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Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="warning.png" alt="WARNING!" /></td>
<td>WARNING! (if persons could be injured)</td>
</tr>
<tr>
<td><img src="attention.png" alt="ATTENTION!" /></td>
<td>ATTENTION! (if property could be damaged)</td>
</tr>
<tr>
<td><img src="sterilizable.png" alt="135°C" /></td>
<td>Sterilizable up to the stated temperature</td>
</tr>
<tr>
<td><img src="service.png" alt="Call customer service" /></td>
<td>Call customer service</td>
</tr>
</tbody>
</table>

in the Instructions for Use

- General explanations, without risk to persons or property
Symbols on the Osstell ISQ module

Follow Instructions for Use

Date of manufacture

Do not dispose of with domestic waste

Type B applied part (not suitable for intracardiac application)

CE mark with identification number of the Notified Body

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

Catalogue number

Serial number

DC – direct current
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>CE mark with identification number of the Notified Body</td>
</tr>
<tr>
<td><img src="image" alt="This way up" /></td>
<td>This way up</td>
</tr>
<tr>
<td><img src="image" alt="Fragile, handle with care" /></td>
<td>Fragile, handle with care</td>
</tr>
<tr>
<td><img src="image" alt="Keep dry" /></td>
<td>Keep dry</td>
</tr>
<tr>
<td><img src="image" alt="&gt;Der Grüne Punkt&lt; (The Green Dot)" /></td>
<td>Trademark of Duales System Deutschland GmbH</td>
</tr>
<tr>
<td><img src="image" alt="Trademark of RESY OfW GmbH" /></td>
<td>Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard</td>
</tr>
</tbody>
</table>

### on the packaging

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Data Matrix code" /></td>
<td>Data Matrix code for product information including UDI (Unique Device Identification)</td>
</tr>
<tr>
<td><img src="image" alt="HIBC" /></td>
<td>Data structure in accordance with Health Industry Bar Code</td>
</tr>
<tr>
<td><img src="image" alt="Permitted temperature range" /></td>
<td>Permitted temperature range</td>
</tr>
<tr>
<td><img src="image" alt="Humidity, Limitation" /></td>
<td>Humidity, Limitation</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 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
Osstell ISQ is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region Osstell ISQ can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the user.

Misuse may damage the Osstell ISQ module and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user
We have based our development and design of the Osstell unit for 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 Osstell ISQ module when compliance with the following instructions is ensured:

> The Osstell ISQ module must be used in accordance with these Instructions for Use.
> The Osstell ISQ module has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 35).
> Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.

In addition to unauthorized assembly, installation, modification of or repairs to the Osstell ISQ module and measuring probe with cable, transmission instrument and non-compliance with our instructions, improper use will invalidate all claims made under warranty or otherwise.
2. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions in regard to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

**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. Scope of delivery

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>30210000</td>
<td>Osstell ISQ module</td>
</tr>
<tr>
<td>07849900</td>
<td>TestPeg</td>
</tr>
<tr>
<td>07721800</td>
<td>Universal support</td>
</tr>
<tr>
<td>07460300</td>
<td>SmartPeg mount</td>
</tr>
</tbody>
</table>
4. Safety notes

> Before using the Osstell ISQ module for the first time, store it at room temperature for 24 hours.
> Check the Osstell ISQ module and the measuring probe with cable for damage and loose parts every time before use.
> Do not operate the Osstell ISQ module and the measuring probe with cable if it is damaged.
> Perform a test measurement with the TestPeg prior to every use.
> 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 Osstell ISQ module is not approved for operation in potentially explosive atmospheres.

> Do not twist or kink the cable! Do not coil it too tightly!

The Osstell ISQ module is classed as “conventional equipment” (closed equipment without protection against the ingress of water).

**Hygiene and maintenance prior to initial use**

> Clean and disinfect the Osstell ISQ module and the measuring probe with cable.
> Sterilize the measuring probe with cable.
5. Description

- SmartPeg mount
- TestPeg
- Osstell ISQ module
- Measuring probe connection
- USB cable
- Measuring probe with cable
6. Start-up

1. Push in the Osstell ISQ module until it locks audibly.
   Pay attention to the positioning of the USB cable!

2. Connect USB.

3. Connect measuring probe.
   Pay attention to the positioning!
7. Operation

- The TestPeg is for testing only and for teaching in the function.
- You can purchase SmartPegs from smartpegs.wh.com or osstell.com.
- SmartPegs are for single use only.
- SmartPegs are available for a range of different implant systems and can be used in combination with all conventionally available implants.*
- Ensure that the sterile chain is not broken.
- Only use SmartPegs with intact packaging.

