



Medtronic, Inc.

Model Tested: HarmoniaBP DR MRI SureScan

Related Family Models*:

**Confirma DR MRI SureScan, Effectra DR MRI SureScan
Refina CSP DR MRI SureScan, Restoria CSP DR MRI SureScan
ReSyncra CSP DR MRI SureScan, HarmoniaBP DR MRI SureScan
Confirma SR MRI SureScan, Effectra SR MRI SureScan
Refina CSP SR MRI SureScan, Restoria CSP SR MRI SureScan**

***See Product Description for details**

FCC 1.1307:2026, FCC 2.1093:2026

Bluetooth Low Energy, Inductive Radio

Report: MDTR1212.10 Rev. 01, Issue Date: July 1, 2026



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CERTIFICATE OF EVALUATION

Last Date of Evaluation: February 23, 2026
Medtronic, Inc.
EUT: HarmoniaBP DR MRI SureScan

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2026 FCC 2.1093:2026	FCC 1.1307:2026

Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(i)(A)	Exemption From RF Exposure Evaluation	Yes	Pass	N/A

Deviations From Evaluation Standards

None

Approved By:



Donald Facteau, Process Architect

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing

REVISION HISTORY



Revision Number		Description	Date (yyyy-mm-dd)	Page Number
00		None		
01		Updated based upon antenna gain changes	2026-06-25	9-11

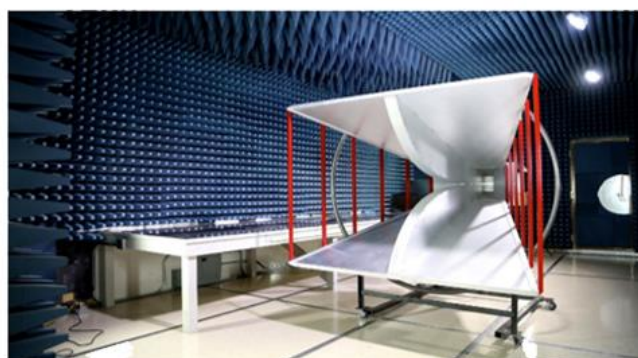
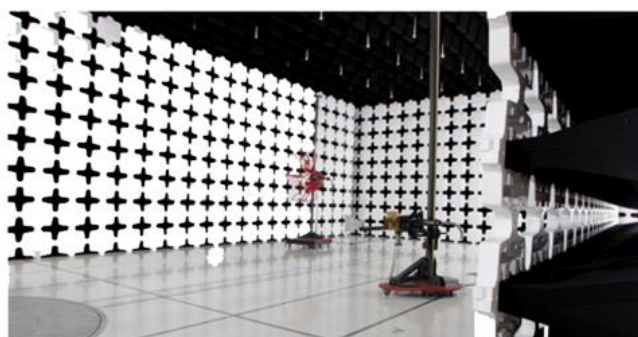
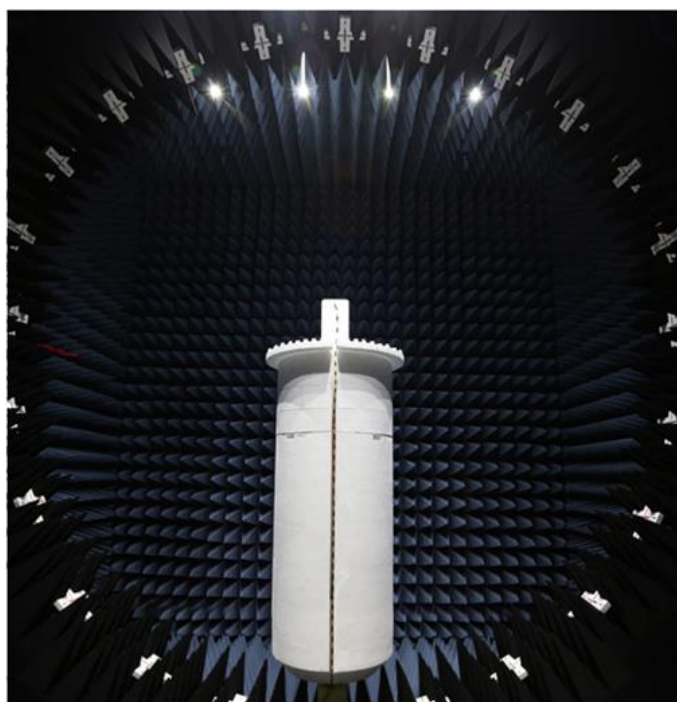
FACILITIES

