

Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity Phonak Models Roger 10, 11, 13, 15, 16, X

With the increased number of electronic devices such as PC's and other portable and mobile radio frequency communication equipment (e.g. mobile phones), medical devices in use may be susceptible to electromagnetic interference from other devices. The use of accessories and cables other than those specified (other than Phonak original parts) may result in increased emissions or decreased immunity of the unit. The EMC (Electro Magnetic Compatibility) standard IEC60601-1-2 defines the levels of immunity to these electromagnetic interferences. From the other hand, medical devices must not interfere with other devices. IEC60601-1-2 also defines the maximum levels of emissions for these medical devices. Phonak wireless accessories conform to this IEC60601-1-2 standard for immunity and emission. Nevertheless, medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions

The Phonak models Roger 10, 11, 13, 15, 16, X are intended for use in the electromagnetic environment specified below. The customer or the user of the models Roger 10, 11, 13, 15, 16, X should assure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment – guidance |
|--|----------------|---|
| RF emissions CISPR 11 | Group 1 | The models Roger 10, 11, 13, 15, 16, X use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The models Roger 10, 11, 13, 15, 16, X are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | |

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity


The Phonak models Roger 10, 11, 13, 15, 16, X are intended for use in the electromagnetic environment specified below. The customer or the user of the models Roger 10, 11, 13, 15, 16, X should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|---|------------------------------|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | Not applicable | Not applicable |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Not applicable | Not applicable |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s | Not applicable | Not applicable |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 4: Guidance and manufacturer's declaration – electromagnetic immunity

The Phonak models Roger 10, 11, 13, 15, 16, X are intended for use in the electromagnetic environment specified below. The customer or the user of the models Roger 10, 11, 13, 15, 16, X should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|-------------------------------|-----------------------------|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | Not applicable | Portable and mobile RF communications equipment should be used no closer to any part of the Phonak models Roger 10, 11, 13, 15, 16, X, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 30 V/m | |

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 and people.

a 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 Phonak models Roger 10, 11, 13, 15, 16, X are used exceeds the applicable RF compliance level above, the models Roger 10, 11, 13, 15, 16, X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the models Roger 10, 11, 13, 15, 16, X.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6: Recommended separation distances between portable and mobile RF communications equipment and the Phonak models Roger 10, 11, 13, 15, 16, X

The Phonak models Roger 10, 11, 13, 15, 16, X are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the models Roger 10, 11, 13, 15, 16, X can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Roger 10, 11, 13, 15, 16, X as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|--|
| | 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$ |
| 0.01 | Not applicable | 0.12 | 0.23 |
| 0.1 | Not applicable | 0.38 | 0.73 |
| 1 | Not applicable | 1.2 | 2.3 |
| 10 | Not applicable | 3.8 | 7.3 |
| 100 | Not applicable | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 separation distance for 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 and people.

Statements

The Phonak Roger 10, 11, 13, 15, 16, X models are MEDICAL ELECTRICAL EQUIPMENT and needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT!

Declaration

The device under test has no essential performance.

For surveillance purposes the audio quality of the FM signal was monitored at the hearing aid output.