1. Select ISQ program.
   - The ISQ program always appears after the last program.

2. Pull a thread through the SmartPeg mount.
   - Tie the thread to your wrist to prevent loss.

3. Insert the SmartPeg into the SmartPeg mount.
   - The SmartPeg is magnetic and is held in place by SmartPeg mount. Check that it is retained secure hold.

4. Attach the SmartPeg to the implant or abutment by screwing the SmartPeg mount using finger force of approximately 4-6 Ncm.
   - Do not overtighten the SmartPeg or the SmartPeg thread may be damage

* For further information, please contact an authorized W&H service partner or visit osstell.com
**Operation**

5 Press the foot control pedal once to start the measurement.
   - Press the foot control pedal again to stop the measurement early.

6 Hold the measuring probe about 3 to 5 mm from the tip of the SmartPeg until the measured value is displayed.
   - Measure in both the mesiodistal direction (a) and the buccolingual direction (b).
   - Do not measure from above.
   - Repeat 5 and 6 to perform multiple measurements.

   The measured value is underlined in colour and confirmed by a signal tone.

7 Remove the SmartPeg with the SmartPeg mount.
Measurement result*

The measurement result can be used as part of a general assessment program. The user bears the ultimate responsibility for the decision for implant treatment.

To monitor osseointegration, measurements should be taken after implant insertion and before restoration of the implant. Scientific studies can be found here www.osstell.com

**ISQ value**
The resonance frequency as a measure of implant stability is calculated from the oscillation frequency of the SmartPeg. The results of this calculation are displayed as the ISQ value. The scale from the ISQ value ranges from 1 to 100.

* For further information, please contact an authorized W&H service partner or visit osstell.com
8. 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 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 measuring probe with cable after 250 processing cycles or one year.

> We recommend a regular service for the W&H universal support after 250 processing cycles.
Wipe the Osstell ISQ module, the measuring probe with cable and 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

Manual cleaning

Measuring probe with cable / Universal support

Do not immerse the measuring probe with cable and the universal support in liquid disinfectant or in an ultrasonic bath.

Measuring probe with cable / Universal support

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

Osstell ISQ module

> Do not immerse the Osstell ISQ module in water or clean under running water.
Hygiene and maintenance

Measuring probe with cable / Universal support

> W&H recommends wipe-down disinfection.

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

Automated cleaning and disinfection

Universal support

Evidence of the universal support basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

- Cleaning at 55°C (131°F) – 5 minutes
- Disinfection at 93°C (200°F) – 5 minutes

Osstell ISQ module / Measuring probe with cable

The Osstell ISQ module and the measuring probe with cable are not approved for automated cleaning and disinfection.
Hygiene and maintenance

Drying

Measuring probe with cable / Universal support

> Ensure that the measuring probe with cable and the universal support are completely dry internally and externally after cleaning and disinfection.

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

Inspection – Measuring probe with cable / Universal support

> Check the measuring probe with cable and the universal support after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any measuring probe with cable and the universal support that are still soiled.
> Sterilize the measuring probe with cable and the universal support following cleaning and disinfection.
Measuring probe with cable / Universal support

Wrap the measuring probe 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.
Hygiene and maintenance

Measuring probe with cable / Universal support

W&H recommends sterilization according to EN 13060, EN 285.

> 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 measuring probe with cable and the universal support.

Recommended sterilization cycles

> Steam sterilization [type B, S]
> Sterilization time at 3 minutes at 134°C (273°F), 4 minutes at 132°C (270°F)
> Maximum sterilization temperature 135°C (275°F)

Evidence of the measuring probe with cable and the universal support basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)) and the Systec VE-150 steam sterilizer (Systec).

