# Vocera B3000 Series Badges

**Safety with Implantable Devices** **December 2016**

This document addresses questions related to the Wi-Fi technology used in Vocera B3000-series badges and their compatibility with implantable devices such as pacemakers and defibrillators.

Implantable devices are closely regulated by the FDA and have specific safety standards that they must conform to. The primary standard to which they must conform is IEC60601-1 4th edition. IEC60601-1 covers many aspects of implantable devices including mechanical, thermal and electrical safety.

A companion standard, IEC60601-1-2 specifically addresses the immunity of implantable devices to the effects of electromagnetic energy (radio waves). "Immunity" refers to the level of radio frequency energy that the implantable device can be exposed to with no compromises to functionality and safety. For the radio frequencies used by Vocera B3000 series badges, an implantable device must be immune to the following signals.

- 2.4GHz Wi-Fi - immunity to a signal strength of 2 Watts
- 5GHz Wi-Fi – immunity to a signal strength of 200 milliwatts

There are a large number of devices that operate in the 2.4GHz spectrum, including Wi-Fi communication products, Bluetooth devices and microwave ovens. Therefore the likelihood of encountering 2.4GHz radio signals in the work place is very high. This accounts for the higher immunity requirement of 2.4GHz over 5GHz. There are far fewer products that operate in the 5GHz spectrum, Wi-Fi communication products and radar being the most common.

The Vocera B3000 series badges operate at relatively low power levels in order to extend battery life and limit the area covered by their radio signals. The B3000 series badges transmit radio signals at the following levels:

- 2.4GHz Wi-Fi - a maximum signal strength of 43milliwatts
- 5GHz Wi-Fi – a maximum signal strength of 43milliwatts

The maximum levels of energy emitted by Vocera B3000 series badges are far below the minimum levels of immunity that implantable devices conforming to IEC60601-1-2 are required to meet and would therefore have no impact on the implantable devices.