

QRI-SCSIPG Inductive radio RF exposure attestation

1.1. RF Operational characteristic

RF Parameters for inductive communication	
Operating frequency	32 - 64 kHz ¹
Operating range	< 10 cm
Frequency reference	32768Hz Xtal
Modulation	OOK (on off key) with PDC (pulse distance coding) ²
Data rate	< 24kbps
Max voltage at coil	3.9 V ³
Duty cycle	< 50% ⁴
Net power delivered to coil	< 0.3 mW ⁵
Transceiver Vendor	Biotronik ASIC
Emission level tested	40 dB or more below FCC15.209 limits ⁶
FCC regulation	15.209
Planned authorization procedure	Certification via TCB
Inductive coil(s)	Two 40mH coil, 3mm diameter, 1600 turns each

Table 1: Operation characteristic of inductive radio transmitter

¹ 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.

² 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.

³ The max voltage at coil driver is 3.9V.

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

⁵ This includes the effect of 10% duty cycle. Significant part of this power is consumed by ohmic dissipation.

⁶ 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

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

Table 2: Operation characteristic of Bluetooth LE radio

⁷ 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.

⁸ 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 IPG is an implantable medical device. As the transmitter of inductive radio does not operate simultaneously with the Bluetooth LE transmitter, per 47CFR 1.1307(b)(3)(i)(A), it can be treated as a single source. The maximum time average of the sum of the BLE transmitter and inductive transmitter is 0.63mW. Additionally, significant part of this 0.3mW power from inductive transmitter is consumed by Ohmic dissipation and other lossy magnetic material for coil construction. This is confirmed by 47CFR part 15.209 measurement conducted by Element EMC lab.