## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbols</td>
<td>4</td>
</tr>
<tr>
<td>1. Introduction</td>
<td>9</td>
</tr>
<tr>
<td>2. Electromagnetic compatibility (EMC)</td>
<td>11</td>
</tr>
<tr>
<td>3. Unpacking</td>
<td>12</td>
</tr>
<tr>
<td>4. Scope of delivery</td>
<td>13</td>
</tr>
<tr>
<td>5. Safety notes</td>
<td>14</td>
</tr>
<tr>
<td>6. Description</td>
<td>21</td>
</tr>
<tr>
<td>of front panel</td>
<td></td>
</tr>
<tr>
<td>of rear panel</td>
<td></td>
</tr>
<tr>
<td>of foot control S-N2/S-NW</td>
<td>23</td>
</tr>
<tr>
<td>of motor with cable</td>
<td>25</td>
</tr>
<tr>
<td>7. Start-up</td>
<td>26</td>
</tr>
<tr>
<td>8. Control unit</td>
<td>27</td>
</tr>
<tr>
<td>9. Starting operation</td>
<td>28</td>
</tr>
<tr>
<td>10. Control unit operation</td>
<td>29</td>
</tr>
<tr>
<td>Main menu</td>
<td>29</td>
</tr>
<tr>
<td>Menue Navigation</td>
<td>32</td>
</tr>
<tr>
<td>Factory settings</td>
<td>37</td>
</tr>
<tr>
<td>Documentation with USB stick</td>
<td>43</td>
</tr>
<tr>
<td>ioDent® platform</td>
<td>45</td>
</tr>
<tr>
<td>Beacon</td>
<td>47</td>
</tr>
<tr>
<td>11. Error messages</td>
<td>48</td>
</tr>
</tbody>
</table>
## Contents

12. Hygiene and maintenance ................................................................. 51
   General notes ................................................................................. 51
   Limitations on processing .............................................................. 52
   Initial treatment at the point of use .............................................. 53
   Manual cleaning ............................................................................ 54
   Manual disinfection ....................................................................... 55
   Automated cleaning and disinfection ........................................... 56
   Drying .......................................................................................... 57
   Inspection, maintenance and testing ............................................. 58
   Packaging ..................................................................................... 59
   Sterilization .................................................................................. 60
   Storage ......................................................................................... 61
13. Servicing ...................................................................................... 62
14. W&H accessories and spare parts .................................................. 64
15. Technical data .............................................................................. 67
16. Disposal ....................................................................................... 69
   W&H course certificate ................................................................. 70
   Explanation of warranty terms ...................................................... 73
   Authorized W&H service partners .............................................. 74
   Manufacturer’s declaration ........................................................... 75
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
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>on the control unit</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Follow Instructions for Use" /></td>
<td>Follow Instructions for Use</td>
<td><img src="image" alt="Class II equipment" /></td>
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<tr>
<td><img src="image" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
<td><img src="image" alt="Foot control" /></td>
</tr>
<tr>
<td><img src="image" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
<td><img src="image" alt="On / Off" /></td>
</tr>
<tr>
<td><img src="image" alt="Do not dispose of with domestic waste" /></td>
<td>Do not dispose of with domestic waste</td>
<td><img src="image" alt="Electric fuse" /></td>
</tr>
<tr>
<td><img src="image" alt="Data Matrix code" /></td>
<td>Data Matrix code for product information including UDI (Unique Device Identification)</td>
<td><img src="image" alt="Type B applied part (not suitable for intracardiac application)" /></td>
</tr>
<tr>
<td><img src="image" alt="CE marking" /></td>
<td>CE marking with identification number of the Notified Body</td>
<td><img src="image" alt="Earth" /></td>
</tr>
</tbody>
</table>

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

Non-ionizing electromagnetic radiation

Catalogue number

Battery compartment closed

Serial number

Battery compartment open

Date of manufacture

Category AP equipment
Symbols

CE marking with identification number of the Notified Body

This way up

Fragile, handle with care

Keep dry

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

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

on the packaging

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

Data structure in accordance with Health Industry Bar Code

Temperature limitation

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

Consult Instructions for Use

Not for re-use

Latex-free

CE mark
with identification number
of the Notified Body

Use by

Sterilization with
ethylene oxide

Batch code

Rx\text{only}

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 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 medical device. We have based our development and design of the medical device 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 medical device when compliance with the following instructions is ensured:

> 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 75).
> 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 device 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.