Testing was performed at the following location(s)

	Location	Labs ⁽¹⁾	Address	A2LA ⁽²⁾	ISED ⁽³⁾	BSMI ⁽⁴⁾	VCCI ⁽⁵⁾	CAB	FDA ⁽⁶⁾
☐	California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
☒	Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	US0175	TL-57
☐	Oregon	EV01-12	6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	3310.02	2834D	SL2-IN-E-1017	A-0108	US0017	TL-56
☐	Washington	NC01-05	19201 120th Ave NE Bothell, WA 98011 (425) 984-6600	3310.06	2834F	SL2-IN-E-1153R	A-0110	US0157	TL-67
☐	Offsite	N/A	See Product Description	N/A	N/A	N/A	N/A	N/A	N/A

See data sheets for specific labs

- (1) The lab designations denote individual rooms within each location. (OC01, OC02, OC03, etc.)
- (2) A2LA Certificate No.
- (3) ISED Company No.
- (4) BSMI No.
- (5) VCCI Site Filing No.
- (6) FDA ASCA No.



PRODUCT DESCRIPTION

Client and Equipment under Evaluation Information

Company Name:	Medtronic, Inc.
Address:	710 Medtronic Parkway NE
City, State, Zip:	Minneapolis, MN 55432
Evaluation Requested By:	Curt Pies
EUT:	HarmoniaBP DR MRI SureScan HTN3DR2
Date of Evaluation:	February 23, 2026

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The HarmoniaBP system consists of Azure/Astra mechanical architecture with a single chamber and dual chamber MR conditional IPG with wireless communication. The IPG model included in the HarmoniaBP platform technology, spanning the Vitalis device family, is listed in Table 1. SR models are single chamber devices with one (1) IS-1 port in the connector header and DR models are dual chamber devices with two (2) IS-1 ports in the connector header. All models are equivalent from a mechanical perspective with the exception of the connector header and EMA assemblies which account for the different quantities of feedthroughs between SR and DR. All remaining differences between models are related to device features and labeling for different market geographies and have no impact to device/connector test performance. Device models below include two-way short range Inductive telemetry system.

Name
Confirma DR MRI SureScan
Effectra DR MRI SureScan
Refina CSP DR MRI SureScan
Restoria CSP DR MRI SureScan
ReSyncra CSP DR MRI SureScan
HarmoniaBP DR MRI SureScan
Confirma SR MRI SureScan
Effectra SR MRI SureScan
Refina CSP SR MRI SureScan
Restoria CSP SR MRI SureScan

Objective:

To demonstrate compliance with FCC Requirements for RF exposure for 1.1307 RF exempt devices per test plan: Bolt Radio and EMC Compliance Design Verification Plan D01481151 Revision B.

Model Equivalency Statement:

Element Materials Technology tested the models as shown in the datasheets contained within this report. Element Materials Technology does not make any claims of compliance for models not tested.

MEDTRONIC INC. STATEMENT OF SIMILARITY

The products identified have the same RF relevant hardware, software and firmware, with the difference that various therapy features are enabled based on the model.

The SR (single chamber) devices differ from the DR (dual chamber devices) in the header that is connected. SR devices have a connector for a single lead, whereas DR devices have a connector for two leads. This results in two extra connections (feedthroughs) to the PCB.

All models listed above contain a BLE module. Therefore, all models have an additional niobium pin (BLE antenna) located in the headers and connecting to the PCB.

