EMC declaration tables according to IEC 60601-1-2:2014/AMD1:2020

Electromagnetic Compatibility Tables

Medical electrical equipment requires special precautions regarding EMC (electromagnetic compatibility) and needs to be used in accordance to the EMC information provided below.

Portable or mobile RF communications equipment (e.g., mobile phones, pagers…) can affect Dialoq®.

Dialoq® is intended for use in the electromagnetic environment specified below. The user should ensure that Dialoq® is used in such an environment.

Wireless technology	
Wireless Functionality	Bluetooth Low Energy technology
Effective Radiofrequency Radiated Power Output	0 dBm
Operating Frequency Range	2.4 – 2.4835 GHz
Modulation	GFSK (Gaussian Frequency Shift Keying)
Bandwidth of Receiving Section	2.4 – 2.4835 GHz Bandwidth of each channel is 2 MHz
Connectivity	Bluetooth Low Energy technology
Dialoq® complies with the applicable EMC and telecommunications standards	ETSI/EN 300 328 ETSI/EN 301 489-1 ETSI/EN 301 489-17

Guidance and manufacturer's declaration – electromagnetic emission

Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emission CISPR 11 IEC 60601-1-2	Group 1 Class B	The device is suitable for use in domestic and home healthcare environment. The Bluetooth module must transmit RF energy in order to perform its intended function. Nearby electronic equipment may be affected
RF emission CISPR 32 ETSI/EN 301 489-1 ETSI/EN 301 489-17 IEC 60601-1-2 EN 55032	Class B	The device is suitable for use in domestic and home healthcare environment. The Bluetooth module must transmit RF energy in order to perform its intended function. Nearby electronic equipment may be affected
Electromagnetic compatibility and radio spectrum matters ETSI/EN 300 328	The device complies with Radio Spectrum Requirements applicable to Bluetooth Low Energy	The device is suitable for use in domestic and home healthcare environment. The Bluetooth module must transmit RF energy in order to perform its intended function. Nearby electronic equipment may be affected

Guidance and manufacturer's declaration – electromagnetic immunity

<table>
<tr><th>Immunity test</th><th>Test level</th><th>Compliance level / performance criterion</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)
ETSI/EN 301 489-1
ETSI/EN 301 489-17
IEC 60601-1-2
ISO 11608-1
ISO 11608-4</td><td>±2, ±4, and ±8 kV contact discharge

±2, ±4, ±8, ±10, ±12 and ±15 kV air discharge</td><td>±8 kV contact discharge

±15 kV air discharge</td><td>The device is suitable for use in domestic and home healthcare environment</td></tr>
<tr><td>Power frequency magnetic field
IEC 60601-1-2</td><td>30 A/m</td><td>30 A/m</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location of domestic and home healthcare environment</td></tr>
<tr><td>Radiated RF
ETSI/EN 301 489-1
ETSI/EN 301 489-17
EN/IEC 60601-1-2
ISO 11608-4</td><td>10 V/m
26 MHz – 6 GHz</td><td>10 V/m
CT for transmitters, CR for receivers</td><td>The device is intended for use in a typical domestic and home healthcare electromagnetic environment</td></tr>
<tr><td>Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC 60601-1-2 Proximity Fields</td><td>
<table>
<tr><th>Band</th><th>Frequency</th><th>Modulation</th><th>Immunity test level</th></tr>
<tr><td>380-390 MHz</td><td>385 MHz</td><td>PM, 18 Hz, 50%</td><td>27 V/m</td></tr>
<tr><td>430-470 MHz</td><td>450 MHz</td><td>PM, 18 Hz, 50%</td><td>28 V/m</td></tr>
<tr><td rowspan="3">704-787 MHz</td><td>710 MHz</td><td rowspan="3">PM, 217 Hz, 50%</td><td rowspan="3">9 V/m</td></tr>
<tr><td>745 MHz</td></tr>
<tr><td>780 MHz</td></tr>
<tr><td rowspan="3">800-960 MHz</td><td>810 MHz</td><td rowspan="3">PM, 18 Hz, 50%</td><td rowspan="3">28 V/m</td></tr>
<tr><td>870 MHz</td></tr>
<tr><td>930 MHz</td></tr>
<tr><td rowspan="3">1700-1990 MHz</td><td>1720 MHz</td><td rowspan="3">PM, 217 Hz, 50%</td><td rowspan="3">28 V/m</td></tr>
<tr><td>1845 MHz</td></tr>
<tr><td>1970 MHz</td></tr>
<tr><td>2400-2570 MHz</td><td>2450 MHz</td><td>PM, 217 Hz, 50%</td><td>28 V/m</td></tr>
<tr><td rowspan="3">5100-5800 MHz</td><td>5240 MHz</td><td rowspan="3">PM, 217 Hz, 50%</td><td rowspan="3">9 V/m</td></tr>
<tr><td>5500 MHz</td></tr>
<tr><td>5785 MHz</td></tr>
</table>
</td><td>CT for transmitters, CR for receivers</td><td>Portable and mobile RF communications equipment should be used no closer to the device, than the recommended separation distance of 30 cm</td></tr>
</table>

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