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

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

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

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

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>Control unit</th>
<th>SI-1023 (230V) 30288000</th>
<th>SI-1015 (120V) 30289000</th>
<th>SI-1010 (100V) 30290000</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF 436360</td>
<td>Irrigation tubing set 2.2 m (3 pcs, disposable)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>REF 07721800</td>
<td>Universal support</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>REF 04005900</td>
<td>Irrigant support</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Mains cable</td>
<td>country-specific</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

#### Optional included in set

<table>
<thead>
<tr>
<th>Control unit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF 30281000</td>
<td>EM-19 LC motor with electrical contacts and 1.8 m cable</td>
</tr>
<tr>
<td>REF 30185000</td>
<td>EM-19 motor without electrical contacts with 1.8 m cable</td>
</tr>
<tr>
<td>REF 30264000</td>
<td>Foot control S-NW</td>
</tr>
<tr>
<td>REF 30285000</td>
<td>Foot control S-N2</td>
</tr>
<tr>
<td>REF 07759700</td>
<td>SPI dongle</td>
</tr>
</tbody>
</table>
5. Safety notes

> Before using the medical device for the first time, store it at room temperature for 24 hours.
> Check the medical device and the motor with cable for damage and loose parts every time before use.
> Do not operate the medical device 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 units or instruments fail.

The medical device 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.
- Make sure that no computer viruses are transferred to the control unit by an external data medium (USB stick).

The connection of a USB hard drive with an external power source is not permitted.

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

Use the WS-75 and WI-75 (20:1) ratios exclusively with the 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 therefore 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.

Note that when using or setting low speeds, the operation or run-down of rotary instruments is more difficult to detect.
Safety notes

Risks due to electromagnetic fields
The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillator (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.

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

Foot control S-NW
Keep the ORANGE button depressed to switch between the control units.
Safety notes

The medical device 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.
Safety notes

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.

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 malfunctions (e.g. vibrations, unusual noises or overheating), stop the motor immediately and contact an authorized W&H service partner.
6. Description

- Display (touchscreen)
- Pump cover
- Irrigant support locator
- Connection for motor
- Pump cover OPEN
Description of rear panel:

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

**Locator**
- attach/detach

**ORANGE**
- Change program

**GREEN**
- Pump
- ON/OFF

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

**YELLOW**
- Change motor direction
  - Forward operation/reverse operation

**of foot control S-N2/S-NW**
ORANGE
S-N2 / S-NW: Change program
Press the ORANGE button to change programs in ascending order. The motor direction is automatically set to forward operation every time the program is changed.

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

ORANGE
S-NW: Switching between multiple control units
Press the ORANGE button for 3 seconds

GREEN – pump ON/OFF
Only when the motor is stationary can the pump be switched on or off by pressing the GREEN button of the foot control.

YELLOW – change motor direction
Forward operation/reverse operation
Press the YELLOW button to change from forward operation to reverse operation. A signal sounds on selection and the “Forward/reverse operation mode” symbol flashes. Before the motor starts in reverse operation, 3 audible signals are given.
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

- **Place the medical device on a flat level surface.**
- **Ensure that the medical device can be disconnected from the power supply at any time.**

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 the irrigation tubing.**
   - > Open the pump cover (a,b).
   - > Insert the irrigation tubing (c).
   - > Close the pump cover (d).
### 8. Control unit

#### Switching on the control unit

1. Plug the mains cable into an earthed power socket.
2. Switch on the control unit at the power switch.

#### Switching off the control unit

1. Switch off the control unit at the power switch.
2. Pull the power plug out of the socket.
9. Starting operation

The touch screen must only be touched using fingers. Using hard objects on the touch screen may scratch or damage the surface.

