

# OMRON Battery-operated 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 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 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<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air<br>for enclosure port and patient coupling port |
| Radiated RF electromagnetic fields                         | IEC 61000-4-3      | 10 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1 kHz<br>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      | 6 Vrms<br>150 kHz to 80 MHz<br>80 % AM at 1 kHz<br>for patient coupling port                     |
| Rated power frequency magnetic fields                      | IEC 61000-4-8      | 30 A/m<br>50 Hz or 60 Hz<br>for enclosure port   |

**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,<br>FRS 460  | FM<br>± 5 kHz deviation<br>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,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>LTE Band 5          | Pulse modulation 18 Hz                | 2                 | 0.3          | 28                        |
| 870                  |              |   |                                       |                   |              |                           |
| 930                  |              |   |                                       |                   |              |                           |
| 1720                 | 1700 to 1990 | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT;<br>LTE Band 1, 3, 4, 25; UMTS | Pulse modulation 217 Hz               | 2                 | 0.3          | 28                        |
| 1845                 |              |   |                                       |                   |              |                           |
| 1970                 |              |   |                                       |                   |              |                           |
| 2450                 | 2400 to 2570 | Bluetooth, WLAN,<br>802.11 b/g/n, RFID 2450,<br>LTE Band 7                  | Pulse modulation 217 Hz               | 2                 | 0.3          | 28                        |
| 5240                 | 5100 to 5800 | WLAN 802.11<br>a/n  | Pulse modulation 217 Hz               | 0.2               | 0.3          | 9                         |
| 5500                 |              |   |                                       |                   |              |                           |
| 5785                 |              |   |                                       |                   |              |                           |