Electromagnetic compatibility – Guidance and manufacturer‘s declaration

IEC 60601-1-2

Models:
PARI BOY® free (Type 055)
PARI VELOX® (Type 055)

Information for subject matter experts on Electromagnetic Compatibility (EMC)

1 Essential Performance

There are no essential performance characteristics according to the risk assessment.

2 Electromagnetic environment

The device[1] is intended for use in the electromagnetic environment specified below. The customer or the user of the device[1] should assure that it is used in such environment.

Emission test

Emission test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The device[1] uses RF energy only for its internal function. Therefore, its RF-emission is very low and not likely to cause any interference nearby electronic equipment.
	Class B	The device[1] is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Passed	

Immunity test

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±15 kV	Contact: ±8 kV Air: ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	5/50 ns, 100 kHz, ±2 kV	5/50 ns, 100 kHz, ±2 kV	Mains power quality should be similar to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1.2/50 (8/20) µs LtL: ±1 kV LtG: ±2 kV	1.2/50 (8/20) µs LtL: ±1 kV LtG: ±2 kV	Mains power quality should be similar to that of a typical commercial or hospital environment.

1) Device under test: type 055.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	0 % U_T for 0.5 cycle (1 phase) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles (50/60 Hz) 0 % U_T for 250/300 cycles (50/60 Hz)	Mains power quality should be similar to that of a typical commercial or hospital environment. When the user of the device[1] requires continuous function in the event of disruption of supply, it is recommended the device[1] is operated from an uninterruptible power supply or battery.
Power frequency (50 Hz / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Amplitude modulated	150 kHz – 80 MHz 3 V ISM and amateur radio bands 6 V ☒ 80 % / 1 kHz	150 kHz – 80 MHz 3 V ISM and amateur radio bands 6 V ☒ 80 % / 1 kHz	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 device[1], including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radio-frequency electromagnetic field Amplitude modulated	IEC 61000-4-3	80 MHz – 2.7 GHz ☒ Home Healthcare (10 V/m) ☒ Prof. Healthcare (3 V/m) ☒ 80 % / 1 kHz	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 device[1], including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380 – 390 MHz 27 V/m; PM 50 %; 18 Hz 430 – 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 – 787 MHz 9 V/m; PM 50 %; 217 Hz 800 – 960 MHz 28 V/m; PM 50 %; 18 Hz 1700 – 1990 MHz 28 V/m; PM 50 %; 217 Hz 2400 – 2570 MHz 28 V/m; PM 50 %; 217 Hz 5100 – 5800 MHz 9 V/m; PM 50 %; 217 Hz	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 device[1], including cables, specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Immunity to proximity magnetic fields	IEC 61000-4-39	30 kHz, Modulation, CW 8 A/m 134.2 kHz, 2.1 kHz PM 50 %; 65 A/m 13.56 MHz, 50 kHz PM[2] 7.5 A/m	This test is applicable only to the device[1] intended for use in a home environment.

2) The carrier shall be modulated using a 50 % duty cycle square wave signal.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Measurement of radiated broadband and narrowband electromagnetic emissions	ECE R10, Rev. 5, annex 7 and 8 CISPR 25, 2. Edition + Corrigendum 2004		
Radiated and conducted emission of radio frequency energy	RTCA/DO-160G Section 21	Cat. M	

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