Setting up control unit
Switch on your control unit and follow the directions of the setup wizard. The set-up wizard guides you through the various set-up stages up to the main menu:

- Language selection
- Set Up Medical Device:
  - Customized: Create a user
  - Standard: Default settings
10. Control unit operation

Main menu

- My favorites
- Documentation / Wi-Fi Pairing
- Setup
- Forward/reverse operation mode
- Set coolant volume
- Tooth position
- Set program
- Set speed / torque
- Foot control
- Progress display mode
- Programs
Control unit operation

- My favorites

  - Select drill protocol group
    - An activated drill protocol cannot be deleted
  
  - Edit
    - Adjust factory setting of drill protocol groups.
    - Create drill protocol

- Copy

- Rename

- Activate

- Delete
Control unit operation

Set program

Transmission

rpm  
Speed
At 40,000 rpm the accuracy of the set speed is ±10 %.

Ncm  
Torque
Adjustment range 5 – 80 Ncm with WI-75 and WS-75 only.
The motor switches off automatically when the set torque is reached in forward and reverse operation modes.
The accuracy of the set torque in the 20 – 50 Ncm range for the W&H WI-75 and WS-75 contra-angle handpieces is ± 10 %. Greater deviations may be encountered with other contra-angle handpieces.

Documentation
DOCU only appears once the documentation has been started.

Progress display mode

Bar

%  
Percent

100  
Total
Control unit operation

Menue Navigation
Control unit operation

User

Add user

Manage user
User settings: Copy, Rename, Activate, Delete

Foot control

Pairing – S-NW

Variable

ON/OFF

System

Torque curve

Set screen lock
Activating / deactivating screen lock

Screen lock

Interval
Interval: Select time

LED
Activating / deactivating LED

Fade-out time
Select time

SOUND
Activating/deactivating

Language
Select language

An activated user cannot be deleted
Control unit operation

System check
  Test run

Dental numbering system
  Select dental numbering system: FDI / UNS

FDI (Féderation Dentaire Internationale = International dental numbering system)

UNS (Universal Numbering System = American dental numbering system)

Switch between selected tooth positions (green)

Selected tooth position (black)

New position

New docu

Complete docu

Wi-Fi-dongle

Device info

Service

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

Module info

Osstell

User interface

Motor control unit
Control unit operation

Foot control

Software update

Reset Wi-Fi pairing

Reset
 Restore factory settings

Restart
 Control unit restarts automatically

Import user settings

Export user settings

Beacon

Beacon Pairing
Control unit operation

✅ Confirm/save

🌟 Favorite selected

ℹ️ black = information
❌ green = Information with selection option
❌ red = error message, work cannot be continued
❌ orange = error message, work can be continued

⚠️ red = replace batteries

Foot control S-NW

Foot control S-N2

Drill function
Drill function
Drill function
Thread-cutter function
Implantatinsertion

Implant stability quotient measurement
W&H Osstell ISQ module is available as an accessory (REF 30210000)
## Control unit operation

<table>
<thead>
<tr>
<th></th>
<th>Implantology 1</th>
<th>Factory settings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transmission</strong></td>
<td>1:1</td>
<td>WS-75 (20:1)</td>
</tr>
<tr>
<td><strong>Speed rpm</strong></td>
<td>35,000</td>
<td>1,200</td>
</tr>
<tr>
<td><strong>Setting range rpm</strong></td>
<td>200 – 40,000</td>
<td>10 – 2,000</td>
</tr>
<tr>
<td><strong>Motor direction of rotation</strong></td>
<td>forward</td>
<td>forward</td>
</tr>
<tr>
<td><strong>Pump</strong></td>
<td>on</td>
<td>on</td>
</tr>
<tr>
<td><strong>Torque Ncm</strong></td>
<td>100 %</td>
<td>100 %</td>
</tr>
</tbody>
</table>

**Factory settings**

- Transmission: WS-75 (20:1)
- Speed rpm: 1,200rpm
- Setting range rpm: 10 – 2,000rpm
- Motor direction of rotation: forward
- Pump: on
- Torque Ncm: 100 %
## Control unit operation

