<tr>
<td>Signature of the user</td>
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The signature confirms that the user has been trained to use the medical device and has understood the content.

<table>
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W&H course certificate for the instructor

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This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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 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 cassettes, irrigation tubing sets, clips, nozzle cleaners, O-rings, fuses and adaptor sets) 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.
Authorized W&H service partners

Find your nearest W&H service partner at http://wh.com
Simply go to the menu option »Service« for full details.
Alternatively please contact:

**W&H (UK) LIMITED**, 6 Stroud Wood Business Centre, Park Street, St Albans, Hertfordshire AL2 2NJ, United Kingdom
* t + 44 1727 874990, f + 44 1727 872254, E-Mail: technical.uk@wh.com

**W&H Impex Inc.**, 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
* t + 1 800 2656277, 1 519 9446739, f + 1 519 9746121, E-Mail: service.ca@wh.com

**A-DEC AUSTRALIA CO. INC.**, Unit 8, 5-9 Ricketty Street, Mascot NWS 2020, Australia
* t + 61 2 83324000, f + 61 2 83324099, E-Mail: a-dec@a-dec.com.au
Open Source Software

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

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

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

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

You will find further information concerning the applied license versions and the complete license text under www.wh.com/en_global/gnu
Alternatively, you can obtain it directly from the manufacturer.
Manufacturer

W&H Dentalwerk Bürmoos GmbH
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office@wh.com wh.com

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