

2 EMC Safety

2.1 General EMC Safety

Special precautions are to be taken while using medical electrical equipment with regards to electromagnetic compatibility (EMC). You must operate the LifePath-C Monitoring System according to the EMC information provided in this manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment, including the LifePath-C monitoring system.



Warning

Consult an EMC test lab or regulatory body for assistance in identifying the EMC compliance status of other equipment if there is suspicion that this equipment may be causing the LifePath-C Monitoring System to malfunction.

The LifePath-C Monitoring System is intended to be used in healthcare, residential, commercial, business, and light industrial environments. Users and operators of the system should assure that the device is used in such an environment.

The use of accessories (eg, chargers, cables, etc) other than those supplied by Elastic Care is not recommended and may result in increased emissions or decreased immunity of the device.

Use of accessories other than those supplied by Elastic Care may cause the LifePath-C Monitoring System to malfunction, or may cause interference to nearby televisions, radios, or other electronic equipment.

Interference may occur in the vicinity of other equipment marked with this symbol: 

Do not stack LifePath-C components with other equipment.

Changes or modifications to this product not authorized by Elastic Care could void the electromagnetic compatibility (EMC) and wireless compliance and negate your authority to operate the product.

2.2 FCC Compliance Statements

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or experienced radio/TV technician for help.

The equipment does not contain any user serviceable components. Any unauthorized modifications to the equipment invalidates the equipments regulatory approvals, including authority to operate the equipment.

The equipment contains a 2.4GHz radio system registered under FCC ID: 2BA2T-LPC1.



The System complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

2.3 Recommended Separation Distances

The LifePath-C system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or operator of the LifePath-C system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifePath-C system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency transmitter m		
	150 kHz to 80MHz d= 1.2√P	80 MHz to 800 MHz d= 1.2√P	800 MHz to 2.7 GHz d= 2.3√P
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

2.4 Electromagnetic Emissions Test Summary

CISPR 11 Emissions

Basic Standard	Test Type	Class	Result
RF Emissions CISPR 11	Power Line-Conducted Emissions	Class B	Pass
RF Emissions CISPR 11	Radiated Emissions	Class B	Pass
Harmonic Emissions IEC - 61000-3-2	Harmonic Current Emissions	Class A	Pass
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Flickers	--/ Complies	Pass

2.5 Electromagnetic Immunity Test Summary

IEC - 60601-1-2 Immunity

Basic Standard	Test Type	Test Level	Result
IEC-61000-4-2	Electro-Static Discharge	± 8kV Contact ± 15kV Air	Pass
IEC-61000-4-3	Radiated Field Immunity	10 V/m, 80 MHz-2.7GHz & Proximity Fields	Pass
IEC-61000-4-4	Electrical Fast Transients (Bursts)	± 2kV-Mains	Pass
IEC-61000-4-5	Surge Immunity	± 1 kV Line-Line	Pass
IEC-61000-4-6	Conducted RF Immunity	3 Vrms, 150kHz - 80MHz 6 Vrms, ISM/Amateur radio bands	Pass
IEC-61000-4-8	Power Frequency Magnetic Field	30 A/m	Pass
IEC-61000-4-11	Voltage Dips	0% for 0.5 cycle 0% for 1 cycle 70% for 30 cycles	Pass
IEC-61000-4-11	Short Interruptions	0% for 300 cycles	Pass
IEC-61000-4-39	Proximity Magnetic Fields	8 A/m 30 kHz, CW 65 A/m 134.2kHz, 2.1kHz, 50% PWM 7.5 A/m 13.56MHz, 50 Khz 50% PWM	Pass Pass Pass

2.6 Example of Electromagnetic Immunity Performance

The ECG traces below were acquired by the LifePath-C Monitoring System during IEC-61000-4-3 Radiated Field Immunity Testing. The underlying cardiac waveform becomes noisy towards the end of the third trace segment. This noise is caused by a generated EMC field which is used to assess the equipment's performance. The traces shown represent the worst case ECG signal degradation seen during immunity testing. In actual usage of the device, ECG signal degradation could be more severe due to a higher electromagnetic field strength.

