

OMRON Battery-operated TENS

Information for Accompanying Documents

in the Scope of EN 60601-1-2:2015+A1:2021

Important information regarding Electromagnetic Compatibility (EMC)

This device manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN 60601-1-2:2015+A1:2021 Electromagnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified or provided by OMRON could result in increased electromagnetic emission or decreased electromagnetic immunity of the device and result in improper operation.
- During operation, the use of the device adjacent to or stacked with other device should be avoided because it could result in improper operation. In case such use is necessary, the device and other device should be observed to verify that they are operating normally.
- During operation, portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device, including cables specified by OMRON. Otherwise, degradation of the performance of the device could result.

Table 1 - EMISSION Limits and Compliance

Phenomenon	EMISSION Limits	Compliance
Radiated RF EMISSIONS	CISPR 11	Group1, Class B

Table 2 - IMMUNITY TEST LEVELS

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air for enclosure port and patient coupling port
Radiated RF electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz for enclosure port
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80 % AM at 1 kHz for patient coupling port
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz for enclosure port
Proximity magnetic fields	IEC 61000-4-39	See table 4

Table 3 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n , RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 4 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5