Table 1 – Antenna Information

Device Description	Model Number	Inductive Antenna	BLE Antenna
Confirma DR MRI SureScan	BRD1DR1	Inductive antenna is located within the titanium enclosure and not header. No inductive antenna location variation between models.	Both dual and single header devices use the same BLE antenna.
Effectra DR MRI SureScan	BRD1DR2		
Refina CSP DR MRI SureScan	BRD2DR1		
Restoria CSP DR MRI SureScan	BRD2DR2		
ReSyncra CSP DR MRI SureScan	BRD3DR2		
HarmoniaBP DR MRI SureScan	HTN3DR2		
Confirma SR MRI SureScan	BRD1SR1		
Effectra SR MRI SureScan	BRD1SR2		
Refina CSP SR MRI SureScan	BRD2SR1		
Restoria CSP SR MRI SureScan	BRD2SR2		

Table 2 – Electrical/Mechanical Information

Device Description	Model Number	Electrical	Mechanical
Confirma DR MRI SureScan	BRD1DR1	All device variants contain the same main board (hybrid). Various therapy features are enabled based on model.	Dual Lead Header
Effectra DR MRI SureScan	BRD1DR2		Dual Lead Header
Refina CSP DR MRI SureScan	BRD2DR1		Dual Lead Header
Restoria CSP DR MRI SureScan	BRD2DR2		Dual Lead Header
ReSyncra CSP DR MRI SureScan	BRD3DR2		Dual Lead Header
HarmoniaBP DR MRI SureScan	HTN3DR2		Dual Lead Header
Confirma SR MRI SureScan	BRD1SR1		Single Lead Header
Effectra SR MRI SureScan	BRD1SR2		Single Lead Header
Refina CSP SR MRI SureScan	BRD2SR1		Single Lead Header
Restoria CSP SR MRI SureScan	BRD2SR2		Single Lead Header

RF EXPOSURE CONDITION



The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	The equipment is implanted in a human
Radios Contained in the Same Host Device	Bluetooth Low Energy Inductive
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

EXEMPTION FROM RF EXPOSURE EVALUATION



OVERVIEW

Section 1.3 of KDB 44798 D04 v01 states that, “Under the new rules, all radio services and operations are subject to Routine Evaluation [§§ 1.1307(b)(1), 2.1033(f), etc.], unless shown to qualify under the exemptions provided in the rules and OET Lab policies for equipment authorization.”

The glossary of KDB 44798 D04 v01 specifies that an exempt RF device is defined “solely from the obligation to perform a routine environmental evaluation to demonstrate compliance with the RF exposure limits in § 1.1310; it is not exemption from the equipment authorization procedures described in 47 CFR Part 2, not exemption from general obligations of compliance with the RF exposure limits in § 1.1310 of this chapter, and not exemption from determination of whether there is no significant effect on the quality of the human environment under § 1.1306.” Compliance with the exemption criteria defined in 1.1307(b) confirm compliance with the limits in § 1.1310.

COMPLIANCE WITH FCC LIMITS IN 47 CFR §1.1310

Per §1.1307(b)(3), (i) For single RF sources (*i.e.*, any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

- (A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);
- (B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

$$P_{th}(mW) = \begin{cases} ERP_{20\text{ cm}}(d/20\text{ cm})^x & d \leq 20\text{ cm} \\ ERP_{20\text{ cm}} & 20\text{ cm} < d \leq 40\text{ cm} \end{cases}$$

Where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\text{ cm}}\sqrt{f}}\right) \text{ and } f \text{ is in GHz};$$

And

$$ERP_{20\text{ cm}}(mW) = \begin{cases} 2040f & 0.3\text{ GHz} \leq f < 1.5\text{ GHz} \\ 3060 & 1.5\text{ GHz} \leq f \leq 6\text{ GHz} \end{cases}$$

- (C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least $\lambda/2\pi$, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of $\lambda/4$ or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

TABLE 1 TO §1.1307(b)(3)(i)(C)—SINGLE RF SOURCES SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	$1,920 R^2$.
1.34-30	$3,450 R^2/f^2$.
30-300	$3.83 R^2$.
300-1,500	$0.0128 R^2 f$.
1,500-100,000	$19.2 R^2$.