<table>
<thead>
<tr>
<th>Control Unit</th>
<th>Setting 1</th>
<th>Setting 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factory settings</td>
<td></td>
<td></td>
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<tr>
<td>Implantology 1</td>
<td><img src="icon1" alt="Icon" /></td>
<td><img src="icon2" alt="Icon" /></td>
</tr>
<tr>
<td>Transmission</td>
<td>WS-75 (20:1)</td>
<td>WS-75 (20:1)</td>
</tr>
<tr>
<td>Speed rpm</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Setting range rpm</td>
<td>10 – 50</td>
<td>10 – 50</td>
</tr>
<tr>
<td>Motor direction of rotation</td>
<td>forward</td>
<td>reverse</td>
</tr>
<tr>
<td>Pump</td>
<td>off</td>
<td>off</td>
</tr>
<tr>
<td>Torque Ncm</td>
<td>20</td>
<td>50</td>
</tr>
<tr>
<td>Setting range Ncm</td>
<td>5 – 80</td>
<td>5 – 80</td>
</tr>
</tbody>
</table>
## Control unit operation

<table>
<thead>
<tr>
<th>Implantology 2</th>
<th></th>
<th>Factory settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission</td>
<td>1:1</td>
<td>WS-75 (20:1)</td>
</tr>
<tr>
<td>Speed rpm</td>
<td>35,000</td>
<td>1,200</td>
</tr>
<tr>
<td>Setting range rpm</td>
<td>200 – 40,000</td>
<td>10 – 2,000</td>
</tr>
<tr>
<td>Motor direction of rotation</td>
<td>forward</td>
<td>forward</td>
</tr>
<tr>
<td>Pump</td>
<td>on</td>
<td>on</td>
</tr>
<tr>
<td>Torque Ncm</td>
<td>100 %</td>
<td>100 %</td>
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</tbody>
</table>
### Control unit operation

<table>
<thead>
<tr>
<th>Implantology 2</th>
<th>Factory settings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transmission</strong></td>
<td>WS-75 (20:1)</td>
</tr>
<tr>
<td><strong>Speed rpm</strong></td>
<td>20</td>
</tr>
<tr>
<td><strong>Setting range rpm</strong></td>
<td>10 – 50</td>
</tr>
<tr>
<td><strong>Motor direction of rotation</strong></td>
<td>forward</td>
</tr>
<tr>
<td><strong>Pump</strong></td>
<td>on</td>
</tr>
<tr>
<td><strong>Torque Ncm</strong></td>
<td>20</td>
</tr>
<tr>
<td><strong>Setting range Ncm</strong></td>
<td>5 – 80</td>
</tr>
</tbody>
</table>
## Control unit operation

<table>
<thead>
<tr>
<th>Oral Surgery</th>
<th></th>
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<th>Factory settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission</td>
<td>1:1</td>
<td>1:1</td>
<td>1:2.7</td>
</tr>
<tr>
<td>Speed rpm</td>
<td>35,000</td>
<td>10,000</td>
<td>108,000</td>
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<tr>
<td>Setting range rpm</td>
<td>200 – 40,000</td>
<td>200 – 40,000</td>
<td>540 – 108,000</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>
Thread-cutter function (chip breaker mode)

![Warning]

When the pedal (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 pedal will switch the control unit back to forward operation.

![Warning]

If the thread cutter function is in reverse operation mode, the control unit can also start with the maximum torque.
Drill protocols, torque curves and ISQ values can only be documented in the thread-tapping function, implant insertion or ISQ measurement.

Documentation must be activated or deactivated for each program.
A USB stick is required to save the documentation.

> Never remove the USB stick while the motor is running.
> Never remove the USB stick during the measurement.

**Record documentation**
> Connect USB stick

![USB icon]

> Enter ID
> Enter date
> Select tooth quadrant
> Select tooth
> Confirm selection

Documentation starts when the motor starts.
Control unit operation

Further documentation

- Add new position
- Start new docu
- Complete docu

When the motor stops, a diagram appears, which is automatically saved to the USB stick.

