Instructions for Use
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</tr>
</tbody>
</table>
Symbols

WARNING! (if persons could be injured)

ATTENTION! (if property could be damaged)

General explanations, without risk to persons or property

Thermo washer disinfectable

Sterilizable up to the stated temperature

Call customer service
<table>
<thead>
<tr>
<th>Symbols</th>
<th>on the control unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌱 Follow Instructions for Use</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>📚 Consult Instructions for Use</td>
<td>Serial number</td>
</tr>
<tr>
<td>📦 Date of manufacture</td>
<td>Supply voltage of the unit</td>
</tr>
<tr>
<td>🚫 Do not dispose of with domestic waste</td>
<td>Alternating current</td>
</tr>
<tr>
<td>🚰 Data Matrix code for product information including UDI (Unique Device Identification)</td>
<td>Electric power consumption of the unit</td>
</tr>
<tr>
<td>☑ CE marking with identification number of the Notified Body</td>
<td>Supply current</td>
</tr>
</tbody>
</table>

**Symbols**

- Class II equipment
- Foot control
- On / Off
- Electric fuse
- Type B applied part (not suitable for intracardiac application)
- Control No.
Symbols

CE marking with identification number of the Notified Body

Do not dispose of with domestic waste

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

UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements

Catalogue number

Serial number

Date of manufacture

Category AP equipment
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.
<table>
<thead>
<tr>
<th>Symbols</th>
<th>on the irrigation tubing set</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="Not for re-use" /></td>
<td>Not for re-use</td>
</tr>
<tr>
<td><img src="image" alt="Latex-free" /></td>
<td>Latex-free</td>
</tr>
<tr>
<td><img src="image" alt="CE marking" /></td>
<td>CE marking</td>
</tr>
<tr>
<td><img src="image" alt="Use by" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image" alt="Sterilization with ethylene oxide" /></td>
<td>Sterilization with ethylene oxide</td>
</tr>
<tr>
<td><img src="image" alt="Batch code" /></td>
<td>Batch code</td>
</tr>
<tr>
<td><img src="image" alt="Rx only" /></td>
<td>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 who intends to use or order the use of this medical device.</td>
</tr>
</tbody>
</table>
1. Introduction

For your safety and the safety of your patients
These Instructions for Use 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.

Observe the safety notes.

Intended use
Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 [DIN 13940] compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery [CMF].

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

Qualifications of the user
Only suitably qualified medical, technical and specialist trained staff may use the W&H Implantmed. We have based our developed and design of the Implantmed on the »physician« target group.
Introduction

Production according to EU Directive
The medical device complies with the regulations of Directive 93/42/EEC.

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the Implantmed when compliance with the following instructions is ensured:

> The Implantmed must be used in accordance with these Instructions for Use.
> The Implantmed 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 62).
> 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 control unit invalidates all claims under warranty and any other claims.

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

Medical electrical device 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 device.
3. Unpacking

1. Remove the packaging.

2. Remove the motor with cable.

3. Remove the foot control, Instructions for Use and accessories.

4. Lift out the insert with the control unit. Remove the mains cable, irrigant support, universal support, irrigation tubing set and Instructions for Use.

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>REF</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30286000</td>
<td>Control unit SI-923 (230 V)</td>
</tr>
<tr>
<td>30287000</td>
<td>Control unit SI-915 (115 V)</td>
</tr>
<tr>
<td>30185000</td>
<td>EM-19 motor without electrical contacts with 1.8 m cable incl. 5 hose clips</td>
</tr>
<tr>
<td>04363600</td>
<td>Irrigation tubing set 2.2 m (3 pcs, disposable)</td>
</tr>
<tr>
<td>07721800</td>
<td>Universal support</td>
</tr>
<tr>
<td>04005900</td>
<td>Irrigant support</td>
</tr>
<tr>
<td>30285000</td>
<td>Foot control S-N2</td>
</tr>
<tr>
<td>01343700</td>
<td>Mains cable EU</td>
</tr>
<tr>
<td>02821400</td>
<td>Mains cable USA, CAN, J</td>
</tr>
<tr>
<td>03212700</td>
<td>Mains cable UK, IRL</td>
</tr>
<tr>
<td>04280600</td>
<td>Mains cable CH</td>
</tr>
<tr>
<td>05901800</td>
<td>Mains cable DK</td>
</tr>
</tbody>
</table>
5. Safety notes

