

Safety and Electromagnetic Compatibility (EMC) Information

Specifications

Dimensions	85 x 85 x 25mm (3.5 x 3.5 x 1.0")	Maximum vacuum	100mmHg
Weight	<120g	Mode of operation	Continuous
Operating time	7 days	Patient protection	Type BF
Battery type	Lithium AA (LR1)	Storage/transport	5-25°C, 10-75% RH 700 to 1060 mbar atmospheric pressure
Power (Battery)	3V DC	Operating environment	5-35°C, 10-95% RH 700 to 1060 mbar atmospheric pressure
Ingress protection	IP24	Compliance	Certified to: CSA STD C22.2 No 60601-1 Conforms to: ANSI/AAMI STD ES60601-1:2005 IEC 60601-1:2005 IEC 60601-1-2:2014 IEC 60601-1-6:2010 IEC 60601-1-11:2015

Safety and electromagnetic compatibility

When used in accordance with the manufacturer instructions, PICO complies with the general requirements for safety of electrical medical equipment IEC 60601-1 and the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2.


Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation and home use environment.

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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	EC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	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	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1kV lines(s) to lines(s) ±2kV lines(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 cycles	Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/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	10Vrms 150kHz to 80MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of PICO including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10V/m 80MHz to 2.7GHz	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ (80MHz to 800MHz) $d = 2.3\sqrt{P}$ (800MHz to 2.7GHz) 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).
Enclosure port immunity IEC 61000-4-3	IEC 60601-1-2:2014 Table 9	IEC 60601-1-2:2014 Table 9	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80MHz, 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.

a. Field strengths from fixed 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 which PICO is used exceeds 10V/m, PICO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating PICO.

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 10V/m.

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11.	Group 1.	PICO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11.	Class B.	The RF emissions characteristic of PICO make it suitable for use in hospitals, transport and home healthcare use environments.
Harmonic emissions IEC 61000-3-2.	Not applicable.	
Voltage fluctuations/flicker emissions. IEC 61000-3-3.	Not applicable.	

WARNING: PICO should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, PICO should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and PICO. The healthcare professional or the user of PICO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and PICO 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 of transmitter (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 0.35\sqrt{P}$	800MHz to 2.7GHz $d = 0.7\sqrt{P}$
0.01	N/A	0.04	0.07
0.1	N/A	0.11	0.22
1	N/A	0.35	0.7
10	N/A	1.11	2.21
100	N/A	3.5	7

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

NOTE 1: At 80MHz and 800MHz, 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.