

## CareTRx Sensor – EMC Information and Cautions/Warnings

Portable and mobile radio frequency (RF) communications equipment can affect the CareTRx Sensor.

The CareTRx Sensor may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

The CareTRx Sensor should not be stacked with other equipment.

### **Guidance and manufacturer's declaration**

#### **EMC per IEC 60601-1-2:2014 in accordance with IEC 60601-1-11:2015**

<b>RF Emissions tests</b>	<b>Compliance Level</b>	<b>Frequencies and Modulations Tested</b>
CISPR 11	Group 1, Class B	30-1000 MHz sine
47CFR Part 15C	30 dBm	2402-2460 MHz GFSK

<b>Immunity tests</b>	<b>Compliance level</b>	<b>Frequencies Tested</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	n/a
Power frequency magnetic field IEC 61000-4-8	30 A/m	50/60 Hz sine
RF Immunity IEC 61000-4-3	10 V/m 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 28 V/m 9 V/m	80-2700MHz: 80% AM, 1 kHz 385MHz: PM,18Hz 450MHz: FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz: PM, 217 Hz 810, 870, 930MHz: PM, 18Hz 1720, 1845, 1970MHz: PM, 217 Hz 2450MHz: PM, 217 Hz 5240, 5500, 5785MHz: PM, 217 Hz

### **Bluetooth® RF Characteristics**

<b>Technical Specification</b>	<b>Value</b>
Protocol	Bluetooth Smart
Radio Frequency Range	2402 – 2480 MHz
Channels	40
Bandwidth per Channel	2 MHz
Modulation	GFSK
Transmit Power / Effective Radiated Power	+0.54 dBm

**Caution:** Radio Frequency Identification (RFID) systems may interfere with your CareTRx System and may result in a delay in transmission between the Sensor and App. However, once a communication link is re-established, the transmission will occur as intended.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CareTRx, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

**Caution:** Electromagnetic Interference (e.g., electronic article surveillance (EAS) systems, metal detectors, other security systems, strong magnetic fields, MRI, CAT scanner, cell phones, etc.) may interfere with your CareTRx Sensor and may result in a delay in transmission between the Sensor and App. However, once a communication link is re-established, the transmission will occur as intended. Your CareTRx Sensor has been tested for exposure to interference according to

international standards. Nevertheless, it is possible that unforeseen interference may occur. The effects of all types of Electromagnetic Interference on device safety or performance are unknown. The CareTRx Sensor can be taken through standard security systems, such as metal detectors. If your device has stopped working because of exposure to a strong magnetic field, then contact customer support. Never try to open or repair the Sensor yourself.

Caution: Although your CareTRx Sensor has been designed to comply with the most stringent international electromagnetic compatibility standards, the possibility cannot be excluded that it may cause interference with other equipment, such as medical devices.