> »Dynamic-air-removal prevacuum cycle« [type B]: temperature 134°C (273°F) – 3 minutes*
> »Steam-flush pressure-pulse cycle« [type S]: temperature 134°C (273°F) – 3 minutes*

* EN 13060, EN 285, ISO 17665
Hygiene and maintenance

Measuring probe 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.
9. 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:

Osstell ISQ module
- External visual inspection
- Visual inspection of internal components on suspicion of safety interference, e.g., mechanical damage of the enclosure or indicators of overheating

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 measuring probe and do not twist or kink the cable. (Risk of damage)
10. 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

- **07721100**
  Measuring probe with cable*

- **07849900**
  TestPeg

- **07721800**
  Universal support

- **07460300**
  SmartPeg mount

* The measuring probe with cable from Osstell is compatible with the W&H Osstell ISQ module.
## 11. Technical data

<table>
<thead>
<tr>
<th>Osstell ISO module</th>
<th>SI-SQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage from Implantmed:</td>
<td>5.5 V</td>
</tr>
<tr>
<td>Dimensions in mm (height x width x depth):</td>
<td>79 x 138 x 88</td>
</tr>
<tr>
<td>Weight in kg:</td>
<td>0.210 kg</td>
</tr>
<tr>
<td>TestPeg measured value tolerance:</td>
<td>55 +/-5</td>
</tr>
<tr>
<td>SmartPeg measured value tolerance:</td>
<td>+/-1</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 Equipment according to IEC 60601-1/ANSI/AAMI ES 60601-1

☐ Class II medical electrical equipment

Type B applied part (not suitable for intracardiac application)

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

Ensure that the parts are not contaminated on disposal.

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

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

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 W&H service partner under “Service” in the menu.
If you do not have Internet access, please contact:

W&H Impex Inc.
33091 W Jefferson Ave
Brownstown, MI 48173, USA
t +1 800 265 6277 +1 519 944 6739
f +1 519 974 6121
E-Mail: service.us@wh.com
## 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>Osstell ISQ module SI-SQ</td>
<td>0.17 m</td>
<td>Manufacturer: W&amp;H REF 30210xxx</td>
</tr>
<tr>
<td>Probe ISQ</td>
<td>1.3 m</td>
<td>Manufacturer: W&amp;H REF 07721100</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 (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>± 8 kV contact ± 15 kV air</td>
<td>± 8 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/bursts iEC 61000-4-4</td>
<td>± 2 kV for power supply lines ± 1 kV for input/output lines 5kHz 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% $U_r$ (&gt;95% dip in $U_r$) for 0.5 cycle</td>
<td>0% $U_r$: 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° &amp; 315°</td>
<td>0% $U_r$: 1 cycle and 70% $U_r$: 25/30 cycles @ 0° &amp; 1 cycle</td>
<td>Complies to both editions requirements</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 levels characteristic of a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

**Note:** $U_r$ 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>3 V&lt;sub&gt;rms&lt;/sub&gt; 150 kHz to 80 MHz</td>
<td>3 V&lt;sub&gt;rms&lt;/sub&gt; 150 kHz to 80 MHz 6 V&lt;sub&gt;rms&lt;/sub&gt; in ISM and amateur radio bands* between 0.15 MHz and 80 MHz</td>
<td>6 V&lt;sub&gt;rms&lt;/sub&gt;</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. Recommended separation distance: [ d = 1.2 \sqrt{\frac{P}{d}} ]</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V&lt;sub&gt;lim&lt;/sub&gt; 80 MHz to 2.5 GHz</td>
<td>10 V&lt;sub&gt;lim&lt;/sub&gt; 80 MHz to 2.7 GHz</td>
<td>10 V&lt;sub&gt;lim&lt;/sub&gt;</td>
<td></td>
</tr>
</tbody>
</table>

* 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.

**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.

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Interference may occur in the vicinity of equipment marked with the symbol described lateral.
### Manufacturer’s declaration

<table>
<thead>
<tr>
<th>Frequency (MHz)</th>
<th>Test Band</th>
<th>Modulation</th>
<th>Distance (m)</th>
<th>Power (W)</th>
<th>Immunity Level (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>381</td>
<td>GSM 800/900</td>
<td>Pulse</td>
<td>2</td>
<td>0.2</td>
<td>9</td>
</tr>
<tr>
<td>420</td>
<td>TETRA 400</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>470</td>
<td>GSM 850</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>510</td>
<td>CDMA 850</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>550</td>
<td>UMTS</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>580</td>
<td>Bluetooth</td>
<td>Pulse</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
</tbody>
</table>

**NOTE:** Immunity levels were measured using the ETS 300 440-3 TBR TEST level. The distance between the transmitting antenna and the device under test may vary. The immunity levels stated in the table are intended to represent worst-case scenarios.

**For some services, only the digital frequencies are included.**

**As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because the signal does not represent actual modulation.**
Manufacturer’s declaration