



Guidance and Manufacturer's Declaration IEC 60601-1-2

Electromagnetic Compatibility (EMC) Table

Inhalation device with either an:

- eBase® Controller or
- eTrack® Controller or
- eLete® Controller or
- eFlow® Integrated Controller

Performance

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

The controllers were evaluated according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Electromagnetic Environment

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

Emission test	Compliance Electromagnetic environment – Guidance	
RF emissions CISPR 11	Group 1	The device 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 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 / Passed		

Voltage fluctuations flicker emissions IEC 61000-3-3 / Passed		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact :±8 kV Air : ±15 kV	Contact :±8 kV Air : ±15 kV
Electrical fast transient /burst IEC 61000-4-4	5/50 ns, 100 kHz, ±2 kV	5/50 ns, 100 kHz, ±2 kV
Surge IEC 61000-4-5	1.2/50 (8/20) µs LtL: ±1.0 kV LtG: ±2.0 kV	1.2/50 (8/20) µs LtL: ±1.0 kV LtG: ±2.0 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50/60 Hz) 0 % UT for 250/300 cycles (50/60 Hz)
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
Conducted RF Amplitude modulated IEC 61000-4-6	150 kHz - 80 MHz 3 V ISM Bands 6 V 80 % / 1 kHz	150 kHz - 80 MHz 3 V ISM Bands 6 V 80 % / 1 kHz
Radio-frequency electromagnetic field Amplitude modulated IEC 61000-4-3	80 MHz - 2.7 GHz 10 V/m Home Healthcare 10 V/m Prof. Healthcare 3 V/m 80 % / 1 kHz	80 MHz - 2.7 GHz 10 V/m Home Healthcare 10 V/m Prof. Healthcare 3 V/m 80 % / 1 kHz
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	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	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
Proximity magnetic fields IEC 61000-4-39	30 kHz; 8 A/m; CW 134.2 kHz; 65 A/m; PM 50 %; 2.1 kHz 13.56 MHz; 7.5 A/m; PM 50 %; 50 kHz	30 kHz; 8 A/m; CW 134.2 kHz; 65 A/m; PM 50 %; 2.1 kHz 13.56 MHz; 7.5 A/m; PM 50 %; 50 kHz
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 (not applicable for eFlow® Integrated Controller)	RTCA/DO-160G and Section 21	Cat. M

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PARI Pharma GmbH
Moosstrasse 3 • 82319 Starnberg • Germany
E-Mail: info@pari.de • www.pari.com