> Before using the Implantmed for the first time, store it at room temperature for 24 hours.
> Check the control unit and the motor with cable for damage and loose parts every time before use.
> Do not operate the control unit and the motor with cable if it is damaged.
> Check the parameter settings every time the device is restarted.
> Perform a test run prior to every treatment.
> 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 control units or instruments fail.

The Implantmed is not approved for operation in potentially explosive atmospheres.

Do not twist or kink the motor cable! Do not coil it too tightly!
Moisture in the motor with cable may cause a malfunction! (Risk of short circuit)
Safety notes

> Use only original W&H fuses

> Never touch the patient and the electrical connections on the control unit simultaneously.

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

Use the control unit in P4 and P5 programs exclusively with the surgical contra-angle handpieces approved by W&H. Use of other contra-angle handpieces may result in deviation from the indicated torque. The user alone is responsible for the above. The manufacturer does not accept any liability.

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

Mains cable / Power switch
> Only use the mains cable supplied.
> Plug the mains cable only into an earthed power socket.
> Set up the control unit so the power switch and the socket are easily accessible at all times.

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.

Rotational energy
Deceleration of the bur can, cause the selected torque to be temporarily exceeded, compared to the value set, as a result of the rotational energy stored in the drive system.

Observe the manufacturer’s speed and torque specifications for retaining screws for superstructures.
Adjusting these retaining screws with an electric motor presents a potential risk as described above.
Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillators (ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if patient and user have implanted systems before using the medical device and consider the application.
> Weigh the risks and benefits.
> Keep the medical device away from implanted systems.
> Do not place the motor on the patient’s body.
> Make appropriate emergency provisions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.
Follow the directions and safety notes in the Instructions for Use of the foot control.

The foot control is approved for operation in potentially explosive atmospheres (AP).

> Note that when using or setting low speeds, the operation or run-down of rotary instruments is more difficult to detect.
> 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”.
The Implantmed is designed for use with physiological saline solution.

> Always ensure correct operating conditions and that sufficient and adequate coolant is delivered.
> Always provide sufficient coolant and ensure the appropriate suction.
> 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.
Safety notes

Transmission instrument
> Follow the directions and safety notes in the Instructions for Use of the transmission instrument.
> Only use transmission instruments with an ISO 3964 (DIN 13940) compatible coupling system and manufacturer approved transmission instruments.
> Follow the directions of the manufacturer of transmission instrument with reference to transmission ratio, maximum speed and maximum torque.

Hygiene and maintenance prior to initial use
> Clean and disinfect the control unit, the motor with cable, the universal support and the irrigant support.
> Sterilize the motor with cable and the universal support.
6. Description of front panel
Description of rear panel

- Irrigant support locator
- Connection for foot control
- Connection for mains cable
- Fuse holder with 2 fuses
  REF 06352200 (2 x 250 V - T1.6 AH)
- Power switch
  ON / OFF
Description of foot control

**Locator**
- attach / detach

**GREEN**
- Pump
  - ON / OFF

**GREY**
- Start motor [pedal]
  - VARIABLE or ON / OFF
  - [Factory setting = variable]

**ORANGE**
- Change program
  - Programs 1 to 4
  - Program 5 (torque 20 – 60 Ncm)

**YELLOW**
- Change motor direction
  - forward / reverse operation mode
The motor with cable must not be disassembled.
The motor with cable must not be oiled (pre-oiled for entire service life).

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

Temperature information
Temperature of the motor on the operator side: max. 55 °C (131°F)
7. Start-up

Always place the Implantmed on a flat level surface.

