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108mm

140mm

Guidance and manufacturer's declaration – electromagnetic immunity			
the product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
Immunity test	IEC 60061-1-2	Compliance level	Electromagnetic environment - guidance
Proximity fields from RF wireless communications equipment	See the following table	Complies	
Test frequency (MHz)	Band a) (MHz)	Service ^a	Modulation
385	380 – 390	TETRA 400	Pulse modulation ^b
450	430 – 470	GMRS 460, FRS 460	FM ^c ± 5 kHz deviation 1 kHz sine
710	704 – 787	LTE Band 13, 17	Pulse modulation ^d
780	704 – 787	LTE Band 13, 17	217 Hz
810	800 – 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^e
870	800 – 960	GSM 1800/CDMA 1900, GSM 1900/DECT, UMTS 1, 3, 4, 5, 25; UMTS 217 Hz	18 Hz
930	1700 – 1990	Bluetooth, WLAN, 802.11 b/g/n, WiFi 2450, UMTS Band 7	Pulse modulation ^f
1845	1700 – 1990	Bluetooth, WLAN, 802.11 b/g/n, WiFi 2450, UMTS Band 7	217 Hz
1970	2450 – 2570	Bluetooth, WLAN, 802.11 b/g/n, WiFi 2450, UMTS Band 7	217 Hz
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^g
5500	5100 – 5800	WLAN 802.11 a/n	217 Hz
5785			9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is for some services, only the uplink frequencies are included.
aThe carrier shall be modulated using a 50% duty cycle square wave signal.
bAs an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz, while it does not represent actual modulation, it would be worst case.

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Immunity test	IEC 60061-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3Vrms in 0.15MHz – 80MHz amateur radio bands between 0.15MHz and 80MHz at 1kHz	3Vrms in 0.15MHz – 80MHz amateur radio bands between 0.15MHz and 80MHz at 1kHz	portable and mobile RF communications equipment should be used no closer to any part of these devices, interference may occur in the vicinity of equipment marked with the following symbol
Radiated RF fields IEC 61000-4-3	10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	Floors should be wood, concrete or ceramic tile. If floors are covered with carpet or plastic, the relative humidity should be at least 30%.
Proximity magnetic fields IEC 61000-4-39	13.56 MHz, 65A/m	13.56 MHz, 65A/m	Mains power quality should be that of a typical commercial environment.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
aThe ISM (industrial, scientific, medical) bands between 150 MHz and 80 MHz are 6.765 kHz to 6.955 kHz, 13.252 kHz to 13.287 kHz, 24.050 kHz to 24.200 kHz, and 26.5 kHz to 26.900 kHz. 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. **b**Field strengths from fixed transmitters (radio and television broadcast and relay, amateur radio, AM and FM radio and television 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 field strengths from fixed transmitters are higher than the limits set out above, the user of the device should be advised to verify that the equipment can still be used. If anomalous performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. **c**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m. **d** This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. **e** The carrier shall be modulated using a 50% duty cycle square wave signal. **f**As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz, while it does not represent actual modulation, it would be worst case.

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60061-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF emissions IEC 61000-4-2	±8V contact; ±2kV, 14kV, ±8kV, 15kV, ±8kV, 15kV air	±8kV contact; ±2kV, 14kV, ±8kV, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with carpet or plastic, the relative humidity should be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	±24V AC power supply with 100 kHz repetition frequency	±24V for AC power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial environment.
Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV lines to earth	±0.5kV, ±1kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial environment.
Voltage dips IEC 61000-4-11	0% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT, 1 cycle and 70% UT, 25/30 cycle Single phase at 0°	0% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT, 1 cycle and 70% UT, 25/30 cycle Single phase at 0°	Mains power quality should be that of a typical commercial environment.
Voltage fluctuations and flicker emissions IEC 61000-3-3	0% UT, 250/300 cycle	0% UT, 250/300 cycle	If the user of the product requires continued operation during mains interruptions, it is recommended that the device be connected to a UPS.
Voltage interruptions IEC 61000-4-11	0% UT, 250/300 cycle	0% UT, 250/300 cycle	Pain Relief be powered from an uninterrupted power supply or a battery.

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

EMC-Declaration of conformity			
Guidance and manufacturer's declaration-electromagnetic emission			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Conducted and Radiated RF emissions CISPR 11	Group 1		
Conducted RF emissions CISPR 11	Class B		
Radiated RF emissions CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies		

CAUTION: Changes or Modifications not expressly approved by the party responsible could void the user's authority to operate this device.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

WARNING: Using other accessories, remote controls and charging cables other than those specified or provided by the manufacturer of this device may lead to an increase in the electromagnetic radiation of this device or a decrease in its electromagnetic immunity, and may cause the device to malfunction.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [Product], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

FCC exposure
 This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

1. Product application sites			
Guidance and manufacturer's declaration-electromagnetic emission			
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment-guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3Vrms in 0.15MHz – 80MHz amateur radio bands between 0.15MHz and 80MHz at 1kHz	3Vrms in 0.15MHz – 80MHz amateur radio bands between 0.15MHz and 80MHz at 1kHz	portable and mobile RF communications equipment should be used no closer to any part of these devices, interference may occur in the vicinity of equipment marked with the following symbol
Radiated RF fields IEC 61000-4-3	10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	Floors should be wood, concrete or ceramic tile. If floors are covered with carpet or plastic, the relative humidity should be at least 30%.

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2. Data cable information			
Guidance and manufacturer's declaration-electromagnetic emission			
Immunity test	IEC 60601-1-2 test level	Compliance	Electromagnetic environment – guidance
Conducted and Radiated RF emissions CISPR 11	Group 1		
Conducted RF emissions CISPR 11	Class B		
Radiated RF emissions CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies		

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