OMRON Battery-operated/AC adapter-rechargeable TENS Unit Information for Accompanying Documents in the Scope of IEC60601-1-2:2014

Important information regarding Electromagnetic Compatibility (EMC)

This device manufactured by OMRON HEALTHCARE Co., Ltd. conforms to IEC60601-1-2:2014 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 monitor 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 12 inches (30 cm) to any part of the device, including cables specified by OMRON. Otherwise, degradation of the performance of the device could result.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

Table 1 - EMISSION Limits and Compliance

Phenomenon	EMISSION Limits	Compliance
Conducted and 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
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency for Input a.c. power port
Surges Line-to-line	IEC 61000-4-5	±0.5kV, ±1 kV for Input a.c. power port
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80 % AM at 1 kHz for Input a.c. power port (and patient coupling port if applicable)
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz for enclosure port
Voltage dips	IEC 61000-4-11	0 % U_T ; 0.5 cycle At 0°,45°, 90°, 135°, 180°, 225°, 270° and 315° for Input a.c. power port
		0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles single phase: at 0° for Input a.c. power port
Voltage interruptions	IEC 61000-4-11	0 % U_T ; 250/300 cycle for Input a.c. power port
NOTE: U_T is the A.C. mains voltage prior to application of the test level.		

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						

EMC tests have included the AC adapter.