EXEMPTION FROM RF EXPOSURE EVALUATION

(ii) For multiple RF sources: Multiple RF sources are exempt if:

- (A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of two centimeters between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).
- (B) in the case of fixed RF sources operating in the same time-averaging period, or of multiple mobile or portable RF sources within a device operating in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation.

$$\sum_{i=1}^a \frac{P_i}{P_{th,i}} + \sum_{j=1}^b \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^c \frac{Evaluated_k}{Exposure Limit_k} \leq 1$$

Where:

a = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(B) of this section for P_m , including existing exempt transmitters and those being added.

b = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(C) of this section for Threshold ERP, including existing exempt transmitters and those being added.

c = number of existing fixed, mobile, or portable RF sources with known evaluation for the specified minimum distance including existing evaluated transmitters.

P_i = the available maximum time-averaged power or the ERP, whichever is greater, for fixed, mobile, or portable RF source i at a distance between 0.5 cm and 40 cm (inclusive).

$P_{m,i}$ = the exemption threshold power (P_m) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source i .

ERP_j = the ERP of fixed, mobile, or portable RF source j .

$ERP_{m,j}$ = exemption threshold ERP for fixed, mobile, or portable RF source j , at a distance of at least $\lambda/2\pi$ according to the applicable formula of paragraph (b)(3)(i)(C) of this section.

$Evaluated_k$ = the maximum reported SAR or MPE of fixed, mobile, or portable RF source k either in the device or at the transmitter site from an existing evaluation at the location of exposure.

$Exposure Limit_k$ = either the general population/uncontrolled maximum permissible exposure (MPE) or specific absorption rate (SAR) limit for each fixed, mobile, or portable RF source k , as applicable from §1.1310

The relationship between EIRP and ERP is:

$$ERP \text{ (dBm)} = EIRP \text{ (dBm)} - 2.14 \text{ dB}$$

Where EIRP is the sum of the conducted power (dBm) and the antenna gain (dBi).

EXEMPTION FROM RF EXPOSURE EVALUATION

ASSESSMENT

The exemption from RF exposure evaluation is summarized in the following table(s):

Radio	Frequency Range (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
Inductive	0.15-0.2	4.1 mW	N/A	4.6%	1	0.5	N/A	0.2	1.0	yes

The information in the table above was obtained from:

The maximum rated value was used in these calculations. Referenced MDTR1212.7 Rev 02, Customer supplied information

Radio	Frequency Range (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW)	Limit (mW)	Compliant
Bluetooth Low Energy	2402-2480	1 mW	N/A	50.0%	0.33	0.5	N/A	0.5	1.0	yes

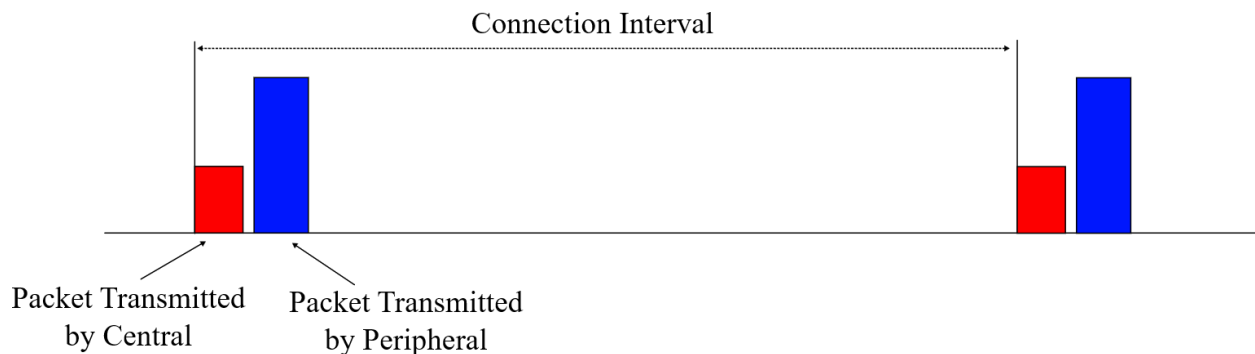
The information in the table above was obtained from:

