

Technical description for electromagnetic disturbances for pulse oximeters

Nissei pulse oximeters comply with the EMD, electromagnetic disturbance, standard, IEC60601-1-2:2014.

The device, as a medical electrical equipment, needs special precautions regarding EMD and needs to be installed and put into service according to the information provided below.

- The device is not intended for use in environments where the intensity of electromagnetic disturbance is high, such as near active HF surgical equipment and MRI (magnetic resonance imaging) equipment etc.
- Use of the device adjacent to or stacked with other equipment must be avoided because it could result in improper operation.
- Use of accessories other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the device. Otherwise, degradation of the performance of this equipment could result.

Please refer to the following tables for specific information regarding the compliance to the standard.

Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity

ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the table "Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment" below.
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

PATIENT coupling PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

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