

January 13, 2014

Ivy Biomedical was granted experimental license WG2XYL in the frequency range 2400 – 2483.5 MHz with less than 1mW power for a wireless body-worn electrocardiogram (ECG) sensor. It has come to our attention that the FCC has allocated 40MHz of spectrum from 2360 to 2400 MHz for Medical Body Area Networks (MBAN) for body-worn sensors and we would like to extend our experimental license to cover these frequencies.

We believe that the same Nordic Semiconductor NRF24LE1 radio that we intend to use in the ISM band can also be used in the MBAN band by operating the chip with a slightly lower-frequency crystal and careful selection of the operating channels. Our body-worn wireless ECG sensor seems like an appropriate device to take advantage of this new MBAN spectrum, and we would like to extend our experimental license to cover this MBAN spectrum as well as the ISM band.

To recap from our original submission:

This research project is being conducted by Ivy Biomedical in Branford CT to determine if a wireless patient monitoring device can be used to replace a wired patient monitoring device during a magnetic resonance imaging (MRI) scan in a hospital environment.

Ivy biomedical currently manufactures and sells cardiac gating modules which collect patient electrocardiogram (ECG) data. The ECG data is used to synchronize scanning on a MRI scanner with the patient's cardiac cycle. This improves image quality and diagnostic utility. With the current wired approach, the patient is tethered to the MRI gantry by a set of lead wires which transfer the ECG data from the patient to the MRI gantry. There would be several advantages if this cardiac gating data could be transmitted wirelessly so that the patient was not directly connected to the MRI gantry. These advantages include improved patient comfort, less risk of patient entanglement in the lead wires, and increased patient throughput from the ability to connect the ECG leads to the patient before entry to the MRI exam room.

After a survey of existing wireless standards (among them: Bluetooth, ZigBee, and 802.11) we were unable to find a standard protocol which could meet our requirements. The ECG data must be processed and a trigger signal delivered to the MRI scanner with minimal delay and variability (dither). The current Ivy Biomedical wired solution provides approximately 10ms of delay from the peak of the patient's ECG signal to the gating signal delivered to the MRI scanner. The dither in the delivery time of the trigger is on the order of 100us. None of the available wireless standards appeared capable of delivering small packets of data with latency and dither that met our requirements and we have started design on a custom wireless solution.