The maximum rated value was used in these calculations. Referenced MDTR1212.3 Rev 04, Customer supplied information, Customer provided duty cycle calculation

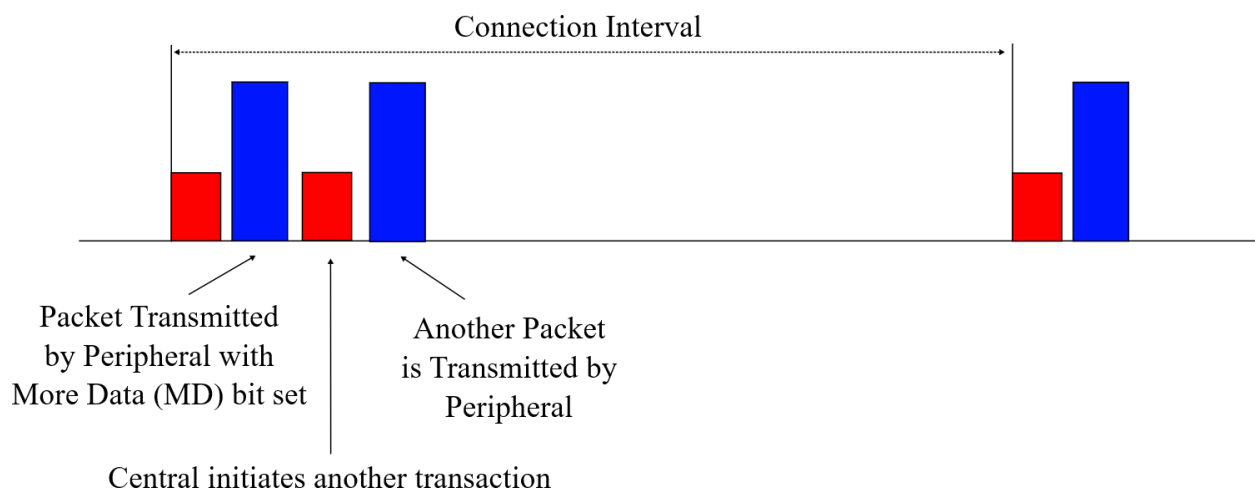
Evaluator: Frank Wong

Worst-Case BLE Transmit Duty Cycle

The Implantable device interface was developed to be compatible with Bluetooth Low Energy (BTLE) Version 4.1 (4.1 is forward compatible with future versions)ⁱ as specified by BLUETOOTH SPECIFICATION Version 4.1ⁱⁱ. It implements the Broadcaster role when outside of a connection, performing extremely low duty cycle advertising, and the Peripheral Role when a connection is established with a remote Central. The worst-case TX duty cycle occurs when there is an active connection in the Peripheral Role, where the implantable device is a slave. In this role, the remote Central initiates periodic exchanges of information at a rate predefined by the Connection Interval. The connection is Half Duplex, meaning that only one side can be transmitting at a time. At the start of the Connection Interval the Central transmits a packet, then a response packet is transmitted by the Peripheral.



The packet transmitted by the peripheral contains a More Data (MD) bit in the Data Channel PDU Headerⁱⁱⁱ. This MD bit allows the Peripheral to say that it has more data to send, and the Central has the option to initiate another exchange of packets within the Connection Interval.



If the MD bit is not set, or the Central chooses not to initiate another transaction, the Connection Event will close and no data will be transmitted until the next Connection Interval.

It is unlikely that the entire Connection Interval will be fully filled with packet exchanges, as Central roles usually limit the number of exchanges per Connection Interval, and the Peripheral will not always have data to send. However, we will still consider the worst case that the Connection Interval is completely full of exchanges.

