

# QRI-SCSTS radio RF exposure attestation

## 1.1. Inductive radio RF Operational characteristic

| RF Parameters for inductive communication |                                                                |
|-------------------------------------------|----------------------------------------------------------------|
| Operating frequency                       | 32 - 64 kHz <sup>1</sup>                                       |
| Operating range                           | < 10 cm                                                        |
| Frequency reference                       | 32768Hz Xtal                                                   |
| Modulation                                | OOK (on off key) with PDC (pulse distance coding) <sup>2</sup> |
| Data rate                                 | < 24kbps                                                       |
| Max voltage at coil                       | 4.3 V <sup>3</sup>                                             |
| Duty cycle                                | 50% <sup>4</sup>                                               |
| Net power delivered to coil               | < 0.6 mW <sup>5</sup>                                          |
| Transceiver Vendor                        | Biotronik ASIC                                                 |
| Emission level tested                     | 40 dB or more below FCC15.209 limits <sup>6</sup>              |
| FCC regulation                            | 15.209                                                         |
| Planned authorization procedure           | Certification via TCB                                          |
| Inductive coil                            | 40mH coil, 3mm diameter, 1600 turns each                       |

**Table 1: Operation characteristic of inductive radio transmitter**

<sup>1</sup> Due to the nature of PDC (pulse distance coding) used for the transmitter, the emission peak frequency may change within this range based on the payload being transmitted.

<sup>2</sup> The modulation (a combination of OOK and PDC) of inductive transmitter is Biotronik proprietary design. It uses OOK as the data detection mechanism and the actual payload is encoded by the distance between each pulse.

<sup>3</sup> The max voltage at coil driver is 4.3V.

<sup>4</sup> The max duty cycle is determined by the Biotronik ASIC used for inductive communication.

<sup>5</sup> This includes the effect of 50% duty cycle. Significant part of this power is consumed by nonradiative ohmic dissipation.

<sup>6</sup> The 15.209 emission test performed at Element lab for the inductive radio is at or below the noise floor. The inductive coil mainly relies on the magnetic field generated for transmitting and the coils are very poor electrical field radiator.

## 1.2. BLE radio RF Operational characteristic

| <i>RF Parameters for Bluetooth LE communication</i>   |                                                        |
|-------------------------------------------------------|--------------------------------------------------------|
| <i>Operating frequency</i>                            | 2400 – 2483.5 MHz                                      |
| <i>Operating Range</i>                                | 0 – 2 m                                                |
| <i>Channel Bandwidth</i>                              | 2 MHz                                                  |
| <i>Raw Data Rate</i>                                  | 1 Mbps only                                            |
| <i>Max. transmission power (EIRP)</i>                 | Class 1: 8 dBm (6.3 mW)                                |
| <i>Power setting of the Nordic chipset</i>            | 4 dBm                                                  |
| <i>Antenna gain (open air condition)</i>              | 2.2 dBi                                                |
| <i>Transceiver Vendor</i>                             | Nordic nRF52840 CCAA                                   |
| <i>Protocol stack for transceiver</i>                 | Bluetooth SIG qualified BLE protocol stack S140 V6.1.1 |
| <i>Frequency Reference</i>                            | 32MHz Xtal                                             |
| <i>Modulation</i>                                     | GFSK                                                   |
| <i>Frequency Hopping</i>                              | Hopping over 37 channels per Bluetooth LE 5.0 standard |
| <i>Tx Duty cycle</i>                                  | < 10% <sup>7</sup>                                     |
| <i>Net power delivered to antenna for RF exposure</i> | < 0.63 mW <sup>8</sup>                                 |
| <i>FCC regulation</i>                                 | Part 15.247                                            |
| <i>Planned authorization procedure</i>                | Certification via TCB                                  |

**Table 2: Operation characteristic of Bluetooth LE radio**

<sup>7</sup> The max Tx duty cycle is determined by the Bluetooth stack and the specific implementation of the device and is tested and verified by Biotronik.

<sup>8</sup> Based on max EIRP 8dBm (including device to device variation) and 10% duty cycle for averaging.

### **1.3. RF exposure consideration for inductive radio**

The TS is a body worn medical device. As the transmitter of inductive radio does not operate simultaneously with the Bluetooth LE transmitter, per 47CFR 1.1307(b)(3)(ii)(A), the available maximum time average analysis is performed and the combined maximum average Tx power level is determined to be less than 0.63mW. Additionally, significant part of the maximum time average of 0.6mW power from inductive radio is consumed by Ohmic dissipation and other lossy magnetic material for coil construction, real RF emission level is much lower.