Ensure that the Implantmed can be disconnected easily from the power supply.

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

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

3. Insert the irrigant support.
   Pay attention to the positioning!
   (maximum load capacity 1.5 kg)

4. Attach the universal support and lock it.

5. Insert/remove the irrigation tubing.
   Pay attention to the correct order.
   > Open the pump cover (a).
   > Insert/remove the irrigation tubing (b, c, d).
   > Close the pump cover (e).
8. Implantmed

Switch on Implantmed

1. Connect the control unit to the power supply.
2. Switch on the control unit at the power switch.

Switch off Implantmed

1. Switch off the control unit at the power switch.
2. Disconnect the control unit from the power supply.

Test run

⚠️ Do not hold the motor with transmission instrument at eye level.

> Connect the transmission instrument to the motor. Point the transmission instrument with the head facing downwards.
> Operate the motor with the foot control.

> In the event of operating malfunction (e.g. vibrations, unusual noises or overheating), stop the motor immediately and contact an authorized W&H service partner.
Activate the desired program (P1 – P5) by pressing the corresponding program button. During selection an audible signal can be heard and the Program button lights up. The selected program appears on the display with the adjusted range in rpm, e.g. for P1:

![Display showing 35.000 rpm]

- **Display settings**
  - > P1 – P3 speed
  - > P4 – P5 torque

- **Pump function**
  - ON / OFF

- **Error messages**
  - > Motor temperature too high
  - > Motor push-in connection

- **Display settings**
  - > P4 – P5 torque in Ncm
  - > P1 – P3 speed in rpm

Always make sure that the LED displays on the buttons and the display itself are all on when switching on the Implantmed.
Control unit operation

Pressing and holding PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

1. Press program button (P1–P3)

2. Increase speed

3. Decrease speed

At 40,000 rpm the accuracy of the speed set is ± 10%.
Control unit operation

Program P4: range 5 – 70 Ncm, intermediate stage 32 Ncm.
Program P5: range 20 – 60 Ncm.

Pressing and holding PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.
A longer confirmation signal is heard on changing from 5 to 70 Ncm (20 to 60) and 70 to 5 Ncm (60 to 20).

The motor switches off automatically when the set torque is reached in forward and reverse operation modes.

1. Press the program button [P4 or P5]

2. P4: increase torque in 5-Ncm steps
   P5: increase torque in 10-Ncm steps

3. P4: decrease torque in 5-Ncm steps
   P5: decrease torque in 10-Ncm steps

The accuracy of the set torque in the 20 – 50 Ncm range for the W&H WI-75 E/KM contra-angle handpiece is ± 10%.
Greater deviations may be encountered with other instruments.
Control unit operation

Factory setting 100 % Range 65 %, 80 % and 100 %.
Press and hold the PLUS / MINUS button to continuously increase or decrease the values.

Press and hold program button P2 during this procedure.

1. Press and hold P2 for approx. 4 seconds
   (the set coolant volume is shown)

2. Continue to press P2 and press PLUS
   to increase the flow rate

3. Continue to press P2 and press MINUS
   to decrease the flow rate

After adjusting, program button P2 is illuminated and active.

Changing coolant volume (P1 – P5)
10. Operation

Change program
Press the ORANGE button to select programs 1 – 4 in ascending order. In program 5 switch the torque steps from 20 – 60 Ncm. The motor direction is automatically set to forward operation every time the program is changed.

⚠️ When changing from program 4 to program 1 and in program 5 from 60 Ncm to 20 Ncm, a longer acknowledgment signal sounds (risk of injury).

Pump ON / OFF
Only when the motor is at complete standstill can the pump be switched on or off by pressing the GREEN button of the foot control. If the pump function is activated, the pump symbol is shown on the display.

