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Purpose

To describe the development of the CardioMEMS system with regard to bringing the device into FCC compliance. The system has recently been tested to FCC Part 18 requirements, and CardioMEMS is currently addressing the issue of a test procedure for Part 15 verification.

System Description

The complete system comprises three main units: the charging/pickup coil, the electronics, and the display. Other components include a printer and accessories.

Charging/Pickup coil: The coil consists of a single loop of copper band (8" in diameter) with some switching and filtering circuitry contained within a shielded box adjacent to the loop. The shielded box is contained within the plastic cover of the coil and cannot be seen from the figures. Currently the structure of the loop (coil) is maintained by a circular piece of polyurethane plastic, 8" in diameter. The custom plastic enclosure also gives the loop strength and support. The single loop performs both the charging and the detection functionality, alternatively. It attaches to the electronic box via two connectors on the front panel as shown in figure 1. Although not shown in any of the figures, a shield has been designed for the loop (coil), however it does not seem to be required in order to meet FCC Part 18 requirements. In practice, a patient lying horizontally (see figure 2) would have the coil placed on top of him to detect the sensor inside his body. In this fashion, a horizontally placed coil would produce little EMI in the horizontal direction. The patient would absorb a limited amount of RF energy, thereby attenuating the electric field in the vertical forward direction (down) while the optional shield attenuates the RF energy in the vertical rear (up) and horizontal directions. Part 18 tests were actually performed as figure 2 was taken, using an employee to simulate a patient while the loop (coil) lies on top of him.

Electronics: The electronics consists of a sensitive receiver, signal processing circuitry, and charging circuitry with a RF power amplifier. The electronics sends data via a RS-232 link to a laptop computer for display. The electronics is the white box in figure 1.

Display unit: The current display unit is a laptop computer running a Labview VI. This software generates the graphics, stores and organizes data, and performs simple calculations for calibration and normalization purposes. In the future, this functionality will be embedded within the complete electronics unit.

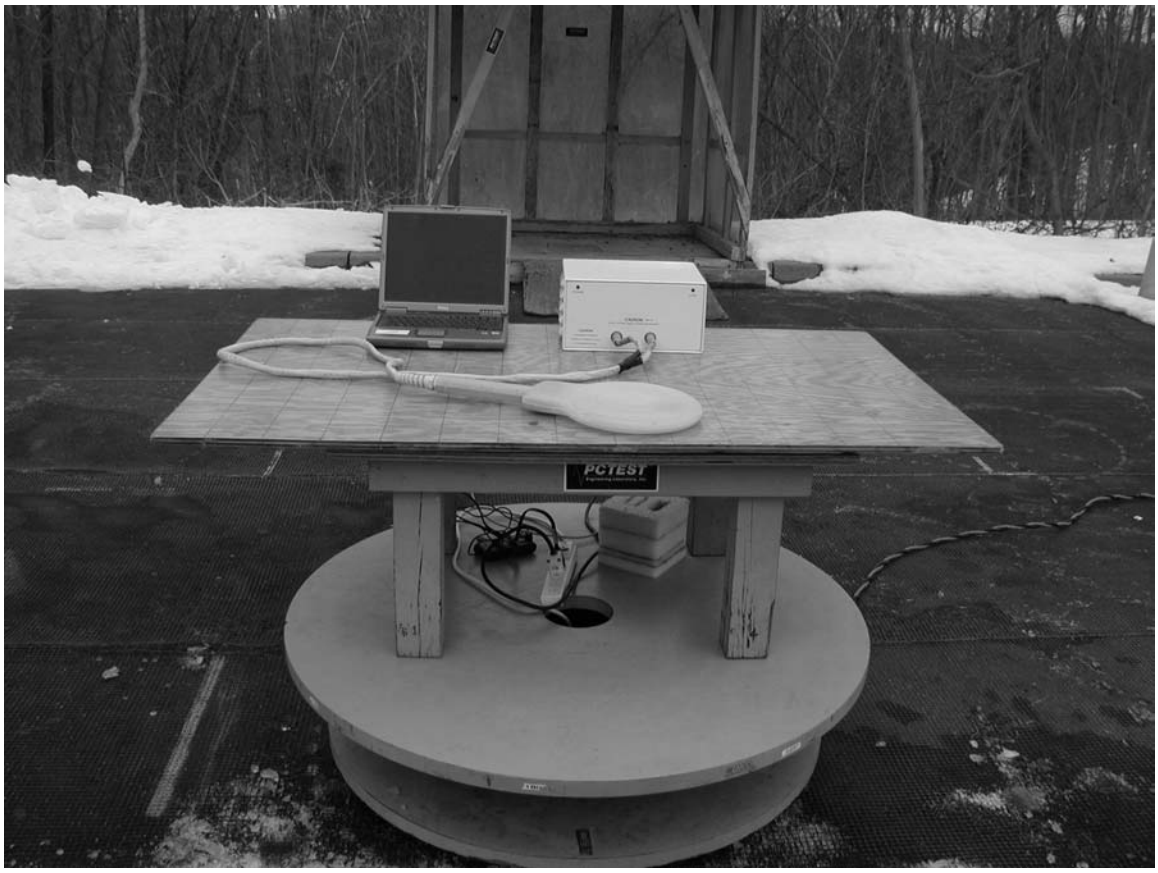

Figure 1. System setup in preparation for Part 18 tests.

Figure 2. Testing for EMI with a “simulated” patient. The coil (loop) is underneath the blue jacket.