Documentation with USB stick

Edit documentation

A text file (csv) and a PDF file are saved on the USB stick.
The text file can be opened in Microsoft® Excel®* for editing.
The pdf file can be opened in Adobe® Reader®**.

* Microsoft® Excel® is a registered trademark of the Microsoft® Corporation in the United States of America and/or other countries.
** Adobe® Reader® is a registered trademark of Adobe Systems Incorporated in the United States of America and/or other countries.
Follow the directions and safety notes in the Instructions for Use of the ioDent® platform.

Check the data exchange between the ioDent® platform and the medical device.

> Check the transferred data for completeness and correctness.

Establishing a connection to the ioDent® platform

> Insert the ioDent® Wi-Fi dongle
> The connection is established

The icon appears

If the icon is green: The documentation is active
If the icon is grey: The system is connected
If the icon is yellow: There is a connection problem

When the motor stops, a diagram appears, which is automatically saved to the ioDent® platform.
Connecting the medical device to an IT network or changing an IT network can lead to previously unidentified risks to patients, operators or third parties. The operator of the IT network is responsible for identification, analyzing, evaluating and controlling these risks. Changes to the IT-Network include changes in the IT-network configuration, connection of additional items to the IT-Network, disconnecting items from the IT-Network, update of equipment connected to the IT-Network, and upgrade of equipment connected to the IT-Network.

<table>
<thead>
<tr>
<th></th>
<th>Not paired device</th>
<th>Paired device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device IP-address</strong></td>
<td>192.168.10.1</td>
<td>192.168.10.x (from Gateway DHCP-Server)</td>
</tr>
<tr>
<td><strong>Device communication port</strong></td>
<td>443 (TLS/SSL)</td>
<td>443 (TLS/SSL)</td>
</tr>
<tr>
<td><strong>Device subnet</strong></td>
<td>255.255.255.0</td>
<td>255.255.255.0</td>
</tr>
<tr>
<td><strong>Device hostname</strong></td>
<td>Implantmed</td>
<td>Implantmed</td>
</tr>
<tr>
<td><strong>Gateway IP</strong></td>
<td>192.168.10.x</td>
<td>192.168.10.1</td>
</tr>
</tbody>
</table>

**Used network layers/protocols**

<table>
<thead>
<tr>
<th></th>
<th>Application layer</th>
<th>https</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transport</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Network layer</strong></td>
<td></td>
<td>IPv4</td>
</tr>
<tr>
<td><strong>Data link layer</strong></td>
<td></td>
<td>Wi-Fi (IEEE 802.11)</td>
</tr>
</tbody>
</table>
Control unit operation

Beacon

Follow the directions and safety notes in the Instructions for Use for the Beacon.

Establishing a connection to the Beacon

> Insert the Osstell dongle.

Beacon pairing (standard)

> Only possible in the ISQ program.
> All Beacons connect to the medical device automatically.

Beacon pairing using the serial number

> Enter the serial number in the system settings.
> Only the Beacon with the entered serial number can connect to the medical device.

Deleting Beacon pairing

> Enter 0 to delete the stored serial number.
# 11. Error messages

The error message disappears when it is clocked or when the pedal (grey) on the foot control is released.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description of error</th>
<th>Solution</th>
</tr>
</thead>
</table>
| ![Icon Foot Control] | **WARNING FOOT CONTROL**  
> Check plug contacts of foot control  
> Check the plug contacts of the dongle | |
| ![Icon Motor] | **WARNING MOTOR**  
> Check the plug contacts of the motor  
> Allow motor to cool for at least 10 minutes | |
| ![Icon Storage Device] | **WARNING STORAGE DEVICE**  
> Insufficient memory available  
> Unknown file system  
> The write protection is active  
> Unknown storage device |  
> Plug in a USB stick with sufficient memory |
| ![Icon Temperature] | **WARNING OVERHEATING**  
> Switch off the control unit  
> Allow the control unit to cool for at least 10 minutes  
> Switch on the control unit | |
## Error messages

