



HEALTHCARE

ELECTROMAGNETIC COMPATABILITY INFORMATION FOR NIAGARA TOYS

Electromagnetic Compatibility

These devices need special precautions regarding EMC as they can affect other RF communication equipment, such as radio and television receivers. Portable or mobile RF communications equipment, such as mobile telephones, can affect the operation of these medical devices. The devices comply with the requirements as shown in following the tables.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Criterion A	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Criterion A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % 240VAC (>95% dip) For 0.5 cycle 40 % 240VAC (>60% dip) For 5 cycles <70 % 240VAC (>30% dip) For 25 cycles <5 % 240VAC (>95% dip) For 5 sec	Criterion A Criterion A Criterion A Criterion A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the equipment be powered from the uninterruptable power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment



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Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR11	Group 1	The equipment emits low levels of RF energy due to internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF Emissions CISPR11	Class B	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	The equipment is suitable for use in all establishments including domestic.



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Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Complies, Criterion A	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	+/-2KV power supply +/-1KV input output lines	Complies, Criterion A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Complies, Criterion A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % 240VAC (>95% dip) For 0.5 cycle <40 % 240VAC (>60% dip) For 5 cycles <70 % 240VAC (>30% dip) For 25 cycles <5 % 240VAC (>95% dip) For 5 sec	Complies, Criterion A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the equipment be powered from the uninterruptable power supply or battery.



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Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz-80MHz	3 VRMS	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,* should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80 -2500 MHz	3 V/m	
NOTE 1: At 80MHZ and 800MHZ, the higher frequency range applies.			
NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
*Field strengths from fix transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.			
**Over the frequency range 150hHz to 80MHz, field strength should be less 3 V/m.			