

# Safety and Electromagnetic Compatibility (EMC) Information

## Specifications

|                           |                                        |                              |                                                                                                                                                 |
|---------------------------|----------------------------------------|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Dimensions</b>         | 65 x 78.5 x 21mm<br>(2.6 x 3.2 x 0.9") | <b>Maximum vacuum</b>        | 100mmHg                                                                                                                                         |
| <b>Weight</b>             | <110g                                  | <b>Mode of operation</b>     | Continuous                                                                                                                                      |
| <b>Operating time</b>     | 7 days                                 | <b>Patient protection</b>    | Defibrillation – proof type BF                                                                                                                  |
| <b>Battery type</b>       | 2 x AA 1.5V (LR6/FR6)                  | <b>Storage/transport</b>     | 5°C - 25°C (-25°C to +5°C allowable for up to 7 days),<br>10 – 75% relative humidity<br>700 to 1060 mbar atmospheric pressure                   |
| <b>Power (Battery)</b>    | 3V DC                                  | <b>Operating environment</b> | 5°C - 40°C, 10 – 95% relative humidity<br>700 to 1060 mbar atmospheric pressure                                                                 |
| <b>Ingress protection</b> | IP22                                   | <b>Compliance</b>            | Certified to:<br>CSA STD C22.2 No 60601-1<br><br>Conforms to:<br>ANSI/AAMI STD ES60601-1:2005<br>IEC 60601-1<br>IEC 60601-1-6<br>IEC 60601-1-11 |

### Safety and electromagnetic compatibility

When used in accordance with the manufacturer instructions, PICO<sup>®</sup> 7 / PICO 14 complies with the general requirements for safety of electrical medical equipment (IEC 60601-1).

### Electromagnetic compatibility

PICO 7 / PICO 14 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 safety with regard to electromagnetic disturbances when PICO 7 / PICO 14 is used 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

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 an environment.

| Immunity test                                                                                          | IEC 60601 test level                                                                                                                                                                                                                                                                     | Compliance level                                                                        | Electromagnetic environment - guidelines                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                         | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air                                                                                                                                                                                                                                         | ±2 kV, ±4 kV, ±6 kV, ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air                   | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.                                                                               |
| Electrical fast transient/burst<br>IEC 61000-4-4                                                       | ±2kV for power supply lines                                                                                                                                                                                                                                                              | PICO 7 / PICO 14 is a battery powered device                                            | Not applicable                                                                                                                                                                                        |
| Surge IEC 61000-4-5                                                                                    | ±0.5 kV, ±1 kV Line-to-line                                                                                                                                                                                                                                                              | PICO 7 / PICO 14 is a battery powered device                                            | Not applicable                                                                                                                                                                                        |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases<br>0% UT (100% dip in UT) for 0.5 cycle<br>At 0° single phase<br>0% UT (100% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br>0% UT (100% dip in UT) for 250 cycles<br>0% UT (100% dip in UT) for 300 cycles | PICO 7 / PICO 14 is a battery powered device                                            | Not applicable                                                                                                                                                                                        |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8                                              | 30 A/m 50 or 60 Hz                                                                                                                                                                                                                                                                       | 30 A/m 50 or 60 Hz<br>100 A/m 50 or 60 Hz<br>150 A/m 50 or 60 Hz<br>200 A/m 50 or 60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital or home healthcare environments.                                           |
| Conducted RF<br>IEC 61000-4-6                                                                          | 3 Vrms 150 kHz to 80 MHz<br>6 Vrms 150 kHz to 80 MHz<br>In ISM and amateur radio bands                                                                                                                                                                                                   | PICO 7 / PICO 14 is a battery powered device                                            | Portable and mobile communications equipment should be separated from the device by no less than distances calculated/listed below:<br><b>Recommended separation distance:</b><br>$d = 0.58 \sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3                                                                           | 10 V/m 80 MHz to 2.7 GHz<br>IEC 60601-1-2:2014 Table 9                                                                                                                                                                                                                                   | 10 V/m 80 MHz to 2.7 GHz<br>IEC 60601-1-2:2014 Table 9                                  | $d = 0.175 \sqrt{P}$ (80 MHz to 800 MHz)<br>$d = 0.35 \sqrt{P}$ (800 MHz to 2.7 GHz)                                                                                                                  |

**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 7 / PICO 14 is used exceeds the applicable RF compliance level above, the PICO 7 / PICO 14 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range<sup>b</sup>. Interference may occur in the vicinity of equipment marked with the following symbol: 

# Guidance and manufacturer's declaration - electromagnetic emissions

PICO 7 / PICO 14 is intended for use in the electromagnetic environment specified below. The customer or the user of PICO 7 / PICO 14 should assure that it is used in such an environment.

| Emissions test                                        | Compliance     | Electromagnetic environment – guidelines                                                                                                                                                                      |
|-------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions CISPR 11                                 | Group 1        | PICO 7 / PICO 14 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        | PICO 7 / PICO 14 is suitable for use in all establishments including domestic 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                      | Not applicable |                                                                                                                                                                                                               |
| Voltage fluctuations/flicker emissions. IEC 61000-3-3 | Not applicable |                                                                                                                                                                                                               |

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

Do not use cables and accessories other than those specified or sold by Smith & Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the PICO 7 / PICO 14 device. Portable and mobile RF communication devices (mobile telephones) can affect PICO 7 / PICO 14.

**Recommended separation distances between portable and mobile RF communications equipment and the device.**

PICO 7 / PICO 14 is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to any part of the PICO 7 / PICO 14 device. Otherwise, degradation of the performance of this equipment could result.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) |                                        |                                        |
|-----------------------------------------------|---------------------------------------------------------------|----------------------------------------|----------------------------------------|
|                                               | 150kHz to 80MHz<br>$d = 0.58\sqrt{P}$                         | 80MHz to 800MHz<br>$d = 0.175\sqrt{P}$ | 800MHz to 2.7GHz<br>$d = 0.35\sqrt{P}$ |
| 0.01                                          | N/A                                                           | 0.02                                   | 0.03                                   |
| 0.1                                           | N/A                                                           | 0.05                                   | 0.1                                    |
| 1                                             | N/A                                                           | 0.2                                    | 0.3                                    |
| 10                                            | N/A                                                           | 0.5                                    | 1.1                                    |
| 100                                           | N/A                                                           | 1.7                                    | 3.5                                    |

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.