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description of error</th>
<th>Solution</th>
</tr>
</thead>
</table>
| ![Icon](image1) | WARNING TIME-OUT | > Release the pedal (grey) on the foot control  
> Allow motor to cool for at least 10 minutes |
| ![Icon](image2) | SYSTEM ERROR | > Switch the control unit off and back on again  
If the error message appears again, contact an authorized W&H service partner immediately. |
| ![Icon](image3) | SYSTEM NOT PAIRED | > System is not paired with the gateway.  
> Please wait and if it occurs repeatedly contact an authorised service partner. |
| ![Icon](image4) | WARNING OSSTELL | > Remove the ISQ module and then assembly  
or  
> Connect probe  
> Remove probe from a source of electromagnetic interference  
> Maintain a distance between the probe and the SmartPeg (3-5 mm)  
or  
> Switch the control unit off and back on again |
| ![Icon](image5) | WARNING Wi-Fi CONNECTION | > Press the ioDent® Wi-Fi dongle symbol  
> Attempt to establish a connection with the Wi-Fi gateway again. |
## Error messages

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description of error</th>
<th>Solution</th>
</tr>
</thead>
</table>
| ![Warning](image) | WARNUNG CONNECTION | > Press the ioDent® Wi-Fi dongle symbol  
> Attempt to establish a connection with the ioDent® platform again. |
| ![Warning](image) | WARNING DATA RECEPTION | > Restart the data transfer on the ioDent® platform. |
| ![Warning](image) | WARNING TIME SYNCHRONISATION | > Restart the gateway  
> Insert the ioDent® Wi-Fi dongle again |
| ![Warning](image) | WARNING SYSTEM MONITORING | > Release the pedal (grey) on the foot control and press it again.  
> If the error occurs again, restart the device. |
| ![Warning](image) | WARNING IMPLANT DOCUMENTATION | > Maximum number of implants (8) for the active documentation has been reached. |
| ![Warning](image) | WARNING DOCUMENTATION ACTIVE | > Finish the current documentation on the device before starting a new one. |
| ![Warning](image) | WARNING SOFTWARE UPDATE FAILED | > Check the update files and copy the data to the USB stick again.  
> Insert the USB stick again. Restart the update. |

> If the described problem cannot be resolved, the unit will need to be inspected by an authorized W&H service partner.  
> In case of a total system failure, switch the control unit off and on again.
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 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 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.

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 it 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 medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer disinfecter (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

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.
Hygiene and maintenance

Motor with cable / Universal support

Wrap the motor with cable and the universal support 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 procedure.
> 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 cycles

- Steam sterilization (Typ B, N)
  - Sterilization time at least 3 minutes at 134°C (273°F), 4 minutes at 132°C (270°F), 30 minutes at 121°C (250°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).

  - “Dynamic-air-removal prevacuum cycle” (type B): temperature 134°C (273°F) – 3 minutes*
    - temperature 132°C (270°F) – 4 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

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.
13. 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
- S-NW: Visual inspection O-Ring

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]
> Foot control S-NW: Remove the batteries.
14. W&H accessories and spare parts

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

Suppliers: W&H partners (Link: https://www.wh.com)

04013500
Sterilization cassette

07962790
Transportation case

07721800
Universal support

04005900
Irrigant support

06352200
Fuse (250 V - T1.6AH)

30281000
EM-19 LC motor with electrical contacts and 1.8 m cable
W&H accessories and spare parts

- **Foot control S-N2**
  - Code: 30285000

- **Foot control S-NW**
  - Code: 30264000

- **Hose clips (5 pcs)**
  - Code: 04653500

- **Locator for foot control**
  - Code: 30285000

- **Irrigation tubing set 2.2 m (6 pcs)**
  - Code: 04653600

- **EM-19 motor without electrical contacts and 1.8 m cable**
  - Code: 04719400

- **Irrigation tubing set 2.2 m**
  - Code: 04719400

- **Hose clips (5 pcs)**
  - Code: 06290600

- **Irrigation tubing set 2,2 m**
  - Code: 06290600

- **EM-19 motor without electrical contacts and 1.8 m cable**
  - Code: 30185000
W&H accessories and spare parts