For worst case Peripheral transmit duty cycle, we will consider that the Central is sending the smallest possible packet of 80 bits, and the Peripheral is sending the largest possible packet of 376 bits^{iv}:

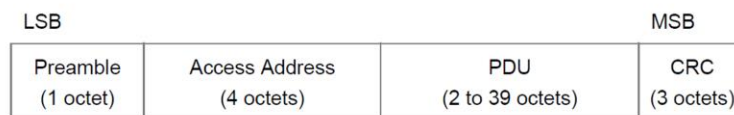


Figure 2.1: Link Layer packet format

The preamble is 1 octet and the Access Address is 4 octets. The PDU range is from 2 to a maximum of 39 octets. The CRC is 3 octets.

The Preamble is transmitted first, followed by the Access Address, followed by the PDU followed by the CRC.

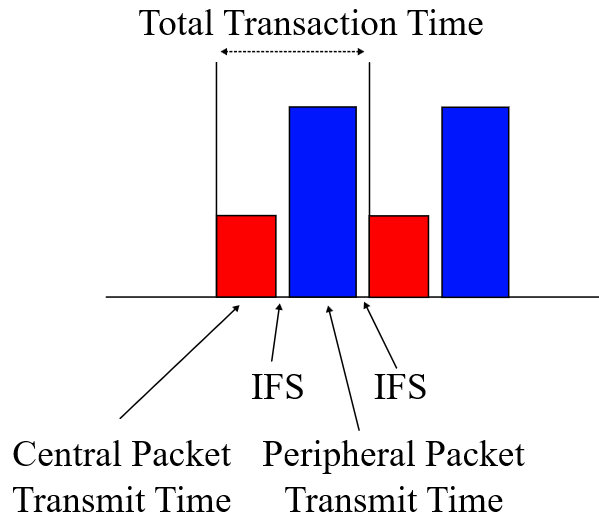
The shortest packet is 80 bits in length. The longest packet is 376 bits in length.

The Bit Rate of BTLE 4.1 is fixed at 1 Mbps^v. With the worst case packet sizes, this translates to a Central transmit time of $80 \text{ bits} \times \frac{1}{1,000,000 \text{ bits/second}} = 80 \mu\text{s}$ and

Peripheral transmit time of $376 \text{ bits} \times \frac{1}{1,000,000 \text{ bits/second}} = 376 \mu\text{s}$.

Additionally, there is a turnaround period between packets called the Inter Frame Space (IFS), specified to be $150 \mu\text{s}$ ^{vi}.

Therefore, the total transaction time is the Central Packet Transmit Time + IFS + Peripheral Packet Transmit Time + IFS.



Without considering how many transactions might fit in a given Connection Interval and how many transactions each side will allow. The worst case Peripheral Transmit duty cycle is $\frac{\text{Peripheral Packet Transmit Time}}{\text{Total Transaction Time}} = \frac{376 \mu s}{80 \mu s + 150 \mu s + 376 \mu s + 150 \mu s} = \sim 50\%$.

Therefore, the worst-case Implantable Device Bluetooth Low Energy Transmit duty cycle will be below 50%.

Worst-Case Inductive Duty Cycle

Tel B duty cycle calculation

- Assume a typical session lasts ten minutes
- 1 period = 282 ms
- 8 pulses of 900 μs per period
- 1 pulse of 5.1 ms per period

Duty cycle = $\frac{\text{on time}}{\text{off time}}$ in a one hour period

$$\text{Duty cycle} = \frac{(8)(900\mu s) + 5.1\text{ms}}{282\text{ms} - [(8)(900\mu s) + 5.1\text{ms}]} * 100 = 4.56\%$$

ⁱ Medtronic DSN024122 (MAP Agile)

ⁱⁱ <https://www.bluetooth.com/specifications/specs/core-specification-4-1/>

ⁱⁱⁱ BLUETOOTH SPECIFICATION Version 4.0 [VOL 6] Part B §4.5.6

^{iv} BLUETOOTH SPECIFICATION Version 4.0 [VOL 6] Part B §2.1

^v BLUETOOTH SPECIFICATION Version 4.0 [VOL 6] Part A §4.6

^{vi} BLUETOOTH SPECIFICATION Version 4.0 [VOL 6] Part B §4.1

End of Test Report