Reverse operation
Press the YELLOW button to change from forward operation to reverse operation. On selecting reverse operation, an audible signal can be heard and the selected program button flashes. Before the motor starts in reverse operation, 3 audible warning signals are given.
To change from VARIABLE to ON / OFF

Keep program button P3 depressed throughout this procedure.

1. Keep P3 depressed for approx. 4 seconds

2. Continue to keep P3 depressed and simultaneously press the PLUS and MINUS buttons

3. Continue to keep P3 depressed and adjust the setting.

   01 = VARIABLE (factory setting) – press PLUS button

   00 = ON/OFF – press MINUS button

After adjusting, program button P3 is illuminated and active.
11. Restoring factory settings

The factory setting always starts with program 1 (P1).

1. Switch off the control unit

2. Press and hold P1 and simultaneously switch on the control unit

3. Press and hold P1 until the display shows the setting »DE FAU«
## Factory settings

<table>
<thead>
<tr>
<th></th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission</td>
<td>1:1</td>
<td>20:1</td>
<td>20:1</td>
</tr>
<tr>
<td>Speed rpm</td>
<td>35,000</td>
<td>1,200</td>
<td>800</td>
</tr>
<tr>
<td>Setting range rpm</td>
<td>300 – 40,000</td>
<td>15 – 2,000</td>
<td>15 – 2,000</td>
</tr>
<tr>
<td>Motor direction of rotation</td>
<td>forward</td>
<td>forward</td>
<td>forward</td>
</tr>
<tr>
<td>Pump</td>
<td>on</td>
<td>on</td>
<td>on</td>
</tr>
<tr>
<td>Torque Ncm</td>
<td>100 %</td>
<td>100 %</td>
<td>100 %</td>
</tr>
</tbody>
</table>
## Factory settings

<table>
<thead>
<tr>
<th></th>
<th>P4 forward</th>
<th>P4 reverse</th>
<th>P5 forward</th>
<th>P5 reverse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transmission</strong></td>
<td>20:1</td>
<td>20:1</td>
<td>20:1</td>
<td>20:1</td>
</tr>
<tr>
<td><strong>Speed rpm</strong></td>
<td>15</td>
<td>30</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>Motor direction of rotation</strong></td>
<td>forward</td>
<td>reverse</td>
<td>forward</td>
<td>reverse</td>
</tr>
<tr>
<td><strong>Pump</strong></td>
<td>on</td>
<td>off</td>
<td>on</td>
<td>on</td>
</tr>
<tr>
<td><strong>Torque Ncm</strong></td>
<td>20</td>
<td>60</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>Setting range Ncm</strong></td>
<td>5 – 70</td>
<td>5 – 70</td>
<td>20 – 60</td>
<td>20 – 60</td>
</tr>
<tr>
<td><strong>Intermediate stage Ncm</strong></td>
<td>32</td>
<td>32</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
12. Thread cutter function (chip breaker mode)

When the thread cutter function (P5) is activated, the speed in both forward and reverse operation modes is 20 rpm and can no longer be changed.

When the motor button (grey) on the foot control is pressed, the thread cutter rotates inwards until the set torque is reached. The control unit automatically switches to reverse operation when the set torque is reached. Disengaging and then re-engaging the motor button will switch the control unit back to forward operation.

If the thread cutter function is in reverse operation mode, the control unit can also start with the maximum torque.

1. Press P5 program button.

2. Use Plus/Minus to increase or decrease the torque.
## 13. Error messages

<table>
<thead>
<tr>
<th>Error no.</th>
<th>Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>Electronics overheated – safety shutdown</td>
<td>Switch off device, allow device to cool for at least 10 minutes, re-start</td>
</tr>
<tr>
<td>01</td>
<td>Electronics overloaded</td>
<td>Switch off device, allow device to cool for at least 10 minutes, re-start</td>
</tr>
<tr>
<td>02</td>
<td>Voltage too high</td>
<td>Switch off device, check voltage, re-start</td>
</tr>
<tr>
<td>07</td>
<td>Initialization error</td>
<td>Switch off device, re-start, do not actuate foot control and display when switching on</td>
</tr>
<tr>
<td>09</td>
<td>Foot control error</td>
<td>Switch off device, check plug contacts of foot control, re-start</td>
</tr>
<tr>
<td>19</td>
<td>Running time limiter</td>
<td>Switch off device and re-start</td>
</tr>
<tr>
<td>99</td>
<td>System failure</td>
<td>Switch off device, allow device to cool for at least 10 minutes, re-start</td>
</tr>
<tr>
<td></td>
<td>Motor plug-in connection</td>
<td>Switch off device, check plug contacts, re-start</td>
</tr>
</tbody>
</table>

> Switch the control unit off and on again. If any of the described problems cannot be corrected by the remedy provided above, the unit will need to be inspected by an authorized W&H service partner.

> Switch the control unit off and on again in case of a total system failure.
14. Hygiene and maintenance

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 the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichisch 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 motor with cable after 500 processing cycles or one year.
> We recommend a regular service for the W&H universal support after 250 processing cycles.
Hygiene and maintenance

Initial treatment at the point of use

> Clean and disinfect the medical device immediately after every treatment.

> Wipe the control unit, the motor with cable, the universal support and the irrigant support with disinfectant. Wipe the entire surface of the instrument with disinfectant.

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

Motor with cable / Universal support / Irrigant support
> Do not immerse the motor with cable, the universal support or the irrigant support in liquid disinfectant or in an ultrasonic bath.

Motor with cable / Universal support / Irrigant support
> Clean the motor with cable, the universal support and the irrigant support under running tap water (< 35°C / < 95°F).
> Rinse and brush off all internal and external surfaces.
> Remove any liquid residues using compressed air.

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

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

Motor with cable / Universal support / Irrigant support

> W&H recommends wipe-down disinfection.

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

> Cleaning at 55 °C (131°F) – 5 minutes
> Disinfection at 93 °C (200°F) – 5 minutes
Motor with cable / Universal support / Irrigant support

> Ensure that the motor with cable, the universal support and the irrigant support are completely dry internally and externally after cleaning and disinfection.

> Remove any liquid residues using compressed air.
Hygiene and maintenance

Inspection – Motor with cable / Universal support / Irrigant support

- Check the motor with cable, the universal support and the irrigant support after cleaning and disinfection for damage, visible residual soiling and surface changes.
- Reprocess any motor with cable, universal support and irrigant support that are still soiled.
- Sterilize the motor with cable and the universal support following cleaning and disinfection.
Motor with cable / Universal support

Wrap the motor with cable and 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.
Motor with cable / Universal support

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 motor with cable and the universal support.

**Recommended sterilization procedures**
> Fractionated pre-vacuum process (type B)
> Gravity displacement process (type N)
> Sterilization time at least 30 minutes at 121 °C (250°F) or at least 3 minutes at 134 °C (273°F)
> Maximum sterilization temperature 135 °C (275°F)

Evidence of the basic suitability of the motor with cable and 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)) and the CertoClav MultiControl MC2-S09S273 gravitation sterilizer (CertoClav GmbH, Traun).
> Fractionated pre-vacuum process (type B): temperature 134 °C (273°F) – 3 minutes*
> Gravity displacement process (type N): temperature 121 °C (250°F) – 30 minutes**

* according to EN 13060, EN 285, ISO 17665 / ** according to ANSI/AAMI ST55, ANSI/AAMI ST79
Motor with cable / 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.
15. 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]
16. W&H accessories and spare parts