08026120
iodent® Wi-Fi dongle

08026150
iodent® gateway mini
15. Technical data

<table>
<thead>
<tr>
<th>Control unit</th>
<th>SI-1023</th>
<th>SI-1015</th>
<th>SI-1010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mains voltage:</td>
<td>230 V</td>
<td>120 V</td>
<td>100 V</td>
</tr>
<tr>
<td>Permissible voltage fluctuation:</td>
<td>220 – 240 V</td>
<td>110 – 130 V</td>
<td>90 – 110 V</td>
</tr>
<tr>
<td>Rated current:</td>
<td>0.3 – 0.8 A</td>
<td>0.3 – 1.6 A</td>
<td>0.3 – 1.4 A</td>
</tr>
<tr>
<td>Maximum power consumption:</td>
<td>170 VA</td>
<td>140 VA</td>
<td></td>
</tr>
<tr>
<td>Frequency:</td>
<td></td>
<td></td>
<td>50 – 60 Hz</td>
</tr>
<tr>
<td>Mains fuse (2 pcs):</td>
<td></td>
<td>250 V – T1.6 AH</td>
<td></td>
</tr>
<tr>
<td>Maximum power output:</td>
<td></td>
<td>80 W</td>
<td></td>
</tr>
<tr>
<td>Maximum torque at motor:</td>
<td></td>
<td>6.2 Ncm</td>
<td></td>
</tr>
<tr>
<td>Motor speed range in the rated voltage range:</td>
<td></td>
<td>200 – 40,000 rpm</td>
<td></td>
</tr>
<tr>
<td>Coolant flow rate at 100%:</td>
<td></td>
<td>min. 90 ml/min</td>
<td></td>
</tr>
<tr>
<td>Dimensions in mm (height x width x depth):</td>
<td></td>
<td>100 x 262 x 291</td>
<td></td>
</tr>
<tr>
<td>Weight in kg:</td>
<td></td>
<td>3.5</td>
<td></td>
</tr>
</tbody>
</table>

Ambient conditions

Temperature during storage and transport: -40°C to +70°C (-40°F to +158°F)
Humidity for storage and transport: 8 % to 80 % (relative), non-condensing
Temperature in operation: +10°C to +35°C (+50°F to +95°F)
Humidity in operation: 15 % to 80 % (relative), non-condensing
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 device (protective earth conductor used for functional earth connection only!)

 CommandType B applied part (not suitable for intracardiac application)

S-N2 / S-NW are approved for operation in potentially explosive atmospheres.

S-N2 / S-NW are waterproof according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

Pollution level: 2
Overvoltage category: II
Altitude: up to 3,000 m above sea level
16. 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>
</tbody>
</table>

Signature of the user

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>
</tr>
</thead>
<tbody>
<tr>
<td>Address of the instructor</td>
<td></td>
</tr>
</tbody>
</table>

Signature of 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).

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</thead>
<tbody>
<tr>
<td>Address of the instructor</td>
<td></td>
</tr>
</tbody>
</table>

Signature of the instructor
**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 24 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

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

W&H Impex Inc., 33091 W Jefferson Ave, Mi 48126, Brownstown, MI 48173, 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's declaration

Electromagnetic compatibility (EMC)

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

<table>
<thead>
<tr>
<th>cables and accessories</th>
<th>length</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country specific mains cable according to W&amp;H country list</td>
<td>2.5 to 3.1 m</td>
<td>Manufacturer: Feller GmbH</td>
</tr>
<tr>
<td>Motor with cable EM-19</td>
<td>1.8 m</td>
<td>Manufacturer: W&amp;H REF 30185xxx</td>
</tr>
<tr>
<td>Motor with alternative cable EM-19</td>
<td>3.5 m</td>
<td>Manufacturer: W&amp;H REF 30185xxx</td>
</tr>
<tr>
<td>Motor with cable (with LED) EM-19 LC</td>
<td>1.8 m</td>
<td>Manufacturer: W&amp;H REF 30281xxx</td>
</tr>
<tr>
<td>Motor with alternative cable (with LED) EM-19 LC</td>
<td>3.5 m</td>
<td>Manufacturer: W&amp;H REF 30281xxx</td>
</tr>
<tr>
<td>Foot controller S-N2</td>
<td>2.85 m</td>
<td>Manufacturer: W&amp;H REF 30264xxx</td>
</tr>
<tr>
<td>Foot controller S-NW</td>
<td>Wireless transmission</td>
<td>Manufacturer: W&amp;H REF 30264xxx</td>
</tr>
<tr>
<td>CAN Dongle</td>
<td>Wireless transmission</td>
<td>Manufacturer: W&amp;H REF 07759700</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-Level (3rd Ed.)</th>
<th>IEC 60601-Level (4th Ed.)</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±15 kV air</td>
<td>±6 kV contact ±15 kV air</td>
<td>Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%</td>
</tr>
<tr>
<td>Electrical fast transient/currents IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines 10kHz repetition rate</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines 100kHz repetition rate</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines Both repetition rates</td>
<td>Mains power quality should be that of a typical commercial and/or hospital environment</td>
</tr>
<tr>
<td>Surge IEC61000-4-5</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>±1 kV line(s) to line(s) ±2 kV line(s) to earth</td>
<td>Mains power quality should be that of a typical commercial and/or hospital environment</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11</td>
<td>&lt;5% Ur (&gt;95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles &lt;5% Ur (&gt;99% dip in Ur) for 5 sec</td>
<td>0% Ur: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° &amp; 315° 0% Ur: 1 cycle and 70% Ur: 25/30 cycles @ 0° 0% Ur: 250/300 cycle</td>
<td>Complies to both editions requirements</td>
<td>Mains power quality should be that of a typical commercial and/or hospital environment. It is recommended that the product be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>30A/m</td>
<td>30A/m</td>
<td>Power frequency magnetic fields should be at least characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

*Note: Ur is the mains (AC) voltage before apply test levels
* 25/30 (250/300) means cycles at 50/60Hz.
### Electromagnetic Immunity II (Table 4, IEC 60601-1-2:2007)

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-Level (3rd Ed.)</th>
<th>IEC 60601-Level (4th Ed.)</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td></td>
<td></td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>6 Vrms</td>
<td>Recommended separation distance: d = 1.2√P</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Vrms 150 kHz to 80 MHz</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF</td>
<td></td>
<td></td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note 1:** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

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

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

*Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
### Immunity level of RF fields from wireless communication devices

(Table 9, IEC 60601-1-2:2014)

<table>
<thead>
<tr>
<th>Test frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Servicea)</th>
<th>Modulationb)</th>
<th>Maximum power (W)</th>
<th>Distance (m)</th>
<th>IMMUNITY TEST LEVEL (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380 – 390</td>
<td>TETRA 400</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;18 Hz</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430 – 470</td>
<td>GMRS 460, FRS 460</td>
<td>FM&lt;sup&gt;c&lt;/sup&gt; ± 5 kHz deviation 1 kHz sine</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>710</td>
<td>704 – 787</td>
<td>LTE Band 13, 17</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>810</td>
<td>800 – 960</td>
<td>GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>930</td>
<td>1700 – 1990</td>
<td>GSM 1800; CDMA 1900; GSM 1900; DCT, LTE Band 1, 3, 4, 25; UMTS</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>1845</td>
<td>2400 – 2570</td>
<td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>5240</td>
<td>5100 – 5800</td>
<td>WLAN 802.11 a/n</td>
<td>Pulse modulation&lt;sup&gt;c&lt;/sup&gt;217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
</tbody>
</table>

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

<sup>a)</sup> For some services, only the uplink frequencies are included.

<sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.

<sup>c)</sup> As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Recommended Separation Distances between portable and mobile HF-communications equipment and the product
(Table 6, IEC 60601-1-2:2007)
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product — according on output power and frequency of the communications equipment — as recommended in the following table.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter in watts (W)</th>
<th>Separation distance according to the frequency of transmitter in meter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>( d = 1.2\sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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

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

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

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

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