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

**Suppliers:** W&H partners

- **04013500**
  - Sterilization cassette

- **07948730**
  - Transportation case

- **07721800**
  - Universal support

- **04005900**
  - Irrigant support

- **06352200**
  - Fuse (250 V - T1.6AH)
W&H accessories and spare parts

30185000
EM-19 motor without electrical contacts and 1.8 m cable

30285000
Foot control S-N2

04653500
Locator for foot control

04363600
Irrigation tubing set 2.2 m (6 pcs)

04719400
Irrigation tubing set 2.2 m

06290600
Hose clips (5 pcs)
## 17. Technical data

<table>
<thead>
<tr>
<th>Implantmed</th>
<th>SI-923</th>
<th>SI-915</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mains voltage:</strong></td>
<td>230 V</td>
<td>120 V</td>
</tr>
<tr>
<td><strong>Permissible voltage fluctuation:</strong></td>
<td>220 – 240 V</td>
<td>110 – 130 V</td>
</tr>
<tr>
<td><strong>Rated current:</strong></td>
<td>0.3 – 0.8 A</td>
<td>0.3 – 1.6 A</td>
</tr>
<tr>
<td><strong>Frequency:</strong></td>
<td>50 – 60 Hz</td>
<td></td>
</tr>
<tr>
<td><strong>Mains fuse (2 pcs):</strong></td>
<td>250 V – T1.6 AH</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum power consumption:</strong></td>
<td>160 VA</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum power output:</strong></td>
<td>80 W</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum torque at motor:</strong></td>
<td>5.5 Ncm</td>
<td></td>
</tr>
<tr>
<td><strong>Motor speed range in the rated voltage range:</strong></td>
<td>300 – 40,000 rpm</td>
<td></td>
</tr>
<tr>
<td><strong>Coolant flow rate at 100 %:</strong></td>
<td>min. 90 ml/min</td>
<td></td>
</tr>
<tr>
<td><strong>Dimensions in mm (height x width x depth):</strong></td>
<td>100 x 235 x 240</td>
<td></td>
</tr>
<tr>
<td><strong>Weight in kg:</strong></td>
<td>2.7</td>
<td></td>
</tr>
</tbody>
</table>

### Ambient conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>SI-923</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature during storage and transport:</td>
<td>-40 °C to +70 °C (-40°F to +158°F)</td>
</tr>
<tr>
<td>Air Humidity for storage and transport:</td>
<td>8 % to 80 % (relative), non-condensing</td>
</tr>
<tr>
<td>Temperature in operation:</td>
<td>+10 °C to +35 °C (+50°F to +95°F)</td>
</tr>
<tr>
<td>Air Humidity in operation:</td>
<td>15 % to 80 % (relative), non-condensing</td>
</tr>
</tbody>
</table>
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!)

Type B applied part (not suitable for intracardiac application)

S-N2 (REF 30285000) is approved for operation in potentially explosive atmospheres.

S-N2 (REF 30285000) is waterproof according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

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

Ensure that the parts are not contaminated on disposal.

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

- Medical device
- Waste electrical equipment
- Packaging
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>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer with address</td>
<td></td>
</tr>
<tr>
<td>Distributor with address</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of the user</th>
<th>Date of birth and/or personnel number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital/dental practice/department with address</td>
<td></td>
</tr>
<tr>
<td>Signature of the user</td>
<td></td>
</tr>
</tbody>
</table>

The signature confirms that the user has been trained to use the medical device and has understood the content.

<table>
<thead>
<tr>
<th>Name of the instructor</th>
<th>Date of instruction</th>
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Explanation of warranty terms

This W&H product 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 (universal support, coolant hose, irrigant support, fuse, locator for foot control, hose clips, mains cable, sterilization cassette) 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.
Authorized W&H service partners

Visit W&H on the Internet at http://wh.com
You can find your nearest authorized W&H service partner under “Service” in the menu.
If you do not have Internet access, 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

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t + 1 800 2656277, 1 519 9446739, f + 1 519 9746121, E-Mail: service.ca@wh.com

W&H Impex Inc., 14300 Henn Rd., Dearborn, MI 48126, USA
t + 1 800 2656277, 1 519 9446739, f + 1 519 9746121, E-Mail: service.us@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
Manufacturer

W&H Dentalwerk Bürmoos GmbH
Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria

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